

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF HIV
MEDICINE, et al.,

Plaintiffs,

v.

HEALTH RESOURCES AND SERVICES
ADMINISTRATION, et al.,

Defendants.

Case No. 1:26-cv-12638-WGY

**DECLARATION OF STEPHEN P. FERGUSON
IN SUPPORT OF PLAINTIFFS' MOTION REQUESTING JUDICIAL NOTICE
OF GOVERNMENTAL STATEMENTS, POLICIES, AND REPORTS**

I, Stephen P. Ferguson, hereby state and declare as follows:

1. I am an Attorney at Herbert Smith Freehills Kramer (US) LLP and counsel for Plaintiffs in the above-referenced litigation. I am admitted to practice in the State of New York and am admitted *pro hac vice* in this matter.

2. I have personal knowledge of the matters stated herein and am competent to testify thereto.

3. I submit this Declaration in support of Plaintiffs' Request for Judicial Notice of Governmental Statements, Policies, and Reports. The exhibits attached to this Declaration have not previously been filed on the docket in this action.

4. Attached hereto as **Exhibit A** is a true and correct copy of the Application for Grant Funding by the New York City Health Department in response to a HIV Emergency Relief Program Ryan White HIV/AIDS Program (RWHAP) Part A Funding Opportunity Announcement,

submitted in 2020, and which is publicly available at <https://tinyurl.com/5dauxze2> [<https://perma.cc/TH4Q-EVMH>].

5. Attached hereto as **Exhibit B** is a true and correct copy of *New York State's Integrated HIV Prevention and Care Plan 2022-2026*, published by the New York Department of Health in 2022, and which is publicly available at <https://tinyurl.com/456xpnxd>.

6. Attached hereto as **Exhibit C** is a true and correct copy of the publication *Achieving Gender Affirming Care in the Ryan White Part A Portfolio: Recommendations from the Needs Assessment Committee of the NY HIV Health & Human Services Planning Council*, which was published in July 2018, and which is publicly available at <https://tinyurl.com/838cuteb> [<https://perma.cc/YZ49-QJQG>].

7. Attached hereto as **Exhibit D** is a true and correct copy of *San Francisco's Integrated Ending the Epidemics Plan: 2024-2026 Strategies and Activities*, published by the San Francisco Department of Public Health in 2024, and which is publicly available at <https://tinyurl.com/4hvmze5x> [<https://perma.cc/B82X-HE7B>].

8. Attached hereto as **Exhibit E** is a true and correct copy of the *Los Angeles County Integrated HIV Prevention and Care Plan, 2022-2026*, published by the Los Angeles County Commission on HIV and the Los Angeles County Department of Public Health in December 2022, and which is publicly available at <https://tinyurl.com/552z3uah> [<https://perma.cc/2PUL-NDFG>].

9. Attached hereto as **Exhibit F** is a true and correct copy of the *Agenda and Meeting Materials for the Regular Meeting of the Los Angeles County Commission on HIV Planning, Priorities, and Allocations Committee* that occurred on October 21, 2025, and which is publicly available at <https://tinyurl.com/mwk6utxk>.

10. Attached hereto as **Exhibit G** is a true and correct copy of *Practice Guidelines for the Care of Persons Living with HIV/AIDS*, published by the San Diego HIV Health Services Planning Group on September 22, 2021, and which is publicly available at <https://tinyurl.com/3btnrs69> [<https://perma.cc/L7T6-AMDR>].

11. Attached hereto as **Exhibit H** is a true and correct copy of the *State of Florida Integrated HIV Prevention and Care Plan*, published by the Florida Department of Health on January 20, 2023, and which is publicly available at <https://tinyurl.com/4y5mfwh8> [<https://perma.cc/ELN6-VGFR>].

12. Attached hereto as **Exhibit I** is a true and correct copy of the *FY 2025 Standards of Care & Service Delivery Guidelines: Dallas Planning Area*, prepared by the Ryan White Planning Council of the Dallas Area in collaboration with the Ryan White Grants Management Division of Dallas County Health & Human Services and issued in 2025, and which is publicly available at <https://tinyurl.com/y924sasv> [<https://perma.cc/7YCK-EZHF>].

13. Attached hereto as **Exhibit J** is a true and correct copy of the *Guide for HIV/AIDS Clinical Care* published by the Health Resources and Services Administration in 2014, and which is publicly available at <https://tinyurl.com/3jwvtvc4>.

14. Attached hereto as **Exhibit K** is a true and correct copy of the presentation titled “Providing Gender-Affirming Care to People with HIV” by an employee of the Health Resources and Services Administration’s HIV/AIDS Bureau on August 25, 2022, at the 2022 National Ryan White Conference on HIV Care and Treatment.

15. Attached hereto as **Exhibit L** is a true and correct copy of the Record of the Proceedings of the Virtual Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment that took place on April 26-28, 2022, and which is

publicly available at <https://www.cdc.gov/faca/committees/pdfs/chachspt/chachspt-minutes-20220426-28-508.pdf>.

16. Attached hereto as **Exhibit M** is a true and correct copy of the *Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2027-2031*, published by Centers for Disease Control and Prevention and the Health Resources and Services Administration in December 2024, and which is publicly available at <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-prevention-care-plan-guidance-2027-2031.pdf>.

17. Attached hereto as **Exhibit N** is a true and correct copy of the *National HIV/AIDS Strategy for the United States 2022-2025*, published by The White House in 2021, and which is publicly available at <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>.

18. Attached hereto as **Exhibit O** is a true and correct copy of a social media post by the Health Resources and Services Administration on January 28, 2022 (3:41 PM) through its official @HRSAGov account on X.com concerning the importance of providing gender-affirming HIV care and treatment services for transgender people with HIV, and which is publicly available at <https://tinyurl.com/42pc3uu3>.

19. Attached hereto as **Exhibit P** is a true and correct copy of a social media post by the Health Resources and Services Administration on March 25, 2022 (11:13 AM) through its official @HRSAGov account on X.com concerning gender-affirming HIV care and viral suppression among transgender and gender-diverse clients, and which is publicly available at <https://tinyurl.com/39ka9xhy>.

20. Attached hereto as **Exhibit Q** is a true and correct copy of Executive Order No. 14183, *Prioritizing Military Excellence and Readiness*, 90 Fed. Reg. 8757 (Jan. 27, 2025).

21. Attached hereto as **Exhibit R** is a true and correct copy of Executive Order No. 14187, *Protecting Children From Chemical and Surgical Mutilation*, 90 Fed. Reg. 8771 (Jan. 28, 2025).

22. Attached hereto as **Exhibit S** is a true and correct copy of Executive Order No. 14190, *Ending Radical Indoctrination in K-12 Schooling*, 90 Fed. Reg. 8853 (Jan. 29, 2025).

23. Attached hereto as **Exhibit T** is a true and correct copy of Executive Order No. 14201, *Keeping Men Out of Women's Sports*, 90 Fed. Reg. 9279 (Feb. 11, 2025).

24. Attached hereto as **Exhibit U** is a true and correct copy of the release titled “Supreme Court Bolsters President Trump’s Push to Eliminate Transgender Insanity,” issued by The White House on June 30, 2026, and which is publicly available at <https://perma.cc/484A-4MDN>.

25. Attached hereto as **Exhibit V** is a true and correct copy of the release titled “President Trump Ended Democrats’ ‘Transgender for Everybody’ Insanity,” issued by The White House on March 31, 2026, and which is publicly available at <https://tinyurl.com/2u3jupbf>.

26. Attached hereto as **Exhibit W** is a true and correct copy of the proclamation titled “National Child Abuse Prevention Month, 2025,” issued by The White House on April 3, 2025, and which is publicly available at <https://tinyurl.com/2aywxnsj>.

27. Attached hereto as **Exhibit X** is a true and correct copy of U.S. Office of Personnel Management, Initial Guidance Regarding President Trump’s Executive Order Defending Women (Jan. 29, 2025), which is publicly available at <https://tinyurl.com/243c49d6>.

28. Attached hereto as **Exhibit Y** is a true and correct copy of Matthew J. Vaeth, Office of Management and Budget, Memorandum M-25-13, Temporary Pause of Agency Grant, Loan,

and Other Financial Assistance Programs (Jan. 27, 2025), which is publicly available at <https://tinyurl.com/3zpchy7r>.

29. Attached hereto as **Exhibit Z** is a true and correct copy of the *Directive on NIH Priorities: Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards*, issued by the then-Acting Director of the NIH Matthew J. Memoli on February 21, 2025.

30. Attached hereto as **Exhibit AA** is a true and correct copy of A Guide to Primary Care of People with HIV/AIDS, published by the Health Resources and Services Administration in 2004, and which is publicly available at <https://tinyurl.com/4y7h5xvr>.

31. Attached hereto as **Exhibit BB** is a true and correct copy of a social media post by the U.S. Department of Health and Human Services on August 21, 2025 (5:48 PM) through its official @HHSGov account on X.com concerning removal of references to “gender ideology” from federally funded sex-education materials, and which is publicly available at <https://tinyurl.com/fth82rp7>.

32. Attached hereto as **Exhibit CC** is a true and correct copy of a social media post by the U.S. Department of Health and Human Services on September 27, 2025 (9:00 AM) through its official @HHSGov account on X.com concerning remarks by HHS Secretary Kennedy at the United Nations General Assembly opposing “destructive gender ideology,” and which is publicly available at <https://tinyurl.com/2kuchns5>.

33. Attached hereto as **Exhibit DD** is a true and correct copy of a social medial post by President Donald J. Trump on February 27, 2025 (9:37 PM) through his @realDonaldTrump account on Truth Social concerning Iowa legislation and “Radical Gender Ideology”.

34. Attached hereto as **Exhibit EE** is a true and correct copy of a social medial repost by President Donald J. Trump on January 21, 2025, through his @realDonaldTrump account on Truth Social of a social media post by the @TeamTrump account on January 20, 2026, concerning “radical gender ideology.”

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on September 1, 2026.

/s/ Stephen P. Ferguson
Stephen P. Ferguson

EXHIBIT A

INTRODUCTION

Pursuant to the Grant Year 2021 (GY21) HIV Emergency Relief Program Ryan White HIV/AIDS Program (RWHAP) Part A Funding Opportunity Announcement, dated June 11, 2020, the New York City Health Department (NYC HD), as the Grant Recipient (Recipient) for the New York Eligible Metropolitan Area (NY EMA), respectfully submits this application for grant funding. The application describes the GY21 plan to promote a comprehensive scale-up of high-quality care and treatment through the support of core medical and support services that address gaps in the HIV care continuum for eligible people with HIV (PWH) in the NY EMA. The GY21 plan is responsive to federal, state, and local efforts to end the HIV epidemic.

In February 2019, the United States (U.S.) Department of Health and Human Services (HHS) released an operational plan, Ending the HIV Epidemic: A Plan for America (EHE), which aims to end the HIV epidemic in the U.S. by 2030.ⁱ The plan identifies 48 counties, plus Washington, D.C., and San Juan, Puerto Rico, where more than 50% of HIV diagnoses occurred in 2016 and 2017, and an additional seven states with a substantial number of HIV diagnoses in rural areas. Four NYC counties are designated as part of the EHE plan: Bronx, Kings (Brooklyn), New York (Manhattan), and Queens. The EHE plan is comprised of four pillars: Diagnose, Treat, Prevent, and Respond. The NYC HD Bureau of HIV (BHIV) is engaging all its programs and partners to respond to the EHE plan by leveraging RWHAP Part A, Centers of Disease Control and Prevention (CDC) HIV prevention and surveillance jurisdictional funding (CDC PS-18-1802), City and State ending the epidemic resources alongside additional federal EHE funding from Health Resources and Services Administration (HRSA) and CDC. Initial EHE resources (CDC PS-19-1906) received by NYC in September 2019, support the development of the NYC EHE plan, including an Epidemiological Profile and Situational Analysis for the four EHE counties in NYC. A draft plan was submitted to the CDC in December 2019, followed by an extensive community engagement process currently underway to ensure the NYC EHE plan is responsive to local needs. The version of the NYC EHE plan currently receiving input from the community includes the strategies listed below. A final plan will be submitted by March 2021.

- Strategy 1: Increase the number of people who know their HIV status by diagnosing HIV infection as early as possible, promoting routine testing within health care facilities, and scaling up testing options in non-clinical settings.
- Strategy 2: Prevent new HIV acquisition by increasing access to effective prevention interventions, including pre- and post-exposure prophylaxis (PrEP and PEP), condoms, harm reduction (HR), and supportive services.
- Strategy 3: Improve viral suppression (VS) and health outcomes for PWH by optimizing medication adherence and access to care, improving coordination of clinical and supportive services, and increasing access to immediate antiretroviral treatment (iART).
- Strategy 4: Enhance methods to identify and intervene on HIV transmission networks to better support people and communities at increased risk of exposure.
- Strategy 5: In all NYC EHE strategies, utilize an intersectional, strengths-based, anti-stigma, and community-driven approach to mitigate racism, sexism, homophobia, transphobia, and other systems of oppression that create and exacerbate HIV-related health inequities.

The draft plan also includes two cross-cutting issues—Social and Structural Determinants of HIV-Related Health Inequities—and works to ensure the HIV service delivery system is responsive to these strategies.

To achieve the goals of the federal and NYC EHE plans, CDC EHE funding (CDC PS-20-2010) will support a comprehensive HIV program (Component A) to increase HIV screening and

testing in health care and non-health care settings to reduce new HIV diagnoses and increase awareness of HIV status. The new funding will leverage and enhance existing systems and increase linkage to and engagement and re-engagement in HIV care and treatment and early initiation of treatment to improve engagement in care (EiC) and VS among PWH. Through an array of approaches and providers the funding will seek to increase screening, referral, and linkage to PrEP and other HIV prevention services, including syringe service programs, and improve the ability to respond to HIV transmission clusters and outbreaks. BHIV will work to partner with a diverse set of stakeholders within and outside the NYC HD to help inform the development and implementation of programmatic and advocacy activities.

Additionally, EHE resources from HRSA (HRSA-20-078) support Project Planned Resources for a Specific Population-level Equitable Response (Project PROSPER) which aims to improve access to effective HIV care and treatment and improve VS among PWH (EHE Pillar Two), and quickly respond to potential new HIV outbreaks (EHE Pillar Four) in NYC. Project PROSPER will achieve these goals by increasing organizational capacity through trainings for the HIV workforce; expanding implementation of evidence-informed strategies and interventions as well as emerging practices; and improving data collection and management systems.

All HIV care services in the NY EMA support EHE Pillar Four through efforts to link and retain PWH in care, improve access to antiretroviral treatment (ART), and decrease viral load (VL). Like the federal and NYC EHE plans, the GY21 plan is responsive to Governor Andrew Cuomo's 2015 New York State Blueprint for Ending the Epidemic (NYS ETE Blueprint) and the NYS Integrated HIV Prevention and Care Plan (NYS Integrated Plan), which set forth recommendations to reduce the annual incidence of new HIV infections to 750 from the current 3,000 in NYS. The NYS ETE Blueprint is also a guiding document for the NY EMA.

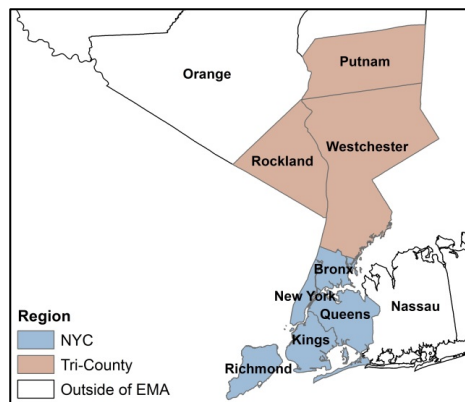
COVID-19 has significantly affected New Yorkers, including PWH, as well as service provision across the NY EMA in GY20, and it is fully expected to continue to do so in GY21. On February 29, 2020, NYC identified its first case of COVID-19. In the ensuing weeks, the number of COVID-19 cases, hospitalizations, and deaths rose. NYC and NYS became the epicenter for the coronavirus pandemic in the U.S. By March 20, 2020, the number of reported daily cases rose to 4,014, with 665 hospitalizations, and 47 deaths. On that day, Governor Cuomo issued an executive order to place NYS on PAUSE requiring all non-essential businesses statewide to close in-office personnel functions effective on March 22, 2020.ⁱⁱ

With the NYS on PAUSE order, many non-clinical community-based organizations (CBOs) ceased providing in-person services in the community while they determined how to meet the needs of clients. Meanwhile, many hospitals were swamped with COVID-19 patients while they sought to set up outpatient telehealth services. Throughout this time, CBOs and clinics worked to transition to providing services virtually or through telehealth. As NYS regions began reopening in phases during the spring and summer, program services started to ramp up, but many continue to experience challenges in delivering services while complying with physical distancing and other requirements mandated by the state. To date, NYC has reported over 238,000 COVID-19 cases, more than 58,000 hospitalizations, and nearly 24,000 confirmed and probable deaths.ⁱⁱⁱ Community members and service providers across the NY EMA are adjusting to COVID-19 and exploring new ways to conduct outreach and provide services while ensuring the safety of staff and clients as the pandemic evolves.

NEEDS ASSESSMENT

A) Demonstrated Need.

1) Epidemiologic Overview.



a) Summary of the HIV epidemic in the EMA geographic area. The NY EMA, which includes the five counties/boroughs of NYC and the adjacent Tri-County Region of Westchester, Rockland, and Putnam Counties, is home to nearly 10 million people (3% of the U.S. population).^{iv} The NY EMA continues to have the largest HIV epidemic in the U.S., reporting in 2018 approximately 5% of all new HIV diagnoses and 13% of PWH nationwide.^v As of December 31, 2019, there were 132,148 people diagnosed and presumed to be living with HIV in the NY EMA, representing 1.4% of the total NY EMA population (*see Table 1*). Of the 1,881 individuals diagnosed with HIV in the NY EMA in 2019, 17% were concurrently diagnosed with AIDS (within 31 days of their HIV diagnosis), a percentage that has remained relatively stable over the last five years.^{vi}

From 2015 to 2019, there was a 28% decrease in HIV diagnoses in the NY EMA; however, the number of PWH remains high due to improved health outcomes associated with ART. These figures demonstrate both the success of the NY EMA's service system in providing HIV care and ongoing need for early intervention and care services to fulfill the goals of the federal EHE plan.

Table 1. NY EMA Population and HIV Diagnoses and Number of PWH by Region and County/Borough, 2019

	Population	HIV Diagnoses*	PWH
New York City	8,336,817	1,772	128,419
Kings (Brooklyn)	2,559,903	459	30,572
Bronx	1,418,207	466	31,280
New York (Manhattan)	1,628,706	344	32,809
Queens	2,253,858	314	18,818
Richmond (Staten Island)	476,143	32	2,564
Outside NYC/Unknown	N/A	157	12,376
Tri-County Region	1,391,615	109	3,729
Putnam	98,320	5	122
Rockland	325,789	24	621
Westchester	967,506	80	2,986
Total	9,728,432	1,881	132,148

Sources: Population estimates: U.S. Census Bureau, American Fact Finder: Quick Facts –2019; New York, Kings, Queens, Bronx, and Richmond counties (NYC): NYC HD, BHIV, data as of 3/31/20; Putnam, Rockland, and Westchester counties: NYSDOH, BHIV, data as of 6/26/20.

*HIV diagnoses include those who were concurrently diagnosed with HIV and AIDS.

b) Socio-demographic characteristics of newly diagnosed, PWH, and persons at high risk.

i-ii) Demographic and socioeconomic data. In 2019, among people newly diagnosed with HIV in the NY EMA, 78% were men, 45% were non-Hispanic Black¹, 38% were Latino/Hispanic, 68% were younger than 40, and 55% were men who have sex with men (MSM), including MSM with a

¹ From this point forward, non-Hispanic Black individuals will be referred to as Black, and non-Hispanic White will be referred to as White. The term “Black” is used throughout this document rather than “African American” because NYC has substantial numbers of people of Caribbean origin who do not identify as “African Americans.”

history of injection drug use (MSM-IDU). In the same year, 3% of new HIV diagnoses in NYC were among transgender people, 96% of whom were transgender women. Data on transgender, gender non-conforming, or non-binary (TGNC/NB) populations are not available for the Tri-County Region. Approximately 90% of newly diagnosed transgender women were Black or Latina, and 56% of newly diagnosed transgender women were Black or Latina ages 20 to 29 years.

In 2019, among PWH in the NY EMA, 72% were men, 43% were Black, 33% were Latino/Hispanic, and 45% were MSM, including MSM-IDU. While new diagnoses remain concentrated among people younger than 40 (68%), people older than 50 accounted for more than half of PWH in 2019 (59%). This highlights the aging of PWH in the NY EMA and underscores the importance of addressing the complex needs of older PWH (OPWH).^{vii}

The number of PWH is highest in low-income Black and Latino/Hispanic communities, where many individuals experience multiple challenges that severely impact health, including racism, stigma, poverty, trauma, mental health (MH) issues, food insecurity, and housing instability. Based on data from NYS Department of Health (NYSDOH), as of July 2020, 64% of PWH diagnosed and reported in the NY EMA were enrolled in Medicaid, and 22% were dually enrolled in Medicaid and Medicare (*see Table 2 on p. 14 for more details*). In comparison, 27% of all NY EMA residents were enrolled in Medicaid in the same time period.^{viii} In 2019 in the NY EMA, PWH residing in high poverty neighborhoods (at least 30% of residents living below the federal poverty level (FPL)) represented 22% of all PWH, and 26% of all deaths among PWH; in comparison, PWH residing in low poverty neighborhoods (less than 10% of residents living below FPL), represented only 10% of all PWH, and 5% of all deaths among PWH in the NY EMA. See *Attachment 3* for the complete diagnoses, number of PWH, and mortality table.

c) Rates of increase in HIV-diagnosed cases within new and emerging populations.

i) Identifying emerging populations, unique challenges, and estimated costs to RWHAP Part

A. As a jurisdiction with a mature epidemic, the number of PWH in the NY EMA has remained relatively stable demographically over the past decade or more. However, the number of new HIV diagnoses reported in NYC from 2001 to 2019 decreased overall and among men and women, all age groups, all NYC boroughs of residence, and within most race/ethnicity and transmission risk categories. This decrease was significant (P value <0.01) for all subgroups except transgender people and Asian/Pacific Islander people.

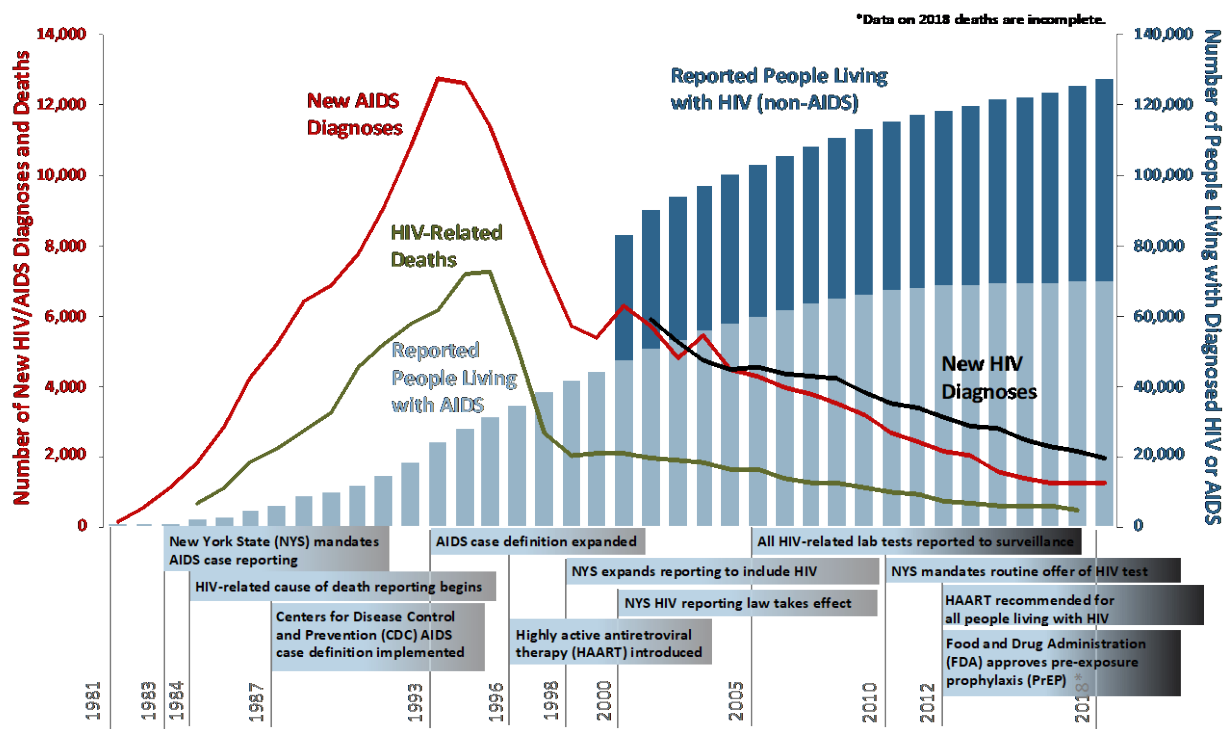
Data from ongoing HIV surveillance, service utilization analyses, and other sources show that HIV continues to disproportionately affect low-income Black and Latino/Hispanic communities; cisgender gay, bisexual, and other MSM, with increased inequities among youth/young adult men ages 13 to 29 years who have sex with men (YMSM) and Black and Latino MSM; Black and Latina cisgender women; and Black and Latina transgender women. As the impact of HIV on the above populations has been persistent within the NY EMA, no population could be considered emerging.

In 2019, ZIP codes in the Chelsea-Clinton, High Bridge-Morrisania, and Central Harlem-Morningside Heights neighborhoods had the highest new HIV diagnosis rates among NYC neighborhoods; ZIP codes in Chelsea-Clinton and West Queens had the highest HIV prevalence. Many ZIP codes with high new HIV diagnosis rates were also among those with the highest poverty rates, including those in High Bridge-Morrisania. However, ZIP codes in the higher income Chelsea-Clinton neighborhoods were the exception, with the highest new HIV diagnosis rates but relatively low poverty and mortality rates.^{ix} In 2017, people living in high poverty neighborhoods were least likely to have VS compared with people living in lower poverty neighborhoods.^x Previous analyses showed that the rate of HIV/hepatitis C (HCV) coinfection

was five times higher in high poverty neighborhoods than in low poverty neighborhoods; a similar pattern was seen for HIV/hepatitis B and HIV/tuberculosis (TB) coinfection.^{xi}

Improving access to basic necessities for the most vulnerable is critical to ensuring people address their HIV health needs. Thus, the NY EMA allocated 46% of GY21 funds to supportive services, including \$12.5 million to housing services and \$9.7 million to food and nutrition services (FNS). NY EMA further invested in oral health care (\$690,630), emergency financial assistance (EFA) (\$685,618), and other professional services (legal services) (\$4.9 million). To support continued engagement of people most at risk for falling out of care and to address their unique challenges, NY EMA's largest investment was in medical case management (MCM) (\$22.6 million), of which there are two models in the GY21 plan: Care Coordination Program (CCP) and Tri-County MCM.² Both programs serve to engage, link, and retain PWH in medical care to further address barriers to VS. CCP, which was rebid in 2018, has medical eligibility criteria that ensure these resources are prioritized for those who most need them, including people with a history of falling out of care, people who have not achieved VS, and people newly diagnosed with HIV. PWH with HCV and PWH who are pregnant, and who need additional adherence support, are also eligible for CCP services.

ii) Increased need for HIV-related services. As the number of PWH has increased and inequities have persisted, demands on the NY EMA's service system and need for RWHAP Part A funding along the entire HIV care continuum have grown. *Figure 1* illustrates that the need for care remains high in NYC despite the decrease in new HIV diagnoses, due to PWH living longer, healthier lives. **Figure 1. History of HIV epidemic, NYC 1981-2018**



² Two subcategories are included under the MCM category: NYC Care Coordination and Tri-County MCM. Note that from here forward the term "Care Coordination Programs (CCP)" refers specifically to NYC Care Coordination efforts, while MCM describes the general category for the entire NY EMA.

While the number of new HIV diagnoses in NYS has declined, the HIV diagnosis rate in NYS is the highest among Northeastern states, and similar to that of some of the Southern states. The average rate of HIV diagnoses in 2018 (per 100,000 people) was 15.6 in the South and 9.9 in the Northeast. However, NYS's HIV diagnosis rate (12.6) is within the range of southern states—where rates range from 4.8 in West Virginia to 23.8 in Georgia, including North Carolina (11.5), South Carolina (14.1), Texas (15.3), and Mississippi (16.0).^{xii}

Despite overall decreases in estimated HIV incidence among MSM of all race/ethnicities in NYC from 2014 to 2018, in 2018 the estimated incidence among Black and Latino MSM was more than twice the incidence among White MSM. MSM ages 25 to 29 years and 30 to 39 years had the highest HIV incidence rate compared to other age groups.^{xiii} HIV incidence among all MSM attending the NYC HD's Sexual Health Clinics (SHCs) declined from 2012 through 2017, but racial and ethnic inequities persist. Among people with newly diagnosed HIV in NYC in 2018, Black people, women, people ages 20 to 29 years and 50 years and older, people reporting heterosexual, MSM, or MSM-IDU risk less frequently initiated care within one month of diagnosis. There were also inequities in VS among newly diagnosed people in 2019, with Black people, people ages 40 years and older, people with a history of IDU, transgender people, and people of unknown transmission risk all having lower VS rates than their counterparts.^{xiv} In 2019, PWH with a history of IDU were disproportionately represented among all PWH who died, making up only 11% of PWH but 25% of deaths among PWH in the NY EMA.

In the 2017 National HIV Behavioral Surveillance cycle, 28% of the NYC MSM interviewed reported engaging in non-injection drug use for one week or more in the previous 12 months, and compared to those over the age of 50, a much higher proportion of MSM under the age of 50 reported binge alcohol use in the previous 12 months.^{xv} NYC HD routinely conducts surveys online and in-person among sexually active NYC MSM, ages 18 to 40 years. Among eligible online participants in fall 2019, 4.7% (48/1,021) reported methamphetamine use in the past six months; there were no statistically significant differences by race/ethnicity.^{xvi} According to data from the Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE)³, recent methamphetamine use among MSM in the RWHAP Part A population increased from 4.2% in fiscal year (FY) 2012 to 9.6% in FY19. Recent methamphetamine use was highest among MSM who are homeless (11.1%) compared to MSM with a residence in any other borough (Bronx, 8.8%; Brooklyn, 9.1%; Manhattan, 11%; Queens, 5.8%; and Staten Island, 9.4%). Previous work by the NYC HD found methamphetamine use to be associated with unsuppressed VL.^{xvii}

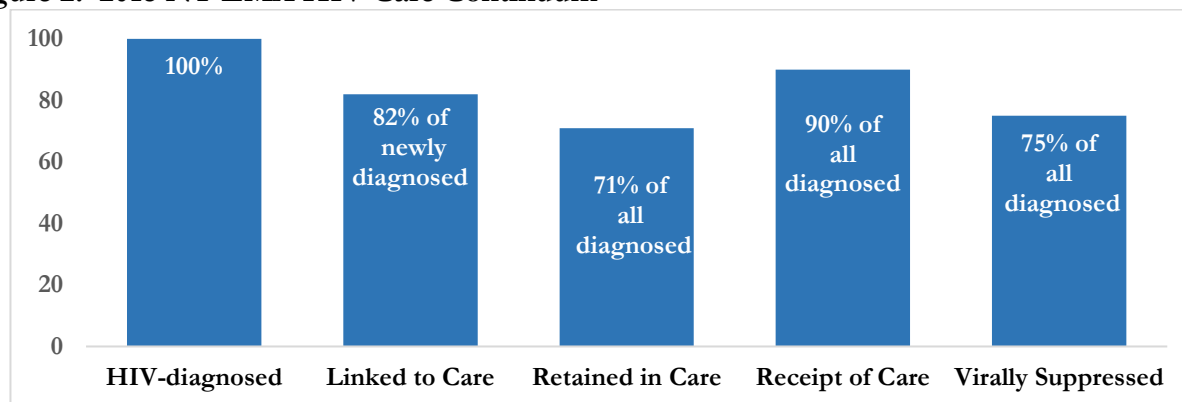
Despite progress toward identifying PWH in the NY EMA and linking them to medical care, HIV still causes significant morbidity and mortality, particularly among Black and Latino/Hispanic communities. A study assessing the relationship between place-based characteristics and VS among MSM in NYC found that residents living in United Hospital Fund (UHF) neighborhoods where less than 30% of residents were Black had a statistically significant higher likelihood of achieving VS, compared to those living in UHF neighborhoods where more than 30% of residents were Black.^{xviii} In another study assessing pre-death care patterns among PWH in NYC, PWH with HIV-related mortality had lower rates of VS, with lowest rates among Black and Latino/Hispanic PWH. In addition, although 54% of deaths between 2007 and 2013 among NYC PWH were due to non-HIV-related causes, 35% of White people compared to 48% of Black and/or Latino/Hispanic people died due to an underlying HIV-related cause.^{xix} Although deaths attributed to HIV have fallen from 2,012 in 2007 to 1,683 in 2018, HIV was the tenth leading cause of

³ eSHARE is a web-based platform for HIV service provider reporting that permits enhanced information-sharing between programs within agencies and real-time access to demographic, services, and outcomes data at the NYC HD.

premature death overall among NYC residents under 65 years of age, and the fifth and sixth leading cause of premature death for Black and Puerto Rican New Yorkers, respectively.^{xx}

2) HIV Care Continuum.

Figure 2. 2018 NY EMA HIV Care Continuum



Sources: Prescribed ART: NYC HD, Medical Monitoring Project (MMP), 2018; All other: NYSDOH, BHIV Epidemiology, data as of 6/26/20.

Notes: “HIV-diagnosed”: those diagnosed by 12/31/18 and living & residing in NYC or the Tri-County Region as of 12/31/2018; “Linked to care”: those newly diagnosed with HIV in 2018 with one or more VL or CD4 count within 30 days of diagnosis; “Retained in care”: those among HIV-diagnosed with at least two VL or CD4 counts in 2018 at least 91 days apart; “Receipt of Care”: the proportion of NYC MMP participants whose medical record documented ART prescription during 12 months prior to MMP interview date (interview date range 9/19/18 – 4/23/19); “Virally suppressed”: those among HIV-diagnosed whose most recent VL in the year was <200 copies/ml.

Although the NY EMA (*as seen in Figure 2*) is working toward EHE goals related to retention in care (90%) and VS (90%), inequities exist among certain subpopulations. In 2018, Black MSM ages 13 to 29 years (YBMSM), Black women, Black OPWH, and Black transgender women were the most disproportionately impacted populations in the NY EMA; these inequities are displayed in *Figures 3a through 3d*. Among YMSM, only 67% of YBMSM were virally suppressed in 2018 as compared to 75% of White MSM ages 13 to 29 years (YWMSM) and 72% of Latino MSM ages 13 to 29 years (YLMSM). Barriers to care include the lack of youth- and young adult-friendly health clinics, lack of social and family support, and lack of technology use to connect patients to a community of other youth/young adults living with HIV and to help them readily access health care providers and track personal data and information.

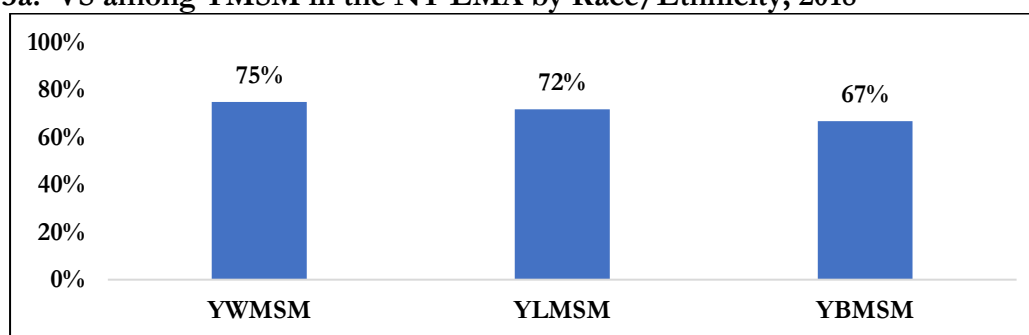
In 2018, among women living with HIV in the NY EMA, VS was lower among Black women (73%) when compared to White women (77%) and Latina women (78%). Among OPWH, VS was lowest among Black OPWH (77%) compared to White OPWH (82%) and Latino/Hispanic OPWH (81%). HIV care has been fraught with stigma and racism, and the impact of age-related conditions coupled with structural inequities in care are a major barrier to care for Black OPWH. Similarly, among transgender women, VS was lowest among Black transgender women (64%) compared to White transgender women (71%) and Latina transgender women (72%).

These inequities are addressed in part by geographically targeting services to underserved neighborhoods with high numbers of PWH and prioritizing service types that address structural inequity, access to and engagement in care, support for adherence to ART, and basic survival needs (e.g., Housing, FNS, CCP). In 2018, the BHIV’s Care and Treatment Program (CTP) also introduced a number of work groups focused on youth, OPWH, Black and Latina transgender women, and Black and Latina cisgender women, to more systematically identify strategies for reducing inequities. The Planning Council (PC) and CTP also created a service directive for

transgender PWH in NYC. A survey by Black and Latina Cisgender Women Work Group members found communities' top unmet needs include the role of race/racism and stigma in treatment of Black and Latina women with HIV; increasing trauma-informed approaches and services to address trauma experienced by Black and Latina women with HIV; and increasing access to comprehensive social supports for Black and Latina women with HIV. The Black and Latina Transgender Women Work Group identified the absence of transgender providers and staff in HIV medical care and service provision as a major barrier to care. Other barriers include internalized and enacted stigma and use of regular business hours for service provision.

Additionally, the NYS ETE initiative includes a goal that by the end of 2020, 75% of PWH will achieve sustained VS⁴. According to data reported to the NYC HD as of March 31, 2020, in 2019, 69% of PWH established in HIV medical care in NYC achieved sustained VS. Continued efforts to reduce inequities in VS among YBMSM, Black women, Black OPWH, and Black transgender women will drive progress towards these goals.

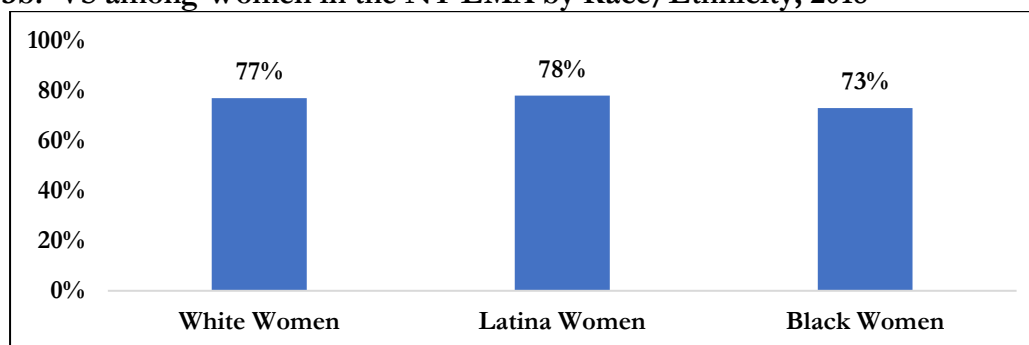
Figure 3a. VS among YMSM in the NY EMA by Race/Ethnicity, 2018



Source: NYSDOH, Bureau of HIV/AIDS Epidemiology, data as of 6/26/20

Notes: Data includes YMSM diagnosed by 12/31/18 and living and residing in NYC or the Tri-County region as of 12/31/18. Virally suppressed includes YMSM whose most recent VL in the year was <200 copies/ml.

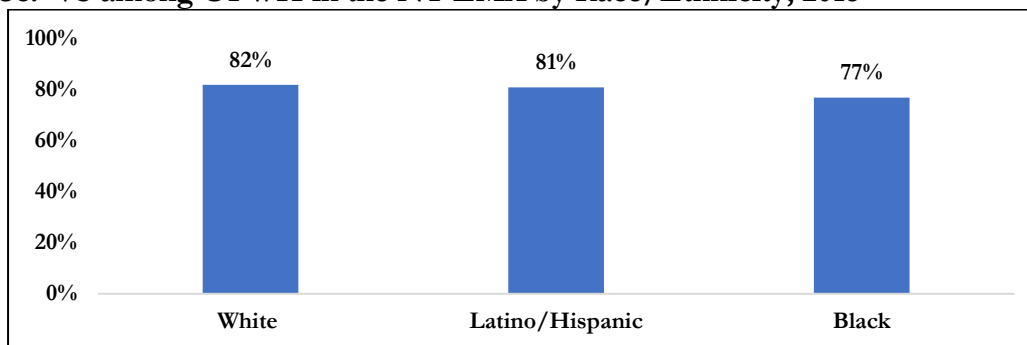
Figure 3b. VS among Women in the NY EMA by Race/Ethnicity, 2018



Source: NYSDOH, Bureau of HIV/AIDS Epidemiology, data as of 6/26/20.

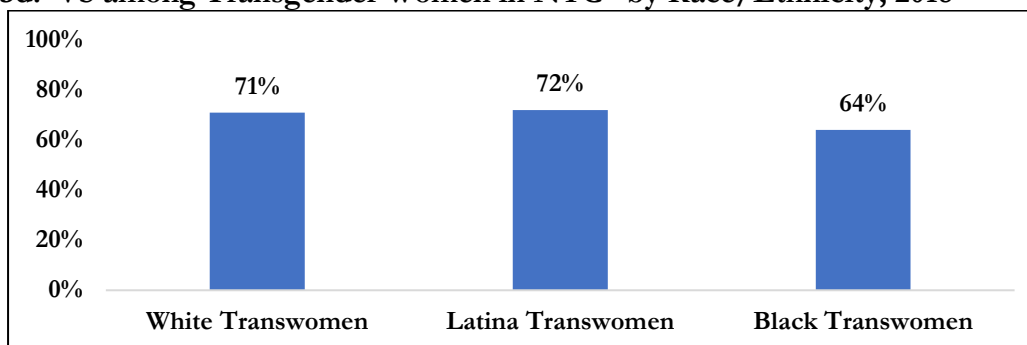
Notes: Data includes women diagnosed by 12/31/18 and living and residing in NYC or the Tri-County region as of 12/31/18. Virally suppressed includes women whose most recent VL in the year was <200 copies/ml.

⁴ Sustained VS defined as VL <200 copies/ml on all VL tests in the previous two years among people with at least two VL tests in the previous two years.

Figure 3c. VS among OPWH in the NY EMA by Race/Ethnicity, 2018

Source: NYSDOH, Bureau of HIV/AIDS Epidemiology, data as of 6/26/20.

Notes: Data includes women diagnosed by 12/31/18 and living and residing in NYC or the Tri-County region as of 12/31/18. Virally suppressed includes women whose most recent VL in the year was <200 copies/ml.

Figure 3d. VS among Transgender Women in NYC* by Race/Ethnicity, 2018

Source: NYC HD, HIV Epidemiology Program, data as of 5/31/19.

Notes: Data includes transwomen diagnosed by 12/31/17 and living and residing in NYC region as of 12/31/18.

Virally suppressed includes transwomen whose most recent VL in the year was <200 copies/ml.

*NYSDOH does not currently collect transgender data for the Tri-County Region.

3) Co-occurring conditions (see Attachment 4).

a) Hepatitis C virus (HCV). Roughly 10.6% of PWH in NYC were diagnosed with HCV by December 31, 2018. HIV/HCV coinfection can lead to higher VLs and accelerate the onset of HCV-related complications, including cirrhosis and end-stage liver failure, particularly when HIV is not well-managed. In an analysis among people with HIV/HCV coinfection in NYC in 2016, those without durable VS were 66% less likely to initiate HCV treatment.^{xxi} Facilitating engagement in HCV treatment is vital; according to preliminary findings from a NYC HD analysis of mortality among RWHAP Part A clients served in at least one long-term RWHAP program from 2013-2015, clients diagnosed with HCV had significantly higher odds of death than those without HCV.

NYS Medicaid covers Direct Acting Agents (DAAs) that cure HCV with very few limitations, but coverage under other forms of insurance varies widely. For PWH who are uninsured, or who need assistance with co-pays and deductibles, NYS AIDS Drug Assistance Program (ADAP) added most DAAs to the formulary in November 2016, with the exception of those made by one drug manufacturer. Despite wider availability of effective, well-tolerated treatments in NYC, only 67% of coinfecting RWHAP Part A clients appear to have initiated HCV treatment by the end of 2018; however, this is an increase from 59% at the end of 2017.^{xxii} In July 2018, Governor Cuomo released the nation's first strategy to eliminate HCV allocating \$5 million primarily to community health centers and local health departments outside of NYC. Further, the plan seeks to expand

access to HCV treatment by implementing new policies that will increase access at HR provider settings such as syringe exchange programs. NYS will also require managed care organizations (MCOs) to (1) extend the prior authorization period to six months; (2) eliminate the requirement that patients undergo VL testing in order to continue receiving HCV medication; and (3) reimburse health care providers for use of telehealth or videoconferencing services as a part of HCV treatment.

b) Sexually transmitted infections (STIs). STIs increase the risk of sexual HIV transmission.^{xxiii} In 2018, NYC's STI case rates were highest in neighborhoods with high HIV prevalence; Central Harlem and Chelsea have high rates of primary and secondary (P&S) syphilis, gonorrhea, and chlamydia. In the NY EMA, rates of STIs are higher among PWH than the general population. In 2019, the preliminary rate (per 100,000) of P&S syphilis was 23.6 for the general population, and nearly nine times higher (209.3) for PWH. This is mirrored in preliminary rates of gonorrhea (344.9 for general population vs. 1,206.1 for PWH) and chlamydia (907.2 for general population vs. 1,738.7 for PWH). Since 2001, the number of P&S syphilis cases has increased six-fold in NYC overall. Preliminary data show that in 2019, 95% (1,865/1,973) of P&S syphilis diagnoses were among men, and among those who reported the sex of their sex partners during interview, 88% were MSM; among MSM with P&S syphilis in 2019, 43% were PWH. These data also show that in 2019, over 76,000 new chlamydia diagnoses and approximately 29,000 new diagnoses of gonorrhea were reported in 2019; the highest case rates were seen among Black and Latino men under 29 years of age. Gonococcal infections with decreased susceptibility to azithromycin continue to be reported; however, there is little current evidence of drug resistance to cephalosporins.

c) Mental illness. In the Community Health Advisory & Information Network (CHAIN)⁵ surveys conducted between June 2015 and February 2020 among PWH, 37% of the NYC cohort and 24% of the Tri-County Region cohort reported having severe mental illness (SMI). Among NYC RWHAP Part A clients enrolled and served in 2019, 25% screened positive for depression and 24% screened positive for anxiety using the PHQ-4 tool. Additionally, analyses have found a VS disparity among GY18 RWHAP Part A clients with a recorded MH screen in eSHARE, 76% of clients with at least one MH diagnoses achieved VS. Clients who indicated psychosis had the lowest proportion of VS (67%), followed by bipolar disorder (69%).^{xxiv} In a study examining the relationship between RWHAP Part A MH services utilization and MH outcomes among PWH, higher utilization of MH services was associated with improvements in MH functioning.^{xxv}

d) Substance use disorder (SUD). Among CHAIN participants surveyed from June 2015 to February 2020, 20% of the NYC cohort and 2.7% of the Tri-County Region cohort reported substance use, including IDU. Additionally, 11% of the NYC cohort and 21% of the Tri-County Region cohort reported lifetime IDU. Among RWHAP Part A clients served in 2019, 19% of those assessed reported recent hard drug use (e.g., cocaine, heroin, methamphetamine, and/or prescription drugs). Of RWHAP Part A clients with some evidence of HIV medical care (i.e., at least one lab report) in 2019, 65% of those who reported recent hard drug use during the year were virally suppressed, compared to 83% of those who did not report recent hard drug use.

e) Homelessness. The NY EMA has a high prevalence of homelessness and housing instability, and a real estate market with an extremely low vacancy rate, creating an affordable housing shortage for those most in need.^{xxvi} Between 2011 and 2016, median rents in low-income neighborhoods

⁵ The CHAIN cohort study, in place since 1994, provides ongoing information on the characteristics, co-morbidities, and care needs and service use patterns of PWH in the NY EMA. More than 4,000 PWH have completed 15,516 interviews conducted by researchers at Columbia University. The cohort is broadly representative of the PWH in the NY EMA, with modest over-representation of Black men and women and Latino men, so that participants more closely represent the NY EMA's RWHAP Part A clients.

increased by 26.2%, while real median household incomes fell by less than 3%.^{xxvii} Rent burden is high; in 2017, 50% of NYC renters paid more than one-third of their incomes for rent and utilities, while 32% paid more than one-half of their incomes for rent and utilities.^{xxviii} The COVID-19 pandemic has exacerbated homelessness and housing instability. During the NYS on PAUSE order, many businesses closed or operated at a reduced capacity, resulting in loss of income for many households, increasing the risk of eviction and homelessness, and decreasing the ability to take shelter in place measures to minimize the risk of exposure to COVID-19.^{xxix}

Nearly 133,000 unique individuals accessed the NYC shelter system in FY19, a 61% increase over the last 10 years.^{xxx} Data from the 2020 annual NYC Homeless Outreach Population Estimate Street Survey suggest that nearly 3,900 homeless individuals may be unsheltered on any given night.^{xxxi} Black and Latino/Hispanic people are disproportionately affected by homelessness and housing insecurity, representing 86% of NYC single adult shelter residents in 2020.^{xxxii} Studies also show that the large majority of NYC street homeless have a MH diagnosis and/or other chronic conditions.^{xxxiii} In response, NYC released its Housing New York 2.0 Plan in 2017, and as of September 30, 2019, has created or preserved 136,912 units of affordable housing.^{xxxiv}

The prevalence of homelessness among PWH is especially high. Among CHAIN participants surveyed from June 2015 to February 2020, 15,146 per 100,000 of the NYC cohort, and 775 per 100,000 of the Tri-County Region cohort were homeless. Housing instability and homelessness were also prevalent among RWHAP Part A clients served in 2019, with 9% of those assessed reporting accessing temporary housing during the year, and 21% reporting being unstably housed. Among those engaged in HIV medical care in 2019, 78% of temporarily housed and 66% of unstably housed clients were virally suppressed, compared to 84% of those with stable housing, underscoring the added health benefits of being stably housed.

The risk of acquiring HIV is 90% lower for homeless people in NYC who receive three or more consecutive years of supportive housing, compared with homeless people in NYC who apply for but are not placed in supportive housing.^{xxxv} The average monthly health care and public service costs for chronically homeless people can fall more than 50% following the provision of housing, substance use treatment, and other needed support services.^{xxxvi} PWH enrolled in CHAIN whose HIV medical care did not meet minimum clinical standards and who receive housing assistance were 1.4 times more likely to enter appropriate HIV primary care than those not receiving housing assistance. PWH adhering to ART and who received housing assistance were 1.5 times more likely to remain adherent to ART treatment than those not receiving housing assistance.^{xxxvii} Research also shows longer-term HOPWA enrollment is associated with better HIV health outcomes compared to shorter enrollment.^{xxxviii}

f) Formerly incarcerated individuals. Over two-thirds of NYS inmates return to NYC and reside in seven ZIP codes located in Central Brooklyn, Central and East Harlem in Manhattan, and the South Bronx, where the number of new HIV diagnoses and prevalence of PWH are among the highest in NYC.^{xxxix} According to the NYC Community Health Survey (CHS), over 50,000 people returned to the NY EMA from NYS prisons and local jails within calendar year 2017. Of those released, an estimated 2,400 (8%) were PWH returning primarily to these three areas. Further, while the overall NYC jail census declined from 5,500 in March 2019 to 4,000 in March 2020, the percent of PWH in NYC jails doubled from 4% to 8%, illustrating the overrepresentation of PWH in NYC jails. Approximately 40% of RWHAP Part A clients assessed in 2019 reported a history of incarceration. Among those in HIV medical care in 2019, 69% of clients with a history of incarceration were virally suppressed, compared to 86% of those who had never been incarcerated.

A 2010 cost analysis found that the mean cost of providing linkages to care and social support services to achieve VS among formerly incarcerated PWH is \$8,432. Compared to standard care, the cost per additional quality-adjusted life year saved is \$72,285 suggesting HIV linkage services for formerly incarcerated people is cost-effective.^{xi} These high costs may be attributable to the challenges that formerly incarcerated people—many of whom are Black or Latino/Hispanic—often face upon release, such as homelessness, MH issues, substance use/addiction, joblessness, and other chronic conditions. The presence of these challenges can undermine continuity of care and linkage to case management, housing, financial assistance, and other services.

g) COVID-19 and HIV. To better understand the intersection of COVID-19 and HIV—including the number of PWH diagnosed with COVID-19, whether PWH are at increased risk for COVID-19, and whether PWH have poorer health outcomes following COVID-19 infection—NYC HD conducted a match of reported COVID-19 case and death data against HIV surveillance data. Using the NYC COVID-19 surveillance dataset of confirmed COVID-19 cases and confirmed and probable deaths attributed to COVID-19 (reported as of June 2, 2020), and data from the HIV Surveillance Registry (reported as of March 31, 2020), NYC HD found that PWH made up 1.2% of people diagnosed with COVID-19; a slight under-representation given PWH are 1.5% of the general NYC population. Of the PWH diagnosed with COVID-19, there was an over-representation of Black (45%) and Latino/Hispanic (41%) people compared with citywide diagnoses of COVID-19 (29% Black, 33% Latino/Hispanic). Furthermore, higher proportions of PWH with COVID-19 experienced more serious COVID-19 complications than citywide cases overall, with 42% hospitalized (vs. 26%), 5% admitted to ICU (vs. 3%), and 13% deceased (vs. 8%). The match also identified that 64.3% of PWH with COVID-19 had an underlying condition, versus 35.4% citywide with COVID-19. To address the needs of PWH and of RWHAP Part A subrecipients, the NY EMA transitioned to a cost-based reimbursement model to ensure clients are served effectively and programs costs are addressed. See *p. 14* for additional details.

h) Tobacco dependence. Despite a record low prevalence of smoking in NYC (less than 14%), heavy tobacco use and dependence persist among several populations, including PWH.^{xii} In addition to the commonly known negative health effects of tobacco use, PWH are at additional risk for HIV-specific adverse health outcomes. An analysis conducted by the NYC HD found that recent tobacco smoking was reported by 39% of PWH enrolled in RWHAP Part A in 2019. Recent tobacco smoking was independently associated with low CD4 cell counts and unsuppressed VL, even after controlling for several clinical and sociodemographic characteristics, including substance use and ART prescription status.^{xiii} Data from a CHAIN study confirmed prior findings of the detrimental effect of smoking on long-term survival. Former smokers had a higher rate of long-term survival than current smokers, suggesting that smoking cessation interventions may be an effective means to lengthen life among PWH.^{xiii} Additional studies have found increased risk for some cancers and death, and a reduction in life expectancy related to tobacco use, regardless of VL and CD4 count.^{xliv} In studies exploring tobacco dependence and behavioral health, tobacco use is associated with worse SUD treatment outcomes and increased depressive symptoms.^{xlv}

Despite mounting evidence of poor health outcomes among PWH who smoke, studies show that tobacco smoking is not routinely addressed by HIV service providers, including support service providers such as those in RWHAP Part A-funded MH or HR services. Among RWHAP Part A clients served in 2019, those receiving HR services in the NY EMA and MH services in the Tri-County Region had the highest rate of recent smoking, at 62% and 67% respectively. The NY EMA works with MH and HR providers to treat tobacco dependence in tandem with medical and behavioral health to support significant short- and long-term health benefits to PWH.

i) Intimate Partner Violence (IPV). The NYC HD's PlaySure Network for HIV prevention is a citywide network of HIV testing sites, CBOs, and clinics working together to promote patient-specific approaches to sexual health and HIV prevention, increase access to PrEP and PEP, and link people who test positive for HIV to care. In 2019, among all PlaySure Network clients with a baseline assessment, approximately two-thirds said that their partner had never: physically hurt them, insulted or talked down to them, threatened them with harm, or screamed or cursed at them. Roughly 3% said that their partner had sometimes, fairly often or frequently physically hurt them, insulted or talked down to them, threatened them with harm, or screamed or cursed at them. However, 27% of clients declined to answer any of the questions. When asked about their interest in a referral to an IPV support program, 1.2% of clients said yes, 6.2% declined to answer, 27% said this was not applicable to them, and 66% said no.

4) Complexities of Providing Care.

a) Impact and response to a reduction of RWHAP Part A funding.

Impact. The NY EMA has seen reductions totaling approximately \$28 million since GY11, including a reduction of 1.4%, or \$1,330,082, in GY20. During this period of reductions, the PC and the Recipient have acted to preserve, to the greatest extent possible, those services that most directly impact the health of PWH. All RWHAP service categories have experienced reductions in funding over the years, and, after a careful review of other payers, four have been eliminated altogether: Home and Community-Based Health Services, Outpatient/Ambulatory Health Services, Transitional Care Coordination, and, most recently, Non-MCM. In the last three years, the ADAP allocation alone has absorbed the bulk of the reductions after frank and thoughtful conversations and planning with the NYS HIV Uninsured Care Programs (NYS HUCP), the state program that administers ADAP and other programs for PWH. NYS HUCP was able to absorb the reductions by refocusing some of its rebate funding and RWHAP Part B supplemental funding to preserve NYS HUCP services. With each year's reduction, the PC and the Recipient have been strategic in their response and proactively plan to ensure funding reductions do not erode the NY EMA's successes in VS and reductions in morbidity and mortality.

Response. To address the reduction in funding, the PC's Priority Setting and Resource Allocation (PSRA) Committee reassessed each category through an extensive review of Service Category-Specific Fact Sheets in GY20. The documents compiled up to five years of data on allocations, expenditures, service utilization (by service unit), and client demographics. The Fact Sheets also summarized data on payer of last resort (POLR) issues and systems-level considerations (e.g., changes in federal, state, and local funding and policies). To meet the reduction in the GY20 award, the PSRA Committee was able to utilize savings of \$298,268 in the carrying costs of four service categories: n-MCM/Currently or Recently Incarcerated, n-MCM/General Population (NMG), MH, and HR. These service categories did not require the same funding level due to permanent contract take-downs or terminations, as reported by the Recipient. In order to cover the remainder of the reduction to the award, the PC worked closely with the NYSDOH to agree on a reduction of \$1,031,814 to the NY EMA's allocation to ADAP to cover both the reduction in the grant award and the enhancements to categories with demonstrated need. Following the PC's approved reprogramming plan, the reduction to ADAP will be partially restored through reprogramming dollars from underspending contracts over the course of the year, and there will be no effect on the availability of medications for ADAP enrollees. In GY20, the PC enhanced two critical services—FNS and EFA—through unallocated Part A funds resulting from an Early Intervention Services (EIS) contract discontinuation and the reduction in the ADAP allocation.

The NY EMA was also able to increase support for housing through funding received under the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

b) Table 2. NY EMA Uninsured and Poverty

Diagnosed and reported PWH in NY EMA	# of PWH	% of PWH
<i>a1.</i> PWH in the NY EMA enrolled in Medicaid	54,945	63.8%
<i>a2.</i> PWH in the NY EMA enrolled in Medicare & Medicaid (dual eligible)	11,983	21.8%
<i>a3.</i> PWH in the NY EMA enrolled in marketplace exchanges	21,840	25.4%
<i>b.</i> PWH in the NY EMA without any insurance coverage	9,326	10.8%
Active RWHAP clients in the NY EMA, GY20		
<i>c1.</i> PWH in the NY EMA living at or below 100% of 2020 FPL	10,587	80.0%
<i>c2.</i> PWH in the NY EMA living at or below 138% of 2020 FPL	11,712	88.5%
<i>c3.</i> PWH in the NY EMA living at or below 400% of 2020 FPL	13,191	99.6%
<i>c4.</i> PWH in the NY EMA living at or below 500% of 2020 FPL*	13,224	99.9%

Sources: Data in sections a. and b. provided by NYSDOH to NYC HD. Dual eligible is a subset of Medicaid enrolled. Numbers and corresponding percentages reflect insurance program enrollment available through July 2020. Numbers and corresponding percentages in section c. are from eSHARE.

*Residents with income under 500% FPL are eligible for RWHAP services. No income restrictions EIS or HE/RR.

As a result of the COVID-19 pandemic, the NYC unemployment rate was reported at 16% in August 2020.^{xlvii} Since health insurance is tied to many individuals' employment, many New Yorkers found themselves without coverage during the pandemic. Insurance coverage is even more critical for PWH to access necessary medical and supportive services that support VS. According to preliminary data from NYSDOH, more than 4,900 PWH in the NY EMA enrolled in Medicaid, Medicaid/Medicare (dual eligible), or the marketplace exchanges since February 2020 as a result of the COVID-19 pandemic (i.e., indicated job loss, COVID-19 positive test, etc.). Further, an estimated 1,600 PWH in the NY EMA have been without insurance coverage since February 2020.

c) Barriers to accessing health care.

COVID-19. In the current era of COVID-19, clients have experienced numerous barriers to care—reported VL labs to NYC surveillance dropped by 77% in April 2020 when compared to April 2019. To address the challenges and ensure the NY EMA preserves the HIV care system, the Recipient directed reimbursement for cost (versus performance-based reimbursement) until further notice. Use of telehealth has been strongly encouraged and taken up by the vast majority of service providers as appropriate (with the exception of housing and FNS providers which require mostly in-person contact with clients using CDC guidelines). Within the first month of the pandemic, the Recipient communicated the expectation that each client enrolled in each program be contacted to determine their needs with follow up as appropriate. As mentioned earlier, the Recipient worked with the PC to allocate additional resources to critical FNS, Housing, and EFA services.

Geographic variation. NYC is well known for its extensive subway system, but the NY EMA also includes three counties north of NYC that are mostly suburban or rural, and that lack many of the resources of NYC. Not only do non-NYC counties lack robust mass transit, they also do not have as many resources that support access to and retention in health care.

Thus, while New Yorkers are a highly insured population, limited transportation services and lack of local specialists and service providers serve as barriers to obtaining appropriate health care. To increase access to services, the NY EMA considers geographic distribution of contractors during procurement and contracting and has allocated \$358,057 to medical transportation to provide access to taxi and gas vouchers, as appropriate, and to mass transit options where available. The medical

transportation program in the Tri-County Region of the NY EMA ensures that clients are able to attend appointments for services related to their HIV primary care, including medical care, SUD treatment, MH appointments, and to pick up prescriptions. In addition, the NY EMA will enhance EFA in GY21 to help address barriers to care for RWHAP Part A participants throughout the NY EMA. The EFA program is housed in the Tri-County Region, and while it was originally set up to serve that area, the program was enhanced in GY20 and GY21 to cover emergent needs directly affecting the care and treatment of RWHAP Part A clients throughout the NY EMA. The EFA service category entitles any RWHAP Part A participant up to \$2,000 to cover the cost of an emergent need relating to their HIV care and treatment.

Adequacy of health insurance coverage. NYS Medicaid, which expanded to include adults up to 138% FPL with the passage of the Affordable Care Act (ACA), provides insurance coverage for eligible PWH. In addition, insurance coverage is available at no cost to PWH with an income up to 500% of the FPL through a combination of expanded Medicaid and NY State of Health insurance exchange plans alongside support for premiums and copays from the NYS HUCP (*see p. 33-35 for details*). These changes affected health insurance options in the jurisdiction, as well as RWHAP Part A service needs and delivery. From June 2016 to December 2019, Medicaid enrollment increased by 17% among PWH in the NY EMA. In order to continue this trend, specific outreach and enrollment activities continue throughout the NY EMA to ensure that people eligible for health care coverage are enrolled and that coverage is maintained.^{xlvi} Specifically, all RWHAP Part A contracts require programs to assess insurance status and maintain linkage and referral relationships with health plan navigation services to facilitate enrollment in health plans for eligible individuals at enrollment and at every six month reassessment.

Cultural and language barriers. The NY EMA is home to more than 200 languages—with half of New Yorkers speaking a language other than English, including monolingual and multilingual people. Within the RWHAP Part A population, 26% of non-EIS clients in GY19 reported a language other than English as their primary language. Of clients reporting a primary language other than English, most speak Spanish (80%), followed by French (4%), Haitian Creole (3%), African languages (2.5%), and French Creole (2.2%). RWHAP Part A clients also speak Russian, Portuguese, Mandarin-Chinese, Arabic, Tagalog, and Thai, among other languages.

To address these diverse language needs, the NY EMA prints materials in the most common languages of the jurisdiction: English, Spanish, and French/Haitian-Creole. Providers will often adapt and translate materials to meet the needs of their client populations. For example, an agency with expertise in serving Chinese-speaking clients translated CCP materials into Chinese.

To improve services to the diverse RWHAP Part A client population, the Recipient has taken steps to implement standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS Standards).^{xlvi} To help subrecipients recognize steps to make services more responsive to the diversity of clients receiving RWHAP Part A services, the Recipient formed a work group to develop a CLAS Standards self-assessment programs may use to compare their organizations against CLAS Standards. It includes 20 questions addressing governance, leadership, workforce, communication, language assistance, engagement, continuous improvement, and accountability. Providers are asked to complete the self-assessment internally, identify areas for improvement, and take action through quality improvement (QI) projects. NYC HD distributed the tool to NYC RWHAP Part A providers in May 2019 and to Tri-County Region providers in July 2019. Providers are contractually required to complete the self-assessment, identify areas for improvement, and include action steps in their annual RWHAP Part A Quality Management Plan.

Service gaps and plans to address them. The RWHAP Part A service portfolio is carefully designed to meet needs identified through surveillance, program evaluation, CHAIN data, and changes in the NY EMA's health care landscape. Identified needs are addressed through incorporation of lessons learned and evidence-based interventions in service models to support effective diagnosis, linkage to and retention in care, and adherence to ART. COVID-19 has presented additional service needs that the RWHAP Part A program in the NY EMA has sought to address. As previously stated, the Recipient added funds to Housing, FNS, and EFA services to help ensure participants are housed, fed, and able to focus on their HIV care and treatment during the pandemic.

Individuals diagnosed but not currently engaged in care. Based on the HIV care continuum, 29% of people diagnosed with HIV and presumed to still be living in the NY EMA are not currently engaged in care. In addition to robust supportive services to locate and engage these individuals back into care, the RWHAP Part A program provides \$818,259 in funding to the nationally recognized Assess. Connect. Engage. (ACE) Team (formerly Field Services Unit) within the NYC HD's BHIV, which uses a data-to-care (D2C) model to identify PWH who, according to surveillance data, have been lost to care. The aim is to identify and reach people deemed to have never been in care since HIV diagnosis to: (1) ensure that they were aware of their own diagnosis, and (2) assist them with linkage to HIV primary care and services. To do so, the ACE Team has established collaborative relationships with NYC HIV medical providers, social services agencies, and community-based case management providers. In 2019, the ACE Team located 627 PWH who had been out of care for at least 13 months or had never been in care since their HIV diagnosis. Of these, 409 (65%) were re-engaged or linked to HIV care; and 108 clients had unmet needs (e.g., housing, health benefits, transportation), 82 referrals were made to address their needs, and 35 accessed services. Fifty-seven percent (343/606) of people currently not in care who refused to name partners were offered home test kits (Oraquick Rapid) to deliver to any unnamed partners they might think would benefit from HIV testing. Fifteen percent (50/343) accepted the home test kit and 88% (44/50) were confirmed to have received the test kit. Forty-one percent (18/44) of those who received the kits agreed to complete a follow-up interview about their experience. Among people not in care, 12% (74) were found to have an HCV infection per the NYC HD Viral Hepatitis Registry. Therefore, in addition to HIV linkage to care, 38% (28) of people with HIV/HCV coinfection were linked to HCV care.

Individuals who are not currently virally suppressed. In 2018, 25% of PWH in the NY EMA were virally unsuppressed. In GY21, as in previous years, RWHAP Part A services will be distributed to reach high-need, underserved Black and Latino/Hispanic communities, with consideration given to the geographic distribution of Medicaid and RWHAP Parts B-, C-, D-, and F-funded services and providers' capacity to address health inequities. In addition, CCP clients obtain services co-located or linked with primary care providers. CCP programs linked with primary care are required to have a Memorandum of Understanding (MOU) between the program and the primary care provider to ensure CCP staff are included as members of the care team, have access to the clients' clinical information, and participate in joint case conferences. RWHAP Part A-funded initiatives will continue to be complemented by targeted Minority AIDS Initiative (MAI) programs that promote early diagnosis and linkage, adherence to treatment, and stable housing for PWH of color.

Efforts to retain PWH in care and support ART adherence and VS include the RWHAP Part A MH programs, which engage people with psychiatric diagnoses through navigation; educate on MH issues; coordinate care between MH and medical care providers; treatment adherence support; and provide psychiatric, individual, family, and group MH services for those without another payer. Similar services are also provided in HR programs for those using substances.

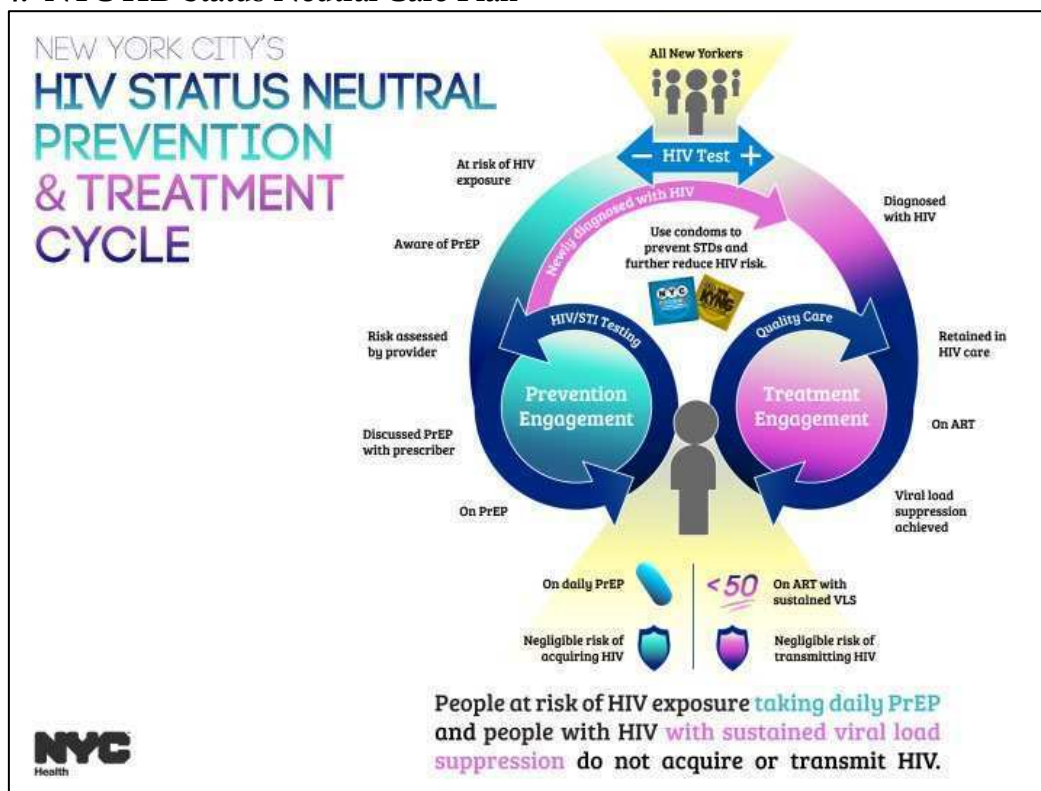
Lastly, as described on p. 53 in the Clinical Quality Management (CQM) section, each NY EMA RWHAP Part A provider receives client-level reports of those reported to eSHARE as not virally suppressed, in an effort to ensure that these clients are referred to services addressing barriers to VS.

Early Identification of Individuals with HIV/AIDS (EIIHA).

1) Planned Activities of the NY EMA EIIHA Plan for GY21.

a) Primary activities. The primary activities in the NY EMA's EIIHA plan for GY21 are (1) to promote and increase HIV testing, (2) to improve timely linkage of people newly diagnosed with HIV to medical care, and (3) to increase awareness of and referral to HIV prevention services, including PrEP, PEP, treatment as prevention, and condoms. In 2016, the NYC HD rolled out a "status neutral" approach to HIV prevention and care services that simultaneously addresses the needs of PWH and people not living with HIV (see Figure 4). The NY EMA's EIIHA plan for GY21 will build upon the City's successes with this approach and align with the final NYC EHE plan, including building upon activities funded through CDC PS-18-1802, RWHAP Part A, and other local, state, and federal funding sources, and those being planned and implemented under Project PROSPER and CDC EHE funding (see pgs. 1-2). The ultimate aim of all activities is to strategically advance HIV prevention efforts in the four EHE counties to accelerate NYC's progress in reaching the national goal of a 75% reduction in new HIV infections by 2025.

Figure 4. NYC HD Status Neutral Care Plan



Testing. The NY EMA uses a two-tier approach to pursue the EIIHA goal to increase status awareness and reduce the number of undiagnosed and late diagnosed individuals.

Tier 1. The first tier supports sustainable access to HIV testing services for the general population citywide by promoting routine HIV screening programs in health care facilities. The first-tier approach is consistent with the CDC's 2006 Revised Recommendations for HIV Testing of Adults,

Adolescents, and Pregnant Women in Health-Care Settings. Routine screening enables large numbers of people to be tested by taking advantage of established systems for service provision and provides HIV testing to all, regardless of risk, including those who do not perceive themselves to be at risk or whose providers do not perceive them to be at risk for HIV.

The NY EMA has supported routine screening in the past by issuing guidance to clinicians on HIV testing, conducting public health detailing to clinicians' offices on HIV testing, and delivering grand round presentations to clinical practices and medical training programs. The NY EMA also uses City, CDC, and RWHAP Part A funding to support, but not supplant, HIV testing programs in health care settings and to support the implementation of community-level initiatives that promote HIV testing and normalize the testing experience, which has proven to be effective. In 2019, an estimated 7% of PWH in NYC were undiagnosed.^{xlix} To maximize the impact of funding, routine screening funding is focused on clinical facilities serving neighborhoods that are disproportionately affected by HIV and are underserved, such as the South Bronx, Central Brooklyn, and East and Central Harlem. *Table 3* below provides a breakdown by race/ethnicity of people who receive an HIV test during testing events across NYC among the NY EMA-contracted clinical and non-clinical providers. In GY19, the number of HIV tests was particularly high among enrolled Black and Latino/Hispanic people, with a higher proportion of Black individuals receiving a newly diagnosed confirmed positive test compared to Latino/Hispanic and other MSM individuals. Under CDC EHE funding (PS-20-2010), the NY EMA plans to expand capacity for routine testing by funding two cohorts of clinical providers to make system and policy level changes within their institutions to support routine HIV testing. The estimated start date for these contracts is mid-2021.

Table 3. Newly Diagnosed Positive HIV Test Events March 1, 2019 – February 29, 2020

	Total		*Black		*Latino/Hispanic		MSM		TGNC/NB ⁶	
	Clinical	Non-Clinical	Clinical	Non-Clinical	Clinical	Non-Clinical	Clinical	Non-Clinical	Clinical	Non-Clinical
<i>a</i> # Test events	8,951	10,014	3,127	4,522	3,446	4,485	5,282	1,420	351	287
<i>b</i> # Newly diagnosed positive test events	119	81	66	41	49	36	45	44	7	9
<i>c</i> # Newly diagnosed confirmed positive test events	74	43	40	22	29	20	20	27	6	2
<i>d</i> # Newly diagnosed positive test events with client linked to HIV medical care	81	40	44	20	37	18	23	27	6	2
<i>e</i> # Newly diagnosed confirmed positive test events with client linked to HIV medical care	62	33	32	16	25	16	17	21	5	2
<i>f</i> # Newly diagnosed positive test events with client referred for partner services	19	15	10	8	11	8	3	10	2	-
<i>g</i> # Newly diagnosed confirmed positive test events with client referred for partner services	12	13	4	6	7	8	2	8	1	-
<i>h</i> # Newly diagnosed positive test events with CD4 cell count and VL testing ^{±y}	46	31	24	17	17	14	11	13	2	4
<i>i</i> # Newly diagnosed confirmed positive test events with CD4 cell count and VL testing ^{±y}	38	23	21	11	12	11	9	11	2	2

* Not mutually exclusive groups. Tests of clients identifying as Black and Latino/Hispanic can be found in both sets of columns.

⁶ Transgender, gender non-conforming, or non-binary individuals

[±] Includes clients with lab test(s) occurring on or after confirmatory test date. Restricted to confirmatory test dates from 3/1/19 to 2/29/20 and lab tests that occurred within the same time period.

[¥] CD4 and VL data as of November 2019; data maybe incomplete due to reporting lag.

In the Tri-County Region, Medicaid and private insurers are the primary payers supporting the implementation of the NYS HIV testing law, with supplemental RWHAP Part A support for targeted testing among the uninsured and linkage to care for those who test positive for HIV.

Beyond directly contracting for testing services, the NYC HD has taken an additional approach to engage hospitals and community health centers in routine HIV screening through the citywide HIV testing initiative, *New York Knows*. *New York Knows* represents a NYC HD partnership with CBOs, community health centers, hospitals, colleges and universities, faith-based organizations, and businesses to provide voluntary HIV testing to all New Yorkers, routinize HIV testing in health care, identify PWH who are undiagnosed and link them to care, and connect people at risk of HIV to PrEP and other prevention services. Approximately five million HIV tests have been performed by *New York Knows* partners since 2008, with over 460,000 tests conducted in 2019. In 2019, *New York Knows* announced it will expand its focus to include other STIs and HCV.

Approximately 57,000 HIV tests are conducted each year at NYC HD's eight SHCs. Integrated, opt-out HIV testing is available at NYC HD's TB Chest Centers and SHCs for all patients presenting to a clinic. For over 10 years, SHCs have performed pooled nucleic acid amplification testing (pNAAT) to detect acute HIV infections. pNAAT testing is limited to those individuals who are most likely to present with acute infection, including MSM, people who have shared injection drug equipment, and people who exchange sex for money or other material goods. For the general population, the SHCs test clients with the 4th generation Alere Determine test.

Tier 2. The second tier of the NY EMA's EIIHA approach aims to decrease inequities in health outcomes by targeting HIV testing services in non-clinical settings. The NY EMA uses surveillance data to identify the priority populations and communities for these services. To align with its status neutral approach as well as new statewide HIV testing legislation and regulations, in 2017 the NYC HD issued a Request for Proposals (RFP) for HIV Testing and Status Neutral Navigation Services, which included funding from both CDC and RWHAP Part A EIS. Contracts began January 1, 2018. Under this program, CDC Prevention funds are used to contract with 11 clinical facilities to implement status neutral navigation to iART for those newly diagnosed with HIV or out of care, and navigation to PrEP for those who test negative for HIV; and RWHAP Part A EIS funds are used to contract with CBOs (non-clinical) to conduct targeted testing through community and online outreach with required MOUs with clinical providers for expedited linkage to care. The 14 RWHAP Part A-funded CBOs focus on gay, bisexual, and other MSM and TGNC/NB people and their partners, with particular attention to Black or Latino/Hispanic TGNC/NB individuals under 29 years old; Black and Latina/Hispanic heterosexual women, particularly those over 30 years old or living in areas with a high prevalence of STIs; and other priority populations. Funding was prioritized to applicants whose patient population resides in ZIP codes with high numbers of PWH and documented health inequities and/or that have a history of outreaching to priority populations. Selected agencies also have demonstrated cultural responsiveness in their work and have a history of successfully engaging with the priority populations. From March 2019 to February 2020, these funded testing programs conducted 5,665 HIV testing series, identified 58 people with new HIV diagnoses, and linked 58% of those newly diagnosed to HIV medical care within 30 days of diagnosis. These programs also linked 176 clients to a PrEP provider and 43 clients to a PEP provider. In 2021, this portfolio will be rebid so that all resulting contracts, regardless of funding source, will use similar service definitions, standardized payment points, and updated service

models to support HIV testing, linkage to iART, and linkage to PrEP and PEP. New contracts are expected to begin in July 2021.

In addition, RWHAP Part A and CDC funds support targeted testing at all jails in NYC including Riker's Island. Using City funds, the Riker's Island facility offers opt-out HIV testing at intake, and for those who decline, the RWHAP Part A- and CDC-funded contract supports outreach and follow-up to conduct an HIV test at a later date. Additionally, the Riker's Island contract conducts group health education sessions for clients seen in the medical clinic or supportive services area of the jail. These HIV education sessions address topics such as PrEP, PEP, testing, transmission, and, most recently, COVID-19.

The NYC HD launched the Community Home Test Giveaway Virtual Program in April 2020 to address declines in in-person HIV testing during the COVID-19 pandemic. Participants receive online coupon codes from partner organizations to redeem online for a free OraQuick HIV self-test kit delivered to their home address. The program has partnered with 60 CBOs, community health centers, hospital-based clinics, small businesses, and other settings citywide, with 2,075 online coupon codes distributed and 1,914 codes redeemed to date. By promoting free HIV self-tests on multiple platforms, including social media, dating and hook-up apps, text messaging, and email, the program continues to reach communities most affected by HIV. HIV self-testing allows participants to learn of their HIV status from the safety of their home and helps facilitate initiation of PEP or continued adherence to PrEP, without going to a clinical facility for testing. In June 2020, the NYC HD announced Door 2 Door, a new service through which NYC residents can order condoms and other safe sex products for home delivery. Three of NYC HD's eight SHCs are currently open and offering limited services for New Yorkers' sexual and reproductive health needs during COVID-19. New Yorkers can also call the NYC SHC Hotline for telehealth services. Linkage and retention in medical care. The NY EMA promotes linkage to medical services and immediate initiation of HIV treatment (i.e., iART) for those who have diagnosed HIV infections through various strategies. All funded HIV testing programs are required to link newly diagnosed people to care, as well as those previously diagnosed that have fallen out of care. To meet the revised national goal of earlier linkage to care, in 2018, the Recipient began promoting and funding programs to link people newly diagnosed with HIV to HIV medical care within four days of diagnosis and to offer HIV treatment to these clients on the first HIV medical visit, as well as provide prescription and support services for PrEP and PEP to those with a negative HIV test result. Subrecipients receive higher reimbursement rates for linkage to care within four days of diagnosis, and lower reimbursement for linkage within 14 and 30 days of diagnosis. From the Status Neutral Testing RFP, 25 clinical and non-clinical agencies were funded to provide prompt linkage to care with initiation of HIV treatment at the first medical visit. These facilities also provide prescription and support services for PrEP and PEP. From March 2019 to February 2020, clinical programs initiated 464 clients on ART within four days of HIV diagnosis, initiated 437 clients on PrEP, and prescribed PEP to 167 clients. These funded programs join over 40 other contracted providers in delivering PrEP and PEP education, referral, linkage, and prescription services as part of the PlaySure Network.

Through the JumpstART program, SHCs provide HIV treatment on the day of diagnosis or to PWH who have never engaged in treatment, followed by linkage to care and partner services. The City's SHCs also provide PrEP and PEP prescriptions to eligible patients. In 2019, there were 212 new HIV diagnoses in the SHCs, including 29 acute HIV cases; 40% of newly diagnosed patients received JumpstART on the day of diagnosis. A total of 1,130 patients were initiated on PrEP.

Through the Status Neutral Testing RFP, the NY EMA funded clinical facilities to expand linkage to care services. The programs leverage the NYSDOH's Rapid Access to HIV Medications and Treatment Program (Rapid Tx) by providing wrap-around services (e.g., patient education and linkage to services) to increase access to rapid ART initiation, with higher reimbursement for those linked on the same day. Fifteen CCP programs have opted to include iART in their service provision, whereby RWHAP Part A resources provide wrap-around case management, entitlement services, and client education for newly diagnosed or out of care PWH referred by emergency departments, outpatient and inpatient clinics, and HIV testing programs.

From March 2019 to February 2020, the NYC HD BHIV's Clinical Operations and Technical Assistance (COTA) Program conducted a monthly training to increase iART knowledge and practices among HIV social service providers, navigators, and clinicians. To date, 81 clinical and social service HIV providers have been trained. Of the participants who completed the training evaluation to date, all respondents reported they were very satisfied or satisfied with the overall iART training, and all respondents agreed they were very prepared or prepared to use their learned skills in their job immediately. Since March 2020, the in-person training has been suspended due to COVID-19; however, the training was adapted to a webinar format and was delivered on March 12, 2020 to more than 85 attendees. A recorded version of the webinar has also been made available.

COTA also developed a one-hour iART training adapted from a full day training to strengthen clinical and social service providers' knowledge, attitudes, and practices related to the implementation of iART. During the reporting period, COTA delivered the training three times: once in a public hospital, once in a Federally Qualified Health Center (FQHC), and once in a community-based housing organization, reaching more than 45 clinical and social service providers.

On August 21, 2020, COTA launched an iART public health detailing campaign to promote scaling iART in HIV clinics across NYC. COTA developed an iART public health detailing action kit, which includes a variety of clinic resources (e.g., brief guidance documents, workflow examples, payment options guidance, genotype testing guidance, patient facing materials, etc.) to build the capacity of HIV clinic care teams to adopt and operationalize iART. COTA will deliver virtual outreach education visits (e-detailing visits) to HIV providers to disseminate key messages and resources related to iART. The action kits will be mailed to providers' clinics and shared electronically after the e-detailing visits. Pre- and post-e-detailing visit evaluations will be administered to assess the impact of the visits and kits on iART practices within HIV care settings.

Under Project PROSPER and CDC EHE funding, on August 19, 2020, the NY EMA initiated an RFP for an Enhanced D2C (eD2C) Project, building on BHIV's successful work with Brooklyn-based organizations to improve linkage, re-engagement, and durable retention in HIV care; and sustained VS. The eD2C RFP seeks to contract with clinical agencies providing HIV care and treatment in the Bronx, Queens, Manhattan, and Brooklyn. Funded contractors will work in close partnership with BHIV's ACE Team and COTA to build clinic staff capacity to conduct D2C activities; triangulate clinic, external, and NYC HD data sources; and identify and outreach to PWH who have fallen out of care.

Increase rates of retention in care and VS. The NYC HD has funded a citywide scale-up of The Undetectables VS Program (The Undetectables) as part of the NYS ETE initiative. The Undetectables is an ART adherence intervention designed to promote sustained VS among PWH who face individual and/or structural barriers to adherence such as poverty, housing instability, and behavioral health issues. The intervention combines a toolkit of evidence-based adherence support strategies, including financial incentives, and a superhero-themed social marketing campaign in the context of integrated medical, behavioral, and case management services. The toolkit includes

client-centered adherence planning and support, Motivational Interviewing, adherence support groups, adherence devices (e.g., pill boxes), directly observed therapy (DOT), and financial incentives to promote VS. Participants may receive a \$100 gift card incentive for each quarterly lab result showing VS (<200 copies/ml). The marketing campaign supports organizational culture change by engaging clients and staff on the importance of VS to individual and community health. The intervention was originally developed and pilot tested by Housing Works, an HIV service organization in NYC. In July 2016, the NYC HD awarded over \$1.5 million annually in City-funded contracts to seven agencies across NYC, including one for Housing Works to provide training and TA on program implementation to awardees. As of December 31, 2019, The Undetectables programs have served approximately 2,890 PWH in NYC. Among those engaged in care⁷ (n=2,311), 88.7% were virally suppressed at their most recent lab. Among clients enrolled the entire 2018-19 GY (n=1,185), 76.7% demonstrated evidence of durable VS.⁸

The Undetectables is also being disseminated in NYS through other channels. As part of Medicaid redesign efforts, two Delivery System Reform Incentive Payment (DSRIP) Program Performing Provider Systems (PPSs) implemented The Undetectables in NYC and in Albany; and Amida Care, an HIV-focused MCO, launched Live Your Life Undetectable (LYLU) to provide the same financial incentive also requiring dual engagement in primary care and supportive services. More recently, VNS SelectHealth, another HIV-focused MCO, began providing the same financial incentive. Evaluation of City- and DSRIP-funded programs will assess the potential for financial incentives as components of value-based payment (VBP) models.

In addition to The Undetectables, in FY18, Primary Care Status Measures (PCSM)-based data were presented at meetings with providers and also shared via the program-specific Treatment Status Reports (TSRs). TSRs are line-level reports displaying coded identifiers and the ART status of clients who are overdue for a VL test result update in eSHARE (which is used by all NY EMA RWHAP Part A-funded providers) or who were not virally suppressed as of their last VL test results. The TSRs are generated quarterly and sent to program staff by their quality management specialists (QMS). The Recipient also generates annual Agency-level Viral Suppression Reports (AVSR), which aggregate all agency-specific VS data into one report and compares it to all RWHAP Part A clients in NYC. To improve its utility, the AVSR was redesigned in 2019 with enhanced data visualizations to also look at VS among five specific priority populations (OPWH, Black or Latino cisgender MSM, cisgender YMSM, transgender women, and Black and Latina cisgender women) within each agency. These priority populations were selected to align with the NYC HD's Race to Justice initiatives to advance racial equity and social justice.

Referral to PrEP and PEP services. In 2016, using CDC and City funds, the NY EMA funded the PlaySure Network, a network of over 50 CBOs and health care facilities to provide education on PrEP and PEP, navigation and linkage to clinical providers, and PrEP and PEP initiation with adherence support and clinical follow-up. These contracts will be re-bid in 2021, and in the process, the NY EMA will explore ways to better reach priority populations and use alternative delivery methods. In addition, when long-acting injectables become available, the NY EMA plans to integrate their use into its programs. As noted above, in 2017, the SHCs began providing PrEP services and providing full 28-day courses of PEP. Staff from the SHCs also provide status-neutral navigation services to PrEP/PEP providers and HIV medical care. The NY EMA will continue to support and expand these services in GY21. During the COVID-19 pandemic, providers may prescribe 90 days of medicines to patients taking daily PrEP.

⁷ Engaged in care: Having greater than or equal to two VL labs at least 90 days apart during a period of interest.

⁸ Evidence of durable VS: Having no unsuppressed VL within a 12-month period.

The Westchester County Department of Health (WCDOH) has implemented several programs through NYS funding and NY EMA RWHAP Part A EIS funding to expand HIV testing and linkage to services, including PrEP, in the Tri-County Region. WCDOH has concentrated its focus and expanded its PrEP outreach to priority populations including MSM, transgender women, people who inject drugs (PWID), sex workers, homeless individuals, and currently and formerly incarcerated individuals. In GY19, the Tri-County Region increased resources to reach YMSM and women of color (WoC); and in GY20, a RWHAP Part A-funded EIS contract was awarded to the WCDOH to continue this work, in addition to conducting outreach at the local syringe exchange program and county jail in order to engage PWID and incarcerated individuals. Additionally, WCDOH provides policy and programmatic leadership for NYSDOH AIDS Institute (NYSDOH AI) funded PrEP initiatives throughout the Tri-County Region. WCDOH is a voting member of the NYS HIV Advisory Body and participates in ETE initiatives and NYLinks (*see p. 26 for more detail*) in the Upper and Lower Hudson Valley (which includes the Tri-County Region). In this capacity, the WCDOH oversees HIV education, testing, and PrEP/PEP referral programs, and holds monthly provider meetings focused on training and program strategy.

Other Activities. For all NYC HD-funded testing programs, the NYC HD recommends the use of HIV testing technologies that allow for detection of acute and early HIV infections, such as combination HIV antigen-antibody (4th and 5th generation) HIV tests. To support testing programs, the NYC HD provides trainings and TA for providers and publishes testing and prevention resources online. To promote receipt of confirmatory testing among individuals with a preliminary-positive test result, the NYC HD provides a discrete reimbursement point for confirmatory testing among HIV testing contracts. The specific reimbursement for confirmatory testing and recommended on-site collection of specimens have resulted in a higher proportion of tested clients receiving confirmatory results among those who test preliminary-positive.

To support the primary activities in the EIIHA plan, BHIV has created social marketing campaigns over the past several years to promote improvements in sexual health citywide. These include campaigns to increase awareness of HIV status (*BeSure*); encourage individuals to choose the combination of safer sex practices that work for them (*PlaySure*); emphasize initiation and adherence to HIV medications and biomedical prevention interventions (*StaySure*); encourage consumer and provider communications to improve sexual health and wellness, especially to Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) New Yorkers (*Bare It All*). In 2018, BHIV launched the *Living Sure* and *Listos!* Campaigns, which educate and promote PrEP use among cisgender and transgender women, and the Latino/Hispanic community, respectively; and in 2019, to promote the evidence-based finding of Undetectable=Untransmittable (U=U), BHIV launched its *MadeEqual* campaign. BHIV also utilizes digital media including established social media platforms to promote HIV prevention messaging to priority populations and works with contracted agencies to integrate campaigns and messaging into their digital platforms. With the ongoing COVID-19 pandemic, the NYC HD is prioritizing social marketing resources and activities to support COVID-related topics.

The ACE team, housed within the BHIV HIV Epidemiology Program, and the Tri-County region's Health Departments provide partner notification services to PWH diagnosed by providers. BHIV's ACE Team and Tri-County Region Health Departments' Disease Intervention Specialists elicit the names of potentially HIV-exposed partners, confidentially notify these partners of their possible HIV exposure, and offer HIV testing and linkage to care for people who test positive. In 2019, the ACE team offered partner services to all newly diagnosed citywide. ACE interviewed 83% (1,425/1,712) of newly diagnosed in NYC and elicited 498 HIV-exposed partners. Seventy

percent (231/330) of partners with a negative or unknown HIV status were notified and 54% (124/231) were tested, of whom 17% (21/124) had newly diagnosed HIV infections. If those newly diagnosed do not return to receive their test results, ACE can assist testing providers in locating patients, notifying them of their results, and offering partner services. For partners with a negative or unknown HIV status, ACE offered 77% (179/231) linkage to PrEP services, 23% (42/179) expressed interest in PrEP, and 71% (30/42) accepted the PrEP referral.

b) Major collaborations with other programs and agencies. Many NYC HD programs collaborate to identify individuals unaware of their HIV status. Under the leadership of the BHIV Prevention Program, all contracted HIV testing programs in the NY EMA have standardized service models that ensure one data collection process across funding sources, enforce POLR requirements, eliminate duplication of services across funding streams, and coordinate monitoring and evaluation activities. Further, the Prevention Program's key community partner is the HIV Planning Group (HPG). Similar to the RWHAP Part A PC's role with RWHAP Part A programs, the HPG supports all HIV prevention activities through representation of the perspectives of communities impacted by the local HIV epidemic and by reviewing and providing feedback and input in support of the NYS Integrated Plan. Most recently, BHIV is working collaboratively with the PC and HPG as well as internal programs, the NYSDOH AI, City agencies, and community partners to develop the NYC EHE plan. Listening sessions with each EHE borough and priority populations (youth and transgender people) are currently underway to inform the draft plan presented to the PC and HPG for concurrence in January 2021.

BHIV programs practice a unified approach, collaborating with clinical operations, prevention, policy and external affairs, social media and condom expansion, surveillance, and CTPs. The BHIV also collaborates with other NYC HD programs and City agencies that provide services to populations heavily impacted by HIV, such as the Division of Mental Hygiene, Bureau of Sexually Transmitted Infections (BSTI), Bureau of Tuberculosis Control (BTBC), Bureau of Alcohol and Drug Use Prevention, Care, and Treatment (BADUPTC), CTP, Public Health Lab, Office of School Health, Administration for Children's Services, and NYC Health + Hospitals. The NYC HD also works with NYC Health + Hospitals Correctional Health to coordinate comprehensive medical, dental, and MH services for inmates in NYC correctional facilities, including HIV testing and discharge planning to support linkage of inmates to medical care within 30 days of release. The NY EMA also collaborates with the U.S. HHS Region 2 to promote and support PrEP and PEP implementation in FQHCs, Title X clinics, and provide support to NYC providers to refer clients to MH and SUD services such as NYC Well, a 24/7 hotline staffed by trained MH professionals who provide assessments and treatment referrals.

Through a CDC-funded demonstration project, Project THRIVE, the NYC HD collaborates with state and local agencies, such as the NYS Education Department's ACCES-VR program, Workforce1, and the Mayor's Office of Workforce Development, to support referral and linkage of clients to workforce development and employment services. To further these efforts, the NYC HD hosted a day-long workforce development workshop. Starting from 2017, Project THRIVE's Community Advisory Board (CAB) held multiple discussion sessions on the effects of social determinants of health (i.e., stigma and violence, MH, employment, and criminal justice) on linkage and retention in care. Based on these discussions, the CAB created recommendations for addressing social determinants of health in HIV prevention and treatment. These recommendations have informed the NYC HD's solicitation process for contracted services, guidance on contract scopes, and the process of providing feedback to community members. During the COVID-19 pandemic, the CAB has continued to meet virtually.

The *New York Knows* initiative collaborates with over 200 partner agencies that have pledged to support the goals of the initiative to: test every resident for HIV, link PWH to care, link people not living with HIV to prevention services including PrEP, and make HIV testing a routine part of health care in NYC. The initiative recently added promotion of STI and HCV prevention into its programming. *New York Knows* holds regular steering committee meetings in all five boroughs and an annual all partners meeting. The NY EMA is also working closely with the local AIDS Education and Training Center and other City agencies to keep providers up to date on HIV and COVID-19. Preliminary data from *New York Knows* partners show a reduction in HIV testing in the first half of 2020 due to the COVID-19 pandemic. However, data reporting is incomplete. *New York Knows* has embraced virtual modalities to maintain its full meeting schedule since March 2020 and ensure maintained relationships and connections with and between community partners. Continued engagement has helped agencies adapt to delivering services while maintaining the safety of their clients and staff during COVID-19.

BHIV also collaborates with the NYSDOH AI on NYLinks, a statewide project, and a continuation of a previously funded HRSA/HIV/AIDS Bureau (HAB) Special Projects of National Significance initiative, focused on improving linkage to and retention in care and VS. BHIV is an active participant in the Brooklyn regional collaborative established under NYLinks, with staff serving as co-chair of the work group, and is an implementing partner in a statewide scale-up of strategies that have been shown to have promise, including rapid access to treatment, timely linkage to care, as well as improved peer learning and networking among providers, community leaders, and consumers. BHIV coordinates with NYLinks to facilitate engagement of providers in Queens and Staten Island. In addition, BHIV staff participate in borough-based ETE Regional Group meetings, born out of the process to develop the NYS ETE Blueprint, and provide regular updates on surveillance data and prevention and care activities. NYSDOH AI and BHIV also coordinate NYLinks and ETE Regional Group meetings to align with *New York Knows* meetings; and implement joint annual meetings of *New York Knows*, NYLinks, and NYS ETE Regional Groups in Brooklyn, Queens, and Staten Island.

The NYC HD convenes the NYC DSRIP HIV Coalition, comprised of eight hospital-led PPSs and their community partners. In 2015, NYS established the DSRIP program to redesign the health care delivery system, aiming to reduce avoidable hospital visits among Medicaid beneficiaries by 25%. DSRIP HIV Coalition members share best practices and relevant policy developments, and collaborate on HIV-related projects at the health systems level, such as strategies to improve VS and developing models for peer-delivered services. While DSRIP ended in March 2020, the HIV Coalition continues to meet to discuss the evolving NYS Medicaid environment and its impact on the HIV service delivery system.

Finally, BHIV proactively engages members of priority communities to participate in and plan community events including NYC Pride events and World AIDS Day commemoration, among others. BHIV also actively participates in a number of citywide coalitions, including the End AIDS NY 2020 Coalition, NYC Kiki Coalition, Long Term Survivors Wellness Coalition, and the ACT UP Meth Group. In addition, BHIV also works with the Mayor's Office of Workforce Development, through the Considering Work Efforts Work Group, to inform staff on how to enhance the integration of employment services within HIV prevention, care, and treatment programs (*see p. 45 for more details*). In light of COVID-19, BHIV is engaging priority populations virtually.

c) *Anticipated outcomes of overall EIIHA strategy.* The goals of NY EMA's overall strategy include increasing the number of people aware of their HIV status, increasing the proportion of PWH promptly linked to medical care and achieving VS, and increasing the proportion of

populations at-risk for HIV infection receiving prevention services, including PrEP and PEP (*see p. 29-32 for specific strategies*). These goals directly align with the goals of the EHE plan, NYS's ETE Blueprint and Integrated Plan, and the NYC EHE plan. This status neutral approach addresses the needs of PWH and people not living with HIV with its success contingent on the coordination among providers of testing, prevention, and care services, regardless of an individual's HIV status.

The NY EMA continues to promote and fund testing programs that focus on priority populations, including gay, bisexual, and other MSM; TGNC/NB people and their partners; Black and Latina heterosexual women; and other vulnerable populations. Due to these and additional efforts outlined in the EIIHA plan, the proportion of residents in the NY EMA that have ever been tested for HIV continues to increase. Through the CHS, the NYC HD tracks the percentage of NYC residents, aged 18 and older, who report ever testing for HIV. In 2017, 66% of adult NYC resident CHS respondents had ever been tested for HIV; up from 63% in 2012.¹ At the same time, the number of HIV diagnoses in the NY EMA has decreased (*see p. 17-20 for more details*). This declining trend in the number of new diagnoses is partly due to the NYC HD's rigorous and comprehensive effort to increase HIV testing, link PWH to care, and support increased VS within the first 12 months of care. With the on-going implementation of the EIIHA strategy, the NY EMA expects a continued increase in the percentage of NYC residents reporting ever having received an HIV test and continued decrease in the percentage of new HIV diagnoses.

The NY EMA EIIHA incorporates a planned outcome to increase the percentage of people with new HIV diagnoses initiating care. Currently, the NYC HD tracks this indicator using HIV surveillance data and defines timely linkage as a VL, CD4, or genotype test drawn within one month (30 days) of HIV diagnosis. In recent years there has been a steady increase in timely care initiation among the newly diagnosed in NYC, from 65% in 2013 to 82% in 2018. As noted previously, the NY EMA employs several strategies to retain individuals in care, improve ART adherence, and promote sustained VS. The outcome of these efforts will be measured through changes in the stages of the HIV care continuum.

The NY EMA continues to promote and fund PrEP and PEP referral and care services with the goal of increasing the proportion of priority populations, including MSM, TGNC/NB individuals, and Black and/or Latina women, who are aware of and report using these services. This outcome indicator will be measured through the Sexual Health Survey (SHS). Among sexually active NYC MSM ages 18 to 40 years with an HIV negative/unknown status surveyed through the SHS in fall 2019, 97% were aware of PrEP and 36% had taken PrEP in the past 6 months.ⁱⁱ The low uptake underscores the need for continued services to engage people and link to PrEP as well as intensive social marketing and education efforts, such as *Living Sure* and *Listos!*.

During the COVID-19 pandemic peak (March-April 2020), there were notable changes in services provision within the PlaySure Network. During this time period, there was a 54% decrease in linkages to PEP providers and a 46% decrease in linkages to PrEP providers. However, while PrEP initiations decreased 70% between February and April, PrEP follow-up visits remained stable suggesting that those who were already on PrEP were still maintaining adherence. As a likely result of the decrease in COVID-19 activity and the reopening of NYC, the provision of HIV prevention services increased in May and June 2020, but are still below pre-pandemic levels.

2) GY21 EIIHA Plan priority populations. The three selected distinct priority populations are: (1) Black and Latino MSM; (2) TGNC/NB people and their partners; and (3) Black and Latina cisgender women living in neighborhoods with high numbers of PWH.

a) Populations targeted. Three populations were chosen due to inequities in new diagnoses, EiC, and/or VS after a review of local epidemiologic data.

b) Specific challenges with or opportunities for working with the targeted populations.

a) Black and Latino MSM. Fifty-six percent of new HIV diagnoses in the NY EMA in 2019 were among MSM (including MSM-IDU), more than any other transmission risk group. National data indicate that MSM and YMSM, particularly Black and Latino, are at the highest risk for acquiring HIV. The CDC estimates that one in six MSM will have a diagnosed HIV infection in their lifetime, including one in two among Black MSM and one in four among Latino MSM.^{lii} This holds true in the NY EMA, making them a high priority of the overall EIIHA plan. In 2018, YBMSM and YLMSM accounted for 81% of all YMSM living with HIV in the NY EMA. Research has shown that stigma and discrimination due to race/ethnicity and sexual orientation and lack of access to culturally responsive services for MSM of color are barriers to HIV testing and accessing medical services.^{liii} Further, some YMSM who experience homelessness or housing instability face additional barriers to health care including a lack of transportation, financial resources, and/or health care insurance and lack of awareness of available resources.^{liv}

b) TGNC/NB people and their partners. In 2019, 3% of new HIV diagnoses in NYC were among transgender people, 96% of whom were transgender women. Black or Latina women made up roughly 90% of new diagnoses among transgender women, and 56% of newly diagnosed transgender women were 20 to 29 years. No local estimates of HIV prevalence exist, but a 2019 systematic review and meta-analysis found that an estimated 14% of transgender women in the U.S. have HIV; by race/ethnicity, an estimated 44% of Black transgender women, 26% of Latina transgender women, and 7% of white transgender women have HIV.^{lv} The NYS ETE Blueprint notes that stigma and discrimination, including sexism, transphobia, and racism contribute to HIV risk among transgender people, which is amplified by related contextual factors such as poverty, unemployment, homelessness, violence, undocumented status, sex work and condom confiscation, MH needs, substance use, and poor access to health care and affirming providers.

c) Black and Latina/Hispanic cisgender women in areas with high numbers of PWH. In 2018, Black and Latina/Hispanic cisgender women accounted for 90% of all cisgender women living with HIV in the NY EMA. These proportions indicate a continued need for targeted EIS, including HIV testing and status neutral navigation services. Further, previous analyses by the NYC HD have demonstrated that HIV diagnoses and prevalence are more likely to overlap with areas where increased poverty, health inequities, and poor health outcomes are found; these are areas where Black and Latina/Hispanic women typically reside. Risk factors for increased vulnerability among Black and Latina/Hispanic women include low income, substance use, being born outside the U.S., exposure to IPV, and having formerly incarcerated partners.

Other challenges experienced by Black and Latina women include stigma associated with HIV, cultural and linguistic barriers to care, lack of knowledge of HIV prevention tools such as PrEP and PEP, and low self-perceived risk for HIV. For example, a 2017 telephone survey of Black and Latina/Hispanic women in NYC found that only 34% of respondents had ever heard of PrEP and 60% felt they would not benefit from taking PrEP or PEP.^{lvi} PrEP prescriptions among women are disproportionately lower than among men. Between July and December 2018 in NYC, men received PrEP prescriptions at 12 times the rate of women (18,311 vs. 1,524 prescriptions)^{lvii}; however, men have an HIV diagnosis rate that is more than four times higher than women.

Many Black and Latina/Hispanic women in the NY EMA live in neighborhoods with high numbers of PWH that place them at increased risk due to their social and sexual network, even though their own behaviors would not be perceived as “high-risk.” As such they have low self-perceived risk for HIV which may delay or prevent them from presenting for testing or considering PrEP as a prevention option. People born outside the U.S., especially undocumented, may also

delay HIV testing and care services due to stigma associated with HIV, isolation, fear of exposure, and potential deportation, in addition to differences in culture and language.

c) *Specific strategies that will be utilized with the target populations.* The NY EMA's GY21 EIIHA plan was designed to ensure that services provided to priority populations result in a reduction of the number of undiagnosed and late-diagnosed individuals, and that those newly diagnosed promptly access HIV care and treatment. The NY EMA will continue to support its enhanced HIV testing approach through its contracts awarded in 2018 (*p. 17*), along with several innovative programs that are aligned with the national goals outlined in the EHE plan, NYS's goals detailed in the ETE Blueprint and Integrated Plan, and NYC's EHE plan (*p. 1*) to achieve these objectives. Through Medicaid-funded and other third party-funded HIV screening in clinical settings and NY EMA programs supported by RWHAP Part A, CDC, and other funds including *New York Knows*, the NY EMA promotes and supports routine HIV screening in all health care settings. As stated earlier, to maximize the use of funds and to comply with POLR requirements, with the rebid of testing services in 2018 (Status Neutral Testing RFP), the NYC HD prioritized RWHAP Part A EIS funds to address the needs of prioritized populations to receive HIV medical care by funding 14 CBOs to provide HIV testing and support services. CDC funds 11 status neutral linkage and navigation programs in clinical facilities to provide PrEP and PEP services to eligible patients, and offer iART. As noted previously, between March 2019 to February 2020, these funded testing programs conducted 5,665 HIV testing series, identified 58 individuals with new HIV diagnoses, and linked 58% of those newly diagnosed to HIV medical care within 30 days of diagnosis. These programs also linked 176 clients to a PrEP provider and 43 clients to a PEP provider. Awarded contracts run through December 31, 2020. Additionally, with Project PROSPER and CDC EHE funding, the NY EMA initiated an RFP on August 19, 2020 titled Building Equity: Intervening Together for Health. Launched by NYC HD BHIV's COTA team, this RFP aims to provide HIV clinics with resources to replicate identified evidence-informed interventions that are focused on priority populations, and support clinics to build their human and structural capacity to improve engagement, retention, and VS among priority populations. The awarded contracts will run through February 29, 2024.

Funded CBOs use innovative approaches, such as behavioral risk screenings for PEP and PrEP, brief interventions, status neutral navigation activities to iART, PrEP, or PEP, social marketing and new media engagement to those unaware of their status on dating apps and hook-up sites, and other targeted testing efforts to reach priority populations. A qualitative study^{lviii} of barriers and facilitators to HIV primary care among vulnerable populations (YMSM, African immigrants, formerly incarcerated, and transgender women) in NYC highlights the essential role of CBOs in engaging these populations in care, specifically referencing their tailored and culturally responsive services.

To further increase accessibility of testing services, the NYC HD has conducted giveaways of in-home HIV self-tests since 2015. In 2018, the NYC HD conducted a targeted awareness campaign among MSM and TGNC/NB NYC residents who have sex with men through online ads. By completing a brief eligibility survey, these individuals were able to access free HIV self-tests, and over 2,500 individuals accessed HIV tests through this initiative. During the COVID-19 pandemic response, the NYC HD expanded distribution of self-tests to ensure testing access complied with stay-at-home orders. BHIV is currently exploring the integration of STI testing with the giveaway.

The NY EMA promotes U=U, the message that PWH who maintained an undetectable VL for at least six months do not transmit HIV through sex, which was endorsed by the CDC in September 2017.^{lix} The U=U initiative, in combination with the Status Neutral Testing RFP, provides an opportunity for providers to conduct targeted outreach and testing to the priority populations and

link them to care and iART. The BHIV established a work group to incorporate best practices associated with U=U to help the community understand the concept and incorporate it into sexual health decision-making to reduce stigma. Efforts have included: a standardized slide set to substantiate U=U research including the PARTNERS, PARTNERS II, and HPTN 052 results and training modules for condom providers, ACE team, patient navigators, and health educators to support productive and knowledgeable discussions of U=U with community program clients. BHIV's *Made Equal* campaign launched in June 2019 to align with Global Pride events in NYC and promotes the U=U concept; and was designed to reduce HIV-related stigma, celebrate healthy sexuality and sexual pleasure, and redefine what it means to live with HIV. *Made Equal* appeared through outdoor ads across the City as well as digital media.

In addition to focusing on priority populations in the above-mentioned U=U initiatives and Status Neutral Testing RFP activities, the NYC HD also implements several initiatives specific to the EIIHA-identified priority populations. These initiatives include:

Black and Latino MSM. The CDC demonstration project, Project THRIVE, seeks to improve testing, referral, linkage, and navigation to prevention and care services for MSM of color in Brooklyn. Under Project THRIVE, the NYC HD has conducted three listening sessions with MSM of color in Brooklyn to discuss the social determinants that impact their health. The CAB for Project THRIVE meets monthly with the NYC HD staff to discuss and make recommendations on addressing these social determinants. From fall 2019 to spring 2020, BHIV implemented a storytelling initiative throughout NYC to promote LGBTQ wellness and to address HIV-related stigma. CDC-funded contracts also support Black MSM-led organizations to build organizational capacity and infrastructure, supported with experienced TA providers, to increase culturally appropriate services to these communities in NYC.

In September 2018, in response to being awarded funds for CDC PS-17-1711, the NYC HD formed the Project Sol CAB composed of HIV prevention and care service providers who largely identify as Latino MSM to inform aspects of the project as they are developed, ensuring that work is sensitive and engaging to Latino MSM, particularly in developing quality molecular HIV surveillance protocols, provider trainings, CBO detailing, and social media campaigns. The Project Sol CAB expands relationships with organizations serving Latino MSM to support programming for Latino MSM living with and at risk for HIV in HIV prevention, care, and treatment services.

In 2018, BHIV conducted a series of focus groups among MSM engaged in exchange sex, one of which was specifically with Latino-identified MSM. The purpose of the groups was to understand the overall experience of sex work among MSM in NYC and the impact of exchange sex on MSM sex workers' health and safety to improve understanding of how medical and social service providers can better support MSM sex workers. Findings from the groups revealed that most participants found themselves in a violent situation on at least one occasion and almost all felt it was their personal responsibility to protect themselves and their clients from HIV and STIs. Across both groups, participants recommended provider training to reduce discrimination and improve knowledge of both sex work and available services citywide to provide better referrals. The NYC HD will use this data to inform development of services moving forward.

TGNC/NB people and their partners. TGNC/NB-led organizations are recipients of the City-funded ETE contracts to build organizational capacity and infrastructure to increase the availability of culturally appropriate services. Additional efforts to increase competency include trainings for SHC and BHIV staff to increase their knowledge and competency in working with TGNC/NB people. BHIV also convenes a Black and Latina Transgender Women Work Group to addresses the HIV care needs of Black and Latina transgender women by developing recommendations to

ensure gender affirming best practices are implemented across programs in the RWHAP Part A portfolio. In 2020, BHIV concluded a study with TGNC/NB people who engage in sex work to inform activities to support their health and well-being. The study conducted individual interviews with TGNC/NB people who exchange sex for money to elicit information on: the overall experience of sex work among TGNC/NB people in NYC; the impact of health care, law enforcement and employment policies and practices on their lives and work; the impact of sex work on their health and safety and how they navigate sexual health risks; and their experience accessing health care and supportive services. A comprehensive report is currently under review; it will be utilized to inform future activities and services for TGNC/NB people.

Black and Latina/Hispanic cisgender women in areas with high numbers of PWH. Agencies funded through the Status Neutral Testing RFP conduct outreach to people who live in high poverty areas (placing them at higher risk for HIV) and link them to appropriate services, including HIV testing, iART if they test positive, or to prevention services, such as PrEP and PEP if they test negative. Contracts are structured to incentivize agencies to link PWH promptly to care and initiate iART. In 2019, BHIV implemented the fifth wave of its public health detailing campaign to promote PrEP and PEP focused on women's health care providers. Additionally, the PrEP and PEP Action Kit includes patient and provider resources to raise awareness of PrEP and PEP and support initiation and retention in care and treatment. In 2016, BHIV founded the Women's Advisory Board (WAB), a diverse group of dedicated and passionate women leaders with expertise serving and empowering women within their communities. WAB was founded as a collaboration between *New York Knobs*, HPG, and NYC HD's Center for Health Equity and CTP. Since the first meeting, the WAB has grown to over 50 members, representing 11 organizations across all boroughs, and includes cisgender and transgender women and a majority membership of WoC. The WAB is committed to improving HIV prevention and care for women in NYC through dialogue and concerted action. On March 9, 2019, the WAB led the third annual Women's Health and Activism Summit to garner input where participants identified trauma-informed care, domestic violence/IPV, and immigration as high priority topics to be addressed at future Summits. As noted previously, in March 2018, the NYC HD launched a social marketing campaign, *Living Sure*, promoting PrEP and PEP usage among cisgender and transgender women.^{ix} This is the latest addition to the NYC HD's series of sex-positive campaigns, *BeSure*, *PlaySure*, *StaySure*, and *Bare It All*, which seek to improve sexual health and wellness among their respective priority populations.

3) Planned efforts to remove legal barriers to routine HIV testing. In the last decade, the NYC HD worked with NYSDOH and state elected officials to streamline and routinize HIV testing consistent with the CDC's 2006 recommendations. Prior to 2010, any person to be tested for HIV was required to provide written consent. In 2010, NYS Governor David Paterson signed a testing law requiring HIV testing be offered to all patients ages 13 to 64 years receiving hospital or primary care services, with limited exceptions; allowing consent to HIV testing to be part of a patient's general consent to medical care including specific opt-out language; and, in non-correctional settings, allowing oral consent for rapid HIV testing. In 2014, Governor Cuomo signed legislation that eliminated the requirement for written consent for HIV testing except in correctional settings; the following year, further amendments allowed for oral consent in correctional settings.

To coincide with World AIDS Day 2016, Governor Cuomo signed legislation further streamlining HIV testing by removing the requirement to obtain "informed consent" so that a provider, at a minimum, need only orally advise the patient that an HIV test is being performed and then document the advisement or objection in the patient's record. The legislation also removed the upper age limit, requiring HIV testing to be offered at least once as a routine part of health care to

all patients age 13 or older receiving primary care services at an outpatient clinic or from a physician, physician assistant, nurse practitioner, or midwife. Hospitals must also offer HIV testing to all patients and individuals seeking services in emergency departments, with limited exceptions. NYC HD continues to work with NYSDOH and other state agencies to build public and provider awareness of these changes through FAQs, fact sheets, and webinar and in-person trainings.

Other state legislative and regulatory activity has expanded access to HIV services in recent years. The World AIDS Day 2016 legislation expanded access to STI testing by allowing physicians and nurse practitioners to issue non-patient specific orders to nurses to screen individuals at increased risk for syphilis, gonorrhea, and chlamydia infection; it also expanded access to PEP by allowing physicians and nurse practitioners to issue non-patient specific orders to pharmacists to dispense up to seven days of PEP. In April 2017, NYSDOH finalized regulatory amendments classifying HIV as a STI. With this change, local health department clinics must provide HIV prevention and treatment, including PrEP, to patients either directly or by referral. Providers in any setting may provide these services to minors without parental/guardian consent or notification. Medical and billing records containing information regarding such services may not be sent to the parent/guardian without the minor's consent. The following month, NYSDOH finalized regulatory amendments expanding data sharing to allow care coordinators access to HIV-related information for the purpose of linkage to and retention in care. This change has allowed the RWHAP Part A program to provide surveillance data on clients not virally suppressed to CCPs to encourage continued enrollment and increased adherence services.

C) Local Pharmaceutical Assistance Program (LPAP). The NY EMA does not fund a LPAP.

METHODOLOGY

A) Impact of the Changing Health Care Landscape

1) Description of Health Care Options for PWH. Eligible New Yorkers may enroll in Qualified Health Plans (QHPs) (*see Table 4 below*), including Medicaid and Essential Plans, through the NY State of Health website (nystateofhealth.ny.gov). Consumers with incomes between 138% and 250% of the FPL may be eligible for some premium and cost-sharing assistance. In January 2016, NYS introduced Essential Plans, which are plans available to low-income people who don't qualify for Medicaid or Child Health Plus (*see Table 5 below*). The Essential Plans are for New Yorkers with incomes up to 200% of the FPL, and have very low monthly premiums (maximum of \$20 per person per month), free preventive care, and no deductibles. Enrollment in QHPs and Essential Plans continues to grow, with a 150,000 enrollee increase between 2019 and 2020.^{lxi}

Individual plans vary by in-network provider and pharmacy benefit availability. Clients are encouraged to review resources within their desired health plan to determine if their preferred providers are in-network and if current medications are covered, and at which level. *Tables 4 and 5* provide an overview of the QHPs and Essential Plans available by county in the NY EMA.

Table 4. 2020 NY State of Health Plan Availability by County – Individual Market^{lxii}

County	Emblem Health	Empire BlueCross BlueShield	Fidelis Care	Healthfirst	MetroPlus Health Plan	MVP Health Plan	Oscar	United Healthcare
Bronx	x	x	x	x	x		x	x
Kings	x	x	x	x	x		x	x
New York	x	x	x	x	x		x	x

Putnam	x	x	x			x		x
Queens	x	x	x	x	x		x	x
Richmond	x	x	x	x	x		x	x
Rockland	x	x	x			x	x	x
Westchester	x	x	x			x	x	x

Table 5. 2020 NY State of Health Essential Plan Availability by County^{lxiii}

County	Affinity Health Plan	Emblem Health	Empire BlueCross BlueShield	Fidelis Care	Healthfirst	MetroPlus Health Plan	MVP Health Plan	UHCCP	WellCare of New York
Bronx	x	x	x	x	x	x		x	x
Kings	x	x	x	x	x	x		x	x
New York	x	x	x	x	x	x		x	x
Putnam			x				x		
Queens	x	x	x	x	x	x		x	x
Richmond	x	x	x	x	x	x		x	x
Rockland	x		x	x			x	x	x
Westchester	x	x	x	x	x		x	x	

QHPs are required to contract with “Essential Community Providers,” including many RWHAP Part A provider sites who care for medically underserved populations, and ensure a level of appropriate geographic distribution. There are currently eight QHPs and nine Essential Plans available in the NY EMA. Medicaid Special Needs Plans (SNPs) offer additional coordination of care and include providers who are experienced with the needs of PWH. Current networks for NYS SNPs do not include the Tri-County Region. SNP eligibility includes TGNC/NB and homeless individuals, regardless of HIV status, in order to better address the needs of these underserved populations. Enabled by the NYS Value Based Payment Innovator program, which allows designated entities to maintain 100% of cost savings for the first five years for reinvestment into innovative services, HIV providers in NYC formed an Accountable Care Organization (ACO) for PWH. The ACO’s goals align with EHE goals, and will coordinate care in order to promote HIV prevention, improve PWH health outcomes, and decrease costs associated with poor health outcomes related to HIV and co-morbidities.^{lxiv} The Amida Care Innovator Network (ACIN), was incorporated in 2018, and the ACO Certificate of Authority (COA) was approved in February 2019. Following receipt of the COA, ACIN submitted its Innovator application to the State in June 2019. The Innovator program has been put on hold due to NYS budgetary reasons, but ACIN continues to communicate with NYS partners regarding the importance of the program.

In the lead-up to the effective dates for the ACA and Medicaid Redesign efforts, the NYC HD assessed provisions that might affect consumers and providers in the NY EMA and how to help them adapt to the changes. The CTP continues to allocate resources to support a Policy Advisor to monitor the health care landscape to ensure PWH have continued access to quality care, and to assess impacts of changes in Medicaid, Medicare, and the NY State of Health. This is to ensure that RWHAP Part A-funded services can fill gaps in the service system and adhere to POLR requirements. The Policy Advisor develops consistent communications related to health systems changes, including notices to providers, presentations, and updates to Recipient staff. In light of requirements that RWHAP Part A is the POLR and that Part A providers ensure clients are appropriately enrolled in coverage, contractual language, and data reporting requirements clarify

RWHAP Part A client assessment and reassessment expectations. This ensures that clients have support to access health insurance, should they be eligible.

During the past several years, NYS has undertaken a variety of initiatives to reduce costs and improve health outcomes for Medicaid enrollees. These initiatives have resulted in the creation of several specialized insurance products and service lines that include payment for supplementary services for vulnerable New Yorkers. In addition to the services paid for by Medicaid fee for service (FFS) and mainstream MCO plans, the additional products and services considered applicable to RWHAP Part A clients are Health Homes (HH) for people with a variety of qualifying conditions who can benefit from coordination of care, HIV SNPs for people living with and at increased risk of HIV, Health and Recovery Plans (HARPs) for people with complex behavioral health needs, and Home and Community-Based Services (HCBS) for a subset of HARP enrollees who need additional support to achieve behavioral health goals. In order to ensure the RWHAP Part A continues to function as the POLR in a rapidly shifting and complex environment of Medicaid programs in NYS, BHIV conducted an in-depth review and cross-walk of all RWHAP Part A services that were potentially reimbursable by Medicaid through FFS and mainstream MCO plans, HHs, SNPs, HARPs, and HCBS in the spring of 2019. This analysis resulted in the creation of POLR guidance for service providers and a review tool for contract oversight staff to use during site visits at agencies with contracts in the applicable service categories.

The NYSDOH has notified stakeholders that they intend to submit an 1115 Medicaid Redesign Team Waiver amendment that would allow for pharmacy benefits to be carved out of Medicaid Managed Care starting in April 2021.^{lxv} The carve out is intended to generate Medicaid savings by centralizing pharmacy benefit management under FFS to increase transparency, maximize rebate revenues, and increase negotiating power. 340B entities in NYS such as FQHCs, hospitals, Ryan White providers, Medicaid Managed Care Plans (including HIV SNPs) have expressed concern that the carve out, if implemented, would result in reduced revenues. The revenues from 340B discounts are used to support outreach, engagement, and adherence services for PWH in NYS.

a) Effect on access to health care services and health outcomes. Both consumers and providers find it difficult to navigate pharmacy benefits. NYSDOH AI provides resources such as webinars and trainings to better navigate drug formularies, but providers and consumers continue to voice concerns regarding increases to out-of-pocket costs for patients.

Essential Plans, which cover 2.9 times more New Yorkers than QHPs, help increase access to New Yorkers with the lowest incomes, since these plans include inpatient and outpatient care, physician services, diagnostic services, and prescription drugs with no annual deductible and low out-of-pocket costs. Essential Plan enrollees with incomes up to 150% of the FPL will have no monthly premium and have an annual out-of-pocket payment limit of \$200. Those with incomes between 150% and 200% of the FPL will have a monthly premium of \$20 and an annual out-of-pocket payment limit of \$2,000. To help cover out-of-pocket costs, the NYS HUCP copay assistance is available for those with an income up to 500% of the FPL. The NY EMA has seen steady increases in ART usage (from 78% of all diagnosed in 2014 to 90% in 2018),^{lxvi} and as a result, increased VS (from 67% in 2014 to 75% in 2018). While it is difficult to attribute improved health care outcomes to a single policy or funding change, enrollment in QHP coverage has been significantly associated with achieving VS in at least two studies.^{lxvii} This is consistent with research findings regarding prescription drug coverage and health outcomes: low-income adults are less likely to take medicines as prescribed due to cost;^{lxix} conversely, adults with chronic medical conditions are more adherent when they have prescription drug coverage.^{lxx, lxxi}

2) Effects of the changing health care landscape on service provision and RWHAP Part A allocations.

a) Service provision and complexity of providing care to PWH. The PC has been working to address changes in the health care system since 2011, with the development of its first Core Medical Services (CMS) Waiver application. As such, additional shifts were made in funding allocations to Housing, FNS, EFA, and the newly created Psychosocial Support Services (PSS) for Transgender, Intersex, Gender Non-Conforming or Non-Binary (TIGNCNB) people to increase services that support engagement in medical and MH services that may be funded through other payers. Increasing resources for these services also helped address inequities in access to medical care due to the burdens of poverty, homelessness, food insecurity, race/ethnicity, and sexual/gender identity. Provisions of the ACA led to increased insurance access for RWHAP Part A clients through: (1) Medicaid expansion and (2) the availability of health insurance plans for purchase on the NY State of Health Marketplace. Although there was greater access to insurance coverage due to Medicaid expansion, increases were relatively modest because NYS Medicaid previously covered single adults with income up to 100% of the FPL. The number of people enrolled in the NYS HUCP has remained stable in recent years as NYS achieved rapid Medicaid enrollment in the early years of the ACA through web-based expanded Medicaid access and, thus, had shorter gaps in Medicaid coverage. As stated on *p. 13-14*, the Recipient, PC, and the NYS HUCP have worked together to ensure continued access to medications for PWH through ADAP while ensuring continued resources are available for the core medical and support services at clinics, hospitals, and CBOs. From GY19-20, RWHAP Part A funding for ADAP was reduced by 34%, which allowed the NY EMA to absorb a portion of reduction to the NY EMA RWHAP Part A GY20 award while simultaneously enhancing the capacity of Housing services, FNS, and EFA in the NY EMA, in light of emergent needs of PWH resulting from COVID-19. Additionally, \$50,000 in ADAP funding has been allocated to the newly created service category, PSS for TIGNCNB individuals, specifically for the development of a comprehensive TIGNCNB public resource directory and provider training curriculum.

b) Changes in RWHAP Part A allocations. The NYS HUCP continues to be a resource for those who are unable to access public or private insurance and those who need financial assistance with health insurance premiums and copays. The NY EMA contributes to the ADAP prescription access program, paying directly for medications. The PC and Recipient also coordinate with the NYS HUCP to assess whether RWHAP Part A funding is needed for other services, including health insurance premium and cost-sharing assistance. Through the CMS Waiver, the NY EMA has continued to allocate funding to further support social services, such as food and housing, to meet clients' basic needs. Redirecting funding from the provision of CMS to supportive services enhances the Recipient's efforts to engage and retain clients in care who receive medical services and medications covered by other payers. Barriers to accessing basic necessities can have adverse health effects and offset progress from maintained adherence to ART. Investing in non-core services aligns with the NY EMA's goal to support clients in achieving VS, improving their quality and length of life, and drastically reducing transmission.

B. Planning Responsibilities.

1) Planning and Resource Allocation.

a) Description of the community input process. Consistent with legislative requirements, the NY EMA in GY20 used a systematic, evidence-driven, representative, and inclusive planning process to prioritize services and allocate resources for GY21. The PC and its committees, with aid

from the Recipient, continued a multi-year process to reassess and rebid the RWHAP Part A portfolio, with the aim of ensuring that the NY EMA's service system is responsive to current needs and identified challenges. All PC subcommittees include a diverse range of consumers, providers, and other stakeholders, and provide extensive opportunities for public comment, as described throughout this section.

The PC works closely with the Recipient and other NYC HD staff throughout the planning process and has a dedicated staff liaison from the BHIV Surveillance Unit who is specifically assigned to the PC to provide up-to-date epidemiological data for planning purposes. This year, the PC accomplished the following:

- Received and provided input into EHE efforts including plans for development of the NYC EHE plan for Bronx, Kings, Manhattan, and Queens counties with the expectation of voting on concurrence in January 2021;
- Received an update on the HRSA 20-078 Project PROSPER to ensure coordination of this new NYC EHE effort with the RWHAP Part A system of care;
- Utilized a data-driven planning tool to develop service priorities and determine funding allocations based on up-to-date information on PWH needs, service utilization, and gaps, including the NY EMA's Needs Assessment, the NYS Integrated Plan, a POLR Analysis, Service Category Fact Sheets with multiple years' historical utilization data, and data analyses from the NY EMA's CHAIN study;
- Allocated 54.3% of RWHAP Part A and MAI funding to CMS for GY21;
- Continued funding for MCM/CCP Programs to optimize medical outcomes;
- Allocated 4.9% of the GY21 portfolio for testing services to reduce the number of individuals who are unaware of their HIV status, and planned these resources in conjunction with the NYC HIV Prevention Program to coordinate with other testing resources;
- Allocated substantial resources to promote access to and maintenance in care for newly diagnosed individuals and to re-engage people who had fallen out of care;
- Allocated funds to create oral health services in the NYC portion of the EMA; and
- Approved increases in targeted service categories in order to address ongoing needs of PWH, fill service gaps for special populations, and address new needs arising from the COVID-19 pandemic.

A breakdown of the PC's committees and corresponding activities are provided below: Needs Assessment Committee (NAC). The NAC built on its previously developed comprehensive formal needs assessment for HIV services in the NY EMA. That assessment, produced with the assistance of the Recipient, reviewed a range of reports and presentations by NYC HD surveillance analysts, CHAIN researchers, and the CTP Research and Evaluation Unit (REU) staff. Findings included: the latest estimate of PWH unaware of their status, estimated numbers of PWH not in care, accessibility and quality of services, service barriers, geographic patterns in HIV burden and distribution of resources, impact of co-morbid conditions on HIV care, service utilization trends, unmet need, and provider capacity and capability, with special attention given to the HIV care continuum to identify populations that fall out of the continuum at each stage.

In GY20, the NAC identified PWH with SMI as a special population with inequitable health outcomes and greater likelihood of falling out of care. SMI is defined as a mental, behavioral, or emotional disorder resulting in serious functional impairment in one or more major life activities. A person with SMI may have major depression, schizophrenia or bipolar disorder, among others. NAC has been conducting an exhaustive review of data from multiple sources on the prevalence of SMI among PWH and RWHAP Part A clients, and the proportion of RWHAP Part A clients with an SMI diagnosis who were engaged or retained in care and virally suppressed. NAC reviewed a

data match between the NYC HD MH and HIV registries which found 1,326 individuals with SMI and diagnosed with HIV in NYC. Additionally, REU staff conducted a match between RWHAP clients screened for MH and the NYC Surveillance Registry found that those with reported MH diagnoses had lower rates of VS than those without a MH diagnosis. Those with more serious diagnoses (i.e., bi-polar disorder and/or reported psychosis) had the lowest VS of all. NAC reviewed the current RWHAP MH Services directive and standards of care to retool the category so that clients with SMI can be better linked to and retained in care and have their SMI and HIV diagnoses optimally treated. NAC is expected to complete a set of recommendations in fall 2020 that the PC can use as a road map for improving health outcomes for this population.

Integration of Care Committee (IOC). The IOC guides the PC in defining individual service categories, reaffirming continuing models of care, and creating new evidence-based service directives. Building on work done by the NAC in GY19, the IOC developed a new service directive for Oral Health Services to be provided in the NYC portion of the EMA (the Tri-County Region already has a small Oral Health program). The RWHAP Part A Oral Health program will fill a large identified unmet need through complementary Medicaid, Medicare, ADAP, and Part F services to ensure a robust system of care.

The service directive has many innovative features, including a screening tool to identify oral health discomfort and screening for human papillomavirus and oral cancers. The core of the service model includes: 1) provision of comprehensive preventative dental care, ensuring coverage of four dental cleanings per year including an annual deep scaling; 2) development of recommendations for common co-morbidities with oral health implications (e.g., diabetes, HCV); and 3) required trainings to build provider capacity to deliver services in a manner that is anti-racist and dismantles stigma. A portion of the allocated funding may be used to cover complex, high-cost services on a case by case basis, such as gum and bone grafts and implants. The directive also ensures that dental materials utilized are long lasting and of high quality; and supports replacement of dentures and other apparatus as needed.

The other principle component of the directive is a centralized Dental Case Management service to support: 1) full integration of oral health care into the service system; 2) increased capacity across the service system to improve access and utilization; 3) facilitation of consumer engagement and education; 4) provision of resources to support the more complex dental needs frequently associated with HIV; 5) development of a resource map to support completion of oral health treatment plans; 6) support of coordination of care with client's care team; and 7) ensures emergency care is funded and available. This service will be incorporated into MCM.

PSRA Committee. Using data assembled by the NAC, and service model definitions and eligibility criteria established by the IOC, the PSRA Committee uses an objective, evidence-based tool to determine service priority rankings and financial allocations, forwarding its recommendations to the full PC for consideration. The tool requires the committee to use data to score service categories on a prioritization grid, with four individually weighted criteria described below:

1) *POLR/ Alternate Providers of Services* (weight=15%). The PSRA Committee assessed each service to determine if RWHAP Part A is the primary funding source and whether other sources provide identical or equivalent services to PWH in the NY EMA. The highest value was assigned to services funded only by RWHAP Part A, and where existing provider capacity was found to be inadequate to serve PWH. In planning for GY21, the PSRA Committee examined a POLR and Coordination of Services Analysis compiled the previous year by consultants on behalf of the PSRA Committee. The analysis helped PSRA Committee members understand how RWHAP Part A serves as POLR by providing core medical and supportive services for PWH who have no other

source of coverage or face coverage limits, and provides services not covered by Medicaid and other payers. Due to NYS Medicaid's robust service coverage, the NY EMA prioritizes funding for supportive services, many of which are not covered by NYS insurance plans but are vital to the health and wellbeing of PWH. Services not covered by Medicaid and private insurance include many of the supportive and coordination services that have been expanded since the NY EMA obtained the CMS Waiver. The PSRA Committee also utilized Service Category Fact Sheets produced by the Recipient that examined each service category in depth. The Fact Sheets included POLR data and system-level considerations that examined other payers of RWHAP Part A services in the NY EMA. The addition of continued funding in NYS for HIV CMS through Medicaid expansion, health insurance exchanges, other RWHAP parts, and the NYS HH program was a critical factor in the PC's approval of the GY21 request for a waiver to the CMS requirement.

2) *Access to Care/Maintenance in Care* (weight=35%). The PSRA Committee assesses each service to determine the degree to which it contributes to access to or continuity of HIV primary care, including identifying people who do not know their HIV status. The highest value is assigned to services that have, as their primary goal, either direct provision of primary medical care or promotion of access to and maintenance in care through direct referral and linkage to medical services. Housing and FNS were deemed high priority services due to the importance of their role in addressing gaps in retention in care and VS.

3) *Specific Gaps/Emerging Needs (Demographic/Special Population)* (weight=25%). The PSRA Committee assesses each service to determine the degree to which it reduces documented service gaps or meets the needs of special populations. The PSRA Committee reviewed data from the CHAIN study documenting unmet need for key services in the study's representative cohort. The highest value was assigned to services promoting health care access and re-engagement of underserved populations, including those who are not engaged in later stages of the HIV care continuum.

4) *Consumer Priority* (weight=25%). The PSRA Committee scored services based on consumer input, as provided by the PC Consumer Committee, consumer members of the Council and PSRA Committee, and the CHAIN cohort study. The highest value was assigned to services identified by PWH as significantly contributing to access to or maintenance in primary medical care and representing a key consumer priority.

The Service Category Fact Sheets also provided eSHARE data over a three-year period on enrollment, performance, service utilization by service type, spending rates, and client demographics (including by priority population), which are used in the PSRA Committee's scoring of each criterion for every service category in the RWHAP Part A portfolio, as well as in allocation decisions, resulting in ranked priorities based on the criteria described above.

Tri-County Region Steering Committee. A local Steering Committee functioning as a subcommittee of the PC conducts service planning and makes resource allocation recommendations to the PC for Rockland, Putnam, and Westchester counties. The Tri-County Region's 30-member Steering Committee includes 11 PWH. All committee members received an orientation on the RWHAP legislation and the community planning process. The committee uses the same PSRA tool described above to rank regional service priorities. The Steering Committee reports to the PSRA, Executive Committee (EC), and full PC to obtain final approval of its spending plan. Most of the service portfolio in the Tri-County Region was recently re-bid for GY20, and the Steering Committee recommended proportional increases to the regional RWHAP Part A portfolio to increase capacity.

i. Involvement of PWH. The active, informed engagement of PWH is essential to the planning process and helps ensure that PC decisions address needs of consumers. The PC's Consumers Committee provides a forum for PWH (PC and committee members, as well as other stakeholder

community members) to be actively engaged in the planning process. PC members and staff living with HIV assist community members in understanding the priority setting and resource allocation process; HIV epidemiology; HIV care continuum; principles of community planning, group dynamics, and decision-making; QI/Quality Management (QI/QM); and the changing health care landscape and its effects on RWHAP services. The committee plays a key role in recruiting new members, including distribution of consumer outreach brochures, available in English and Spanish, at all PC meetings and outreach events. The Committee advocates for consumer engagement in the planning process and supports training and mentoring of new PC members (trainings to maximize informed participation and decision-making are available during the planning cycle).

In response to the challenges that COVID-19 presented to consumer involvement, the PC purchased tablets to loan to consumers who do not have appropriate computer equipment to participate in virtual meetings and read documents electronically. PWH participation continued during the planning year at the same high pre-pandemic levels, despite the challenges created by conducting all meetings virtually. In fact, the Consumers Committee held monthly listening sessions during the NYS on PAUSE order which allowed consumers to ask questions, raise issues in regard to gaps and services, and receive updates from the Recipient and NYC HD about COVID-19 guidelines and policy/service changes.

In GY20, PWH constituted 41% of the PC's 49 members. At the beginning of the planning cycle, after a concerted outreach and recruitment effort by PC staff, one-third of members were PWH who are not aligned with a RWHAP Part A agency. The overwhelming majority (71%) of the PC's non-aligned PWH are people of color. PWH actively serve on all PC committees and make up 37% of the Tri-County Region Steering Committee. The acting governmental co-chair is HIV-positive, and the community co-chair and finance officer are both non-aligned PWH. PWH from outside of the PC and its committees were closely involved in feedback on service quality, needs, and priorities through RWHAP Part A Client Experience Surveys and the ongoing CHAIN study.

To develop the GY21 plan, the PC sought the Consumers Committee's input regarding special populations and geographic areas of the NY EMA that remain disproportionately affected by HIV. Members of the Consumers Committee serve on all committees of the PC, and were particularly active in providing input and feedback at the IOC, NAC, PSRA, Tri-County Region Steering, and Rules & Membership Committees, as well as the Consumer Advisory Committee of the NYSDOH HIV Quality of Care Committee, NYS ETE borough and regional-based task forces, and NY EMA QM Committee, ensuring that consumer input and guidance is incorporated across the service system. In addition, committee members conducted a workshop at the NY EMA's 2019 Power of Quality Improvement Conference, where RWHAP Part A providers heard client perspectives on the need for oral health services, and link between oral health, quality of life, and retention in HIV care.

ii. Addressing funding increases or decreases. The PC's data-driven planning tool allows for an objective planning process for funding increases or decreases. The tool includes built-in weighted formulas based on the prioritized ranking of the services that automatically calculate funding increases or decreases for each service category contingent upon the actual award. The PSRA Committee and PC also review data from the Recipient on service category spending in order to consider targeted reductions in the case of a funding decrease. For GY20, there was a decrease of \$1.3 million in the NY EMA's total grant award (not including additional one-time funds received under the CARES Act). The NY EMA was able to absorb the cut through a reduction in the ADAP allocation. As described on *p. 13-14*, the PC worked closely with NYSDOH to agree on a reduction to the NY EMA's RWHAP Part A allocation to ADAP, based on an assessment of NYS and RWHAP Part B resources and projections of ADAP enrollment (which has decreased due to

expanded Medicaid and state insurance exchange enrollment under the ACA). The ADAP reduction allowed the PC to maintain services at their current levels. If the RWHAP Part A award is further reduced in GY21, the PC will adjust allocations based on expected need. However, the PC requests additional funding to cover the increased cost of service provision and to address unmet needs, particularly those arising from the impact of the COVID-19 pandemic such as housing, financial, and food support. Additional resources are also needed to fund the new Oral Health services, as well as to fully fund expanded PSS for TIGNCNB PWH. Given the ongoing reductions in the NY EMA's award since GY11, critical service levels will most certainly be negatively impacted if further reductions in the RWHAP Part A award occur in GY21.

iii. MAI funding. Planning for MAI funding, including prioritization and allocation of services, is integrated into service planning for RWHAP Part A funds and are aligned with the NYS Integrated Plan goal to reduce health inequities. MAI funds are concentrated in three CMS categories (ADAP, MCM, and EIS) and one support service category (Housing), all of which target the most heavily affected, highest need communities, specifically communities comprised of Black and Latino/Hispanic PWH. Data showed continued gaps in these services for these populations, justifying the need for continued targeted programs. In particular, the PC sought to ensure MAI funds were distributed to impact these populations at multiple stages of the HIV care continuum.

iv. Use of data in the priority setting and allocation process. The PC and committees considered all available and relevant data to assess need, develop service models, prioritize services, and allocate resources for GY21, consistent with the goals in the NYS Integrated Plan. The PC utilized multiple data sources, including surveillance reports, the NY EMA RWHAP Part A Service Category Fact Sheets, POLR Analysis, CHAIN data, NYS HUCP data, HOPWA, and RWHAP Part A program data from eSHARE.

In an effort to increase access to CMS and reduce inequities in access to HIV care, the PC examined evidence of service gaps from the CHAIN study and HIV/AIDS surveillance, which supported the PC's allocation of \$22.6 million for MCM in GY21. Thirty-nine percent of CHAIN cohort members met the criteria of needing MCM services, defined so if they reported interrupted HIV medical care, missed HIV medical care appointments, or had no CD4 or VL tests in the last six months. Of those who needed MCM, only a minority reported adequate utilization of the service, defined as receiving referrals to medical services through a case manager during the past six months.

The overwhelming majority of the MCM commitment is the CCP service model, which receives the largest service category allocation in the NY EMA's portfolio. CCP is a core component of promoting retention in medical care and medication adherence through clinical eligibility criteria and intensive services such as client centered care planning, self-management assessment, navigation, accompaniment, health promotion, and modified DOT. In revising the CCP service directive in GY18 for a re-bid of this service category for contracts starting in GY19, the PC examined NYC HD-reported MCM outcomes data from the Costs, HIV Outcomes, and Real-world Determinants of Success (CHORDS) Study. Significant increases in EiC and VS occurred in all subgroups examined, including those with key barriers to HIV care and treatment adherence. Findings showed a link between reducing psychosocial barriers and greater improvement on 12-month EiC/VS outcomes.^{lxxii} In comparisons of CCP clients' 12-month VS to the VS achieved among similar PWH, CCP-enrollees demonstrated higher rates of VS overall, with significant benefits over usual care for individuals who were newly diagnosed or who had no evidence of VS in the year prior to enrollment.^{lxxiii} Evidence of CCP effectiveness over usual care suggests health benefits for enrolled PWH and the public health value of intervention scale-up, focused on PWH with the greatest need.

Continued funding in GY21 at \$22.6 million was allocated to MCM on the basis of CHORDS data indicating statistically significant VS benefits, above those of usual care, for high-need PWH.^{lxiv}

For GY21, the PC also allocated \$4.1 million to continue n-MCM services for currently or recently incarcerated PWH in order to ensure linkage to care upon release for this marginalized population. Through this program, recently incarcerated PWH are connected to medical and support services that address barriers to optimal HIV primary care and assist in enrollment of PWH eligible for the NY State of Health insurance exchange and expanded Medicaid.

After careful review of data from the Service Category Fact Sheets and POLR analysis, the PC chose to end funding in GY21 of NMG. All service types in this category (i.e., outreach, accompaniment, service coordination, client assistance) are provided across numerous RWHAP Part A categories (Health Education/Risk Reduction (HE/RR), MH, MCM, PSS, EIS). NYC HIV/AIDS Services Administration (HASA), Medicaid HHs, SNPs, RWHAP Parts B, C, and D, and RWHAP Part A CCP and Supportive Counseling all provide similar case management services. Almost half of active NMG clients were actively enrolled in at least one other RWHAP Part A-funded service. NMG has historically under-performed (nearly 20% in 2018), and given this category's duplication of RWHAP Part A and other case management services, the PC determined that there is existing capacity to serve these clients through other programs. Furthermore, this funding can be reallocated to higher priority service categories and to fund new needs (e.g., Oral Health, COVID-19 response through increased allocation to FNS, EFA, and Housing).

Through Service Category Fact Sheets, the PC reviewed data highlighting the needs of historically underserved populations, including racial and ethnic minorities. Needs of PWH of color were assessed through an analysis of epidemiologic trends, utilization patterns by race/ethnicity, disproportionate service needs documented in the CHAIN cohort study, and comparison of geographic distribution of HIV/AIDS cases through mapping RWHAP Part A services. Through the Fact Sheets, the PC reviews service utilization data specifically by gender and age as well as by several special populations, including WoC, YMSM of color, OPWH, those who use substances, and TIGNCNB people. The data have shown that women make up a larger percentage of RWHAP Part A clients in the NY EMA (30.6%) than their proportion of the local epidemic (28.5%).

The PC uses these data to prioritize specific service categories that promote access to care for women, such as PSS services, where a disproportionate share of the clients are women, and which provides family-focused services that aim to remove barriers to care. The PC also promotes the meaningful participation of women living with HIV on the PC and its committees, where they bring an invaluable perspective on the barriers to care for women. The NY EMA ensures adequate and continued support of CMS for women, infants, children, and youth (WICY) through ongoing collaboration with the NYS Medicaid program. In FY19, Medicaid expended more than \$686,435,595 to fund CMS for WICY populations far exceeding the NY EMA's required set-aside \$28,730,976. In addition, the NY EMA is home to nine RWHAP Part D grantees, many of them multi-site consortiums, which specialize in serving WICY populations and sub-populations such as LGBTQ teens, pregnant and perinatal women, WoC, perinatally infected youth, and YMSM.

The PC reviewed evidence on inequities in timely EiC for newly diagnosed people. The PC allocated \$4.1 million to EIS in GY21 (including \$1.6 million in MAI funding) for targeted outreach and testing, and for return to care services targeting individuals found to be out of care for at least six months. The PC also allocated \$878,094 under HE/RR to support HIV self-management education programs for newly and previously diagnosed PWH with barriers to maintaining care. The PC also reviews NYS HUCP demographic reports. These reports provided evidence that many

MSM of color depend on the NYS HUCP for health care access, which influenced the PC's decision to continue to prioritize support for ADAP.

Data on unmet need and utilization of MH services among PWH in NYC, along with barriers that PWH with MH issues face with respect to accessing care, led the PC to continue supporting a MH service model that seeks to increase engagement in MH services; provide treatment and care to PWH with MH issues, including those with co-occurring SUDs, to improve quality of life and MH functioning; facilitate ongoing involvement in bio-psychosocial care and treatment, including adherence to ART and/or psychotropic medications; and reduce use of emergency care. The PC directed a total of \$4.2 million to MH services for GY21.

In GY20, the EMA allocated \$449,825 in RWHAP Part A funds to respond to the economic dislocation caused by COVID-19 by providing emergency funds to pay for necessities such as rent and utilities, as well as personal protective equipment for people who lost income due to the pandemic. In GY21, the PC continues the enhancement to the EFA category to respond to the ongoing COVID-19 crisis with a total allocation of \$685,618.

COVID-19 has brought pressing challenges to PWH in the EMA. Food insecurity is at an all-time high and food banks throughout the EMA have reported shortages and an inability to meet the demand for assistance. For GY21, the PC has allocated an additional \$1 million for FNS for a total of \$9.7 million. The PC is also requesting an increase of \$1.5 million in housing assistance for a total of \$14.2 million in order to respond to the increased need for rental assistance due to COVID-19. As has been amply demonstrated, food and housing insecurity are major barriers to access to and retention in medical care and achieving VS.

The PC reviews unit costs for each RWHAP Part A service category, considering the original funding allocations and modifications for each service category over a three-year period along with client utilization, expenditures, and service units. For example, when considering the GY21 allocation for expanded Oral Health services in NYC, the PC examined unit costs of the current Tri-County Region program and determined that an additional \$500,000 would allow for two pilot programs serving 280 clients, accounting for the increased expense of the higher quality services, procedures, and materials.

The PC also developed an annual plan for anticipated unspent funds, reallocating funds based on need and service costs, and prioritizing reallocated funding to over-performing service categories and ADAP as these funds become available to the NY EMA RWHAP Part A portfolio.

v. Changes in the prioritization and allocation process. In developing the GY21 plan, PC and its committees used the same well-established priority setting tools and process as in the previous year. Updated data was incorporated to reflect a greater understanding of the current local epidemic, the needs of PWH, gaps in services, and inequities in access to HIV care, and the ongoing effects of the changing health care landscape. The NYS Integrated Plan was a cornerstone for developing the goals and objectives of RWHAP Part A services. For example, the goals and objectives of the new Oral Health service directive were mapped to the goals and objectives of the NYS Integrated Plan, including: promoting access and maintenance in HIV-specific medical care; increasing proportion of clients with an undetectable VL and improved immunological health; reducing HIV-related morbidity and mortality; and reducing socio-demographic inequities in those areas.

2) Administrative Assessment. Consistent with legislative mandates, the PC assesses the efficiency of the administrative mechanism in timely allocation of RWHAP Part A funds to areas of greatest need in the NY EMA.

a) *Assessment of Recipient's activities.* The PC's EC is charged with assessing the efficiency of the administrative mechanism in the timely allocation and contracting of RWHAP Part A funds according to the PC's priorities and allocations. Recipient staff presented quarterly commitment and expenditure reports for all Base- and MAI-funded service categories in NYC and the Tri-County Region to the EC, and answered inquiries about increases or lags in spending by service category as well as in the Administration and QM lines. The EC also assessed all legislatively required aspects of the administrative mechanisms, including contract executions and renewals, procurement, and timeliness of sub-contractor payments and spending. The EC reported its findings on GY19 to the EC and full PC in July 2020.

b) *Deficiencies.* The EC determined that there were no deficiencies in the administrative mechanism, and no corrective action was needed for GY19.

3) *Letter of Assurance from Planning Council Chair(s) (see Attachment 6).*

4) *Resource Inventory.*

a) *Coordination of services and funding streams.* The flexibility of RWHAP Part A funding has enabled the NY EMA to develop a range of innovative programs and service delivery strategies that respond to the specific access barriers faced by the NY EMA's PWH most in need of services.

i) *HIV resources inventory (see Attachment 5).*

ii) *Needed resources, and steps taken to secure them.* As mentioned in the introduction, new resources from both HRSA and CDC are welcome additions to support NYC's EHE efforts. The BHIV has received awards for developing the NYC EHE plan (CDC PS-19-1906) based on a community engagement process—this effort has transitioned to virtual listening sessions to inform a plan that will be reviewed and voted upon by both the PC and the HPG in January 2021. The BHIV also received additional resources from the CDC to address the four pillars of the EHE plan (CDC PS-20-2010) and funding from HRSA to support EHE efforts in the Treatment and Response pillars (HRSA 20-078; Project PROSPER) while also serving as a Capacity Building Assistance Provider (HRSA-19-1904) to Northeastern EHE jurisdictions. The activities being planned and implemented under Project PROSPER and CDC EHE program will build upon the City's successes and align with the final NYC EHE plan (*see pgs. 1-2*); and aim to strategically advance HIV prevention efforts in the four EHE counties to accelerate NYC's progress in reaching the national goal of a 75% reduction in new HIV infections by 2025. The CTP is supporting Project PROSPER through review of RFPs for replicating evidence-informed models of care and strengthening data collection and utilization in clinical care settings to improve HIV care outcomes. Additional NYC resources fund programs to fulfill the goals of the NYS ETE Blueprint, allowing for contracts to increase the availability of PrEP/PEP, support VS, provide clinical services, pharmacotherapy, HR support for MSM and transgender women using methamphetamines, and increase the capacity of TGNC/NB-led and Black MSM-led CBOs. In GY20, the NYS HUCP adapted their enrollment process to allow for same-day provision of services and ART for the majority of clients to support iART upon diagnosis. This change has allowed RWHAP Part A EIS and MCM-funded providers and CDC-funded Status Neutral navigation clinical contractors to implement iART by leveraging the NYS HUCP resources. The NYS HUCP provides immediate access to ART and related medical and laboratory services through its ADAP and ADAP Plus programs while RWHAP Part A EIS and CCP resources provide support services to newly diagnosed clients in need of iART through coordination of benefits and insurance, assessment of

urgent needs, and the provision of support and accompaniment services through patient navigation to enhance and ensure adequate linkage to and retention in care.

Addressing income as a social determinant of health is an important endeavor to meet the needs of PWH in the EMA given that 88.5% of RWHAP Part A clients earn less than 138% of the FPL. While RWHAP Part A resources are not able to support efforts to engage PWH in employment services, the NYC HD has utilized other resources to address this need. To support PWH needs to engage in employment, the NYC HD leveraged three-years of grant funding from the CDC (15-1506, Project THRIVE) which began in 2017 to launch a demonstration project focused on improving HIV prevention and care outcomes among MSM of color in Brooklyn. In addition, BHIV, in collaboration with the Mayor's Office of Workforce Development, created an internal working group consisting of staff across units, known internally as "Considering Work Efforts Work Group," which is now funded with City resources. A key goal of this group is to inform staff on how to enhance the integration of employment services within HIV prevention, care, and treatment programs to ultimately advance overall health outcomes of PWH throughout the NY EMA. A key deliverable of this initiative was the successful execution of "Career Power Source," an annual community event that took place in October in 2018 and 2019, with current plans to hold a virtual event in 2020. This all-day event brings together consumers, providers, and subject matter experts in an effort to increase access to jobs, employment services, training, and educational resources for the priority populations mentioned above.

The NY EMA used ETE funds to support methamphetamine-specific HR programs to address the harmful effects of methamphetamine use, alongside RWHAP Part A-funded HR services to address the needs of both PWH who use methamphetamines and people not living with HIV who use methamphetamines. In 2020 a crisis line and "come down" room were added to services offered to people who use methamphetamine. Another ETE funded program utilizes elements of CCP to provide status neutral navigation and assessment to PEP, PrEP, MH, housing, and SUD services to those at risk for HIV.

WORKPLAN

A) HIV Care Continuum Table and Narrative.

B) HIV Care Continuum Table (see Attachment 7).

C) HIV Care Continuum Narrative.

a) Utilizing the HIV care continuum in resource planning. The NY EMA takes a strategic systems-level approach to planning for services for those with unmet need. The PC and the CTP Operations and Planning Team regularly use the HIV care continuum to understand gaps and identify new service models that might be able to meet those gaps. The HIV care continuum is also used to measure progress towards ETE goals. The NY EMA was able to produce a combined continuum for NYC and the Tri-County Region, for all PWH, using 2018 data (see Figure 2). Information on all PWH was obtained using the NYS Surveillance Registry. Using NYS's methodology, individuals who have been diagnosed with AIDS with no evidence of care for five years and individuals who have been diagnosed with HIV (non-AIDS) with no evidence of care for eight years are excluded from the total number of diagnosed PWH. This approach yields an accurate estimate of the number of PWH who are still living and residing in the NY EMA and allows for better estimation of progress along the HIV care continuum. The NYC HD's MMP in NYC provides an estimate of ART prescription status for all PWH.

b) Changes in the HIV care continuum. From 2014-2019, the proportion of clients engaged along the different stages of the NY EMA HIV care continuum has remained relatively stable, with

a slight decrease in linkage to care and a slight increase in retention in care, ART prescription, and VS. The NY EMA is invested in evaluating the strategies and interventions necessary to address unmet need and move PWH along the HIV care continuum to VS. As such, the NY EMA was an engaged participant in the HRSA-funded Care Continuum Learning Collaborative, where the NY EMA Recipient staff shared their HIV care continuum-related project plans with peers (Baltimore, Detroit, Tampa/St. Petersburg, Houston/Harris County, and Phoenix/Maricopa County) in their assigned work groups. The NY EMA focused on developing a surveillance-based client-level VS progress report, which was disseminated to CCP providers in July and August 2018 (and semi-annually thereafter), as part of a new D2C initiative. These reports continue to be shared with providers. Also, the NY EMA created a protocol to implement a VBP model across CCP, with the aim of incentivizing QI among subrecipients. The model will be implemented post COVID-19 to ensure the model is based on accurate data.

The NY EMA has been at the forefront of evaluating interventions across the portfolio of services. This includes utilizing resources from the National Institutes of Health (NIH), HRSA, and CDC, among others, to work with academic and other partner institutions to conduct in-depth assessment of outcomes within and across subpopulations of interest. One example has been the work of the CHORDS study to evaluate the CCP model of MCM. This multi-year, multi-phase project evaluated care engagement and VS outcomes among CCP clients overall and according to baseline VL, housing, MH, and SUD status. Initial work of the CHORDS study resulted in CCP being listed as an evidence-informed intervention in the CDC Compendium^{lxxv} of Evidence-Based Interventions and Best Practices for HIV Prevention under the Linkage to, Retention in, and Re-engagement in HIV Care chapter. In addition, this study has highlighted the impact of resolution of psychosocial needs on HIV outcomes. CCP clients reporting cessation of hard drug use post-enrollment showed significantly greater improvement in EiC from the period prior to enrollment than those continuing hard drug use, and clients obtaining stable housing post-baseline showed significantly greater improvement in VS than those remaining in unstable housing.^{lxxvi} In addition, the REU of CTP received new NIH R01 funding for an implementation science study, Program Refinements to Optimize Model Impact & Scalability based on Evidence. This endeavor will evaluate changes in the CCPs resulting from the PC's GY18 service directive.

Other work has demonstrated the need in the NY EMA for supportive services that reduce barriers to VS. As noted above, previous work by the NYC HD among MSM living with HIV enrolled in RWHAP Part A programs in the NY EMA found crystal meth use to be associated with unsuppressed VL.^{lxxvii} In a separate analysis, controlling for sociodemographic and clinical characteristics, recent tobacco smoking was also found to be associated with unsuppressed VL.^{lxxviii} Additionally, in an analysis of the NYC RWHAP Part A FNS program, among clients analyzed between 2011 and 2013, controlling for sociodemographic characteristics, consistent food insufficiency was found to be associated with unsuppressed VL.^{lxxix} The CHAIN study has also demonstrated a relationship between unmet needs and poorer health outcomes, including analyses of the relationship between housing need and retention in HIV medical care,^{lxxx} and has shown that providing services to address these unmet needs reduce the likelihood for poor outcomes. For example, in a longitudinal analysis comparing individuals who were food insecure at one interview and receiving FNS and were then not food insecure by the next interview with individuals who continued to be food insecure, those with resolved food insecurity were less likely to have missed appointments, to have a detectable VL, and to have had an emergency room visit or an inpatient stay compared to those who remained food insecure.^{lxxxi} To address the needs of food insecure PWH the new FNS directive, which is more client-centered and emphasizes the role of healthy

eating and food access on HIV health, was approved by the PC resulting in a procurement process and new contracts in GY20, along with an increased service allocation to support PWH who are food insecure to move through the HIV care continuum. The new contracts are aimed at addressing issues relating to food insecurity, increasing access to care and treatment, and addressing racial and health inequities for PWH in the NY EMA.

B) Funding for Core and Support Services.

1) Service Category Plan.

a) Service Category Plan Table (see Attachment 8).

b) MAI Service Category Plan Narrative.

MAI Initiatives. As previously described, low-income communities of color are disproportionately affected by HIV in the NY EMA. The NY EMA strategically uses MAI funding to reduce health inequities, increase service access, and improve health outcomes for underserved PWH, including Black, Latino/Hispanic, and Asian/Pacific Islander people. In GY20, 94% of PWH served by the MAI program were people of color: 54% were Black, 37% Latino/Hispanic, and 2% Asian/Pacific Islander. The NY EMA strives to use its resources to address HIV health inequities associated with race/ethnicity, particularly among Black and Latino/Hispanic populations who account for 87% of all PWH served by RWHAP Part A, while they constitute only 76% of all PWH in the NY EMA.

Among RWHAP Part A clients served in NYC in 2019, the racial/ethnic inequity in VS rates persisted; 78% of Black RWHAP Part A clients were virally suppressed in 2019, compared to 82% of Latino/Hispanic clients, 87% of White clients, and 91% of Asian/Pacific Islander clients. Across gender categories, VS rates were lowest among transgender clients (74%), 89% of whom were Black or Latino/Hispanic and 80% of whom were transgender women.

Approaches for MAI populations. Due to the large proportion of racial/ethnic populations served by the entire RWHAP Part A program, the PC and the Recipient work to develop strategies and interventions throughout the portfolio that will support positive health outcomes for people of color living with HIV. Thus, there are not separate planning processes for racial/ethnic minority populations or for MAI funding.

MAI activity descriptions. The GY21 MAI funds have been allocated to program services in four service categories: ADAP, EIS, MCM, and Housing Services. These four service categories were selected by the PC to receive MAI dollars because of their combined ability to make an impact along each stage of the HIV care continuum among priority populations by focusing on social determinants of health such as lack of access to regular medical care (including HIV testing and linkage services) and unstable housing. The MAI program service models do not vary from the same service categories in the RWHAP Part A program portfolio; rather, the MAI program prioritizes services to communities where disproportionately burdened minority populations live. All contracted RWHAP Part A services in the NY EMA, including MAI, are required to adhere to CLAS Standards. The NY EMA applies the eligibility criteria below to ensure that MAI funds are directed to high-need communities. Other than ADAP, each MAI-funded agency/program must:

- Direct its services to residents of ZIP code areas with 150 or more reported living HIV/AIDS cases among the MAI populations;
- Have the majority of its program and administrative sites located in ZIP codes with 150 or more reported living HIV/AIDS cases among the MAI populations; and
- Demonstrate that at least 75% of its current active clients who receive HIV/AIDS services are from the MAI populations.

ADAP exclusively serves Black, Latino/Hispanic, and Asian/Pacific Islander clients from the NY EMA who are eligible for ADAP with MAI funds.

c) Core Medical Services waiver (see Attachment 9). A CMS waiver was submitted prior to this grant application.

RESOLUTION OF CHALLENGES

The NY EMA continues to strive to deliver the best possible services aimed at increasing the health of PWH in its concerted effort to end the epidemic while adhering to the RWHAP legislation and accompanying policies. In GY20, the Recipient has worked to resolve a number of challenges through collaboration with the PC, consumers, funded providers, Public Health Solutions (PHS)/Contracting and Management Services (CAMS), and NYSDOH AI colleagues. *Table 6* below highlights the most salient resolved challenges.

Table 6. Resolution of Challenges

Challenges/Barriers	Proposed Resolutions	Intended Outcomes	Current Status for RWHAP Part A/ Care Continuum
Providing Culturally Responsive Care Research has shown that stigma and discrimination related to race, sexual orientation, and gender identity/expression, in addition to lack of access to culturally responsive services, especially for Black and Latino TIGNCNB people, are barriers to HIV medical services. ^{lxxxii} This challenge must be addressed to increase the provision of culturally responsive care to effectively meet the needs of TIGNCNB clients participating in RWHAP Part A services across the NY EMA.	In GY19, the Recipient disseminated a CLAS Standards self-assessment to service providers throughout the NY EMA RWHAP Part A portfolio, results of the assessment are to be incorporated into subrecipient QM plans. The Recipient also collaborates with others in BHIV to engage community partners in addressing stigma, including CHAIN researchers who issued a special report about experiences of stigma among survey participants in GY20. Most importantly, under the newly created PSS for TIGNCNB people, all providers will participate in a comprehensive cultural responsiveness/ awareness training program, with a multi-day curriculum and all-encompassing TIGNCNB resource directory. Both materials will be developed and created by community members identifying as TIGNCNB in GY20 and GY21.	Improve cultural responsiveness across the RWHAP Part A service portfolio, focused on addressing the complex needs of TIGNCNB populations within the NY EMA.	VS among Black Transgender women is 11% lower than the larger population of PWH (64% vs 75%, respectively). This data underscores the need to better meet the needs of Black TIGNCNB PWH by increasing cultural responsiveness at the provider level, engagement at the participant level, and service quality in core medical and support service environments that lead to VS.
Addressing Needs of OPWH (Age 50+) As more of the NY EMA's PWH benefit from the improved health outcomes related to VS, additional co-morbidities associated with HIV and aging must be incorporated in the system of care. As of December 31, 2019, more than half of PWH in the NY EMA were OPWH. Among RWHAP Part A PWH clients in NYC who had	The recipient conducted seven focus groups in collaboration with the community-based Long-Term Survivors Wellness Coalition to assess the unmet needs of OPWH for use in developing future service models aimed at tackling the diverse needs of this priority population. In GY20, the recipient shared results which indicate the needs of OPWH are far more complex than maintaining their HIV care and treatment, and extended to MH and systems navigation for	Address HIV related health inequities and reduce the effect of co-morbidities on OPWH in order to improve health outcomes and reduce preventable mortality.	Work to improve the quality of care to improve retention and VS, and reduce preventable mortality for OPWH.

Challenges/Barriers	Proposed Resolutions	Intended Outcomes	Current Status for RWHAP Part A/ Care Continuum
at least one service during March 2017-February 2018, 58% were OPWH. ^{lxxxiii} Moreover, inequities persist among older people of color with VS rates being the lowest among Black and Latino/Hispanic OPWH when compared to their White counterparts. Moreover, death rates among Black and Latino/Hispanic OPWH were significantly higher than death rates among White OPWH. ^{lxxxiv}	conditions outside of their HIV diagnosis. In GY21, the Recipient will work with the PC to ensure programming is responsive to the needs of those aging with HIV in the NY EMA. In addition, the Recipient will coordinate with Project PROSPER to learn from successes and challenges of the implementation of a clinical model of care for Black and Latino/Hispanic OPWH.		
Addressing Health and Racial Equity Across the RWHAP Part A Portfolio Recent surveillance and eSHARE data analyses indicate that racial and ethnic minority populations are disproportionately affected by HIV. Although the NY EMA is working towards national goals on retention and VS, inequities exist among certain subpopulations, specifically YMSM and Black cisgender women. The overwhelming majority (85%) of YMSM diagnosed with HIV by the end of 2017 and still living in NYC at the end of 2018 were Black or Latino; and over half (59%) of cisgender women diagnosed with HIV by the end of 2017 and still living in NYC at the end of 2018 were Black. YWMSM fared better on VS (at 68% and 71% in 2017 and 2018, respectively) than YBMSM and YLMSM ⁹ . White cisgender women had the same level of VS as Black cisgender women (at 72% in 2018); they also represented a small share (6%) of the population of cisgender women living with HIV ^{lxxxv} .	The Recipient developed, implemented, and maintained work groups designed to advance racial health equity and influence future RWHAP Part A programming focused on: Black and Latina Women; Youth; Mortality; Housing; OPWH; and Transgender women. In GY21, the recipient will collect information to inform the development of locally-defined strategies to improve the accessibility and responsiveness of services for young adult PWH. The Black and Latina Women work group, with support from the Recipient is planning to hold an open forum in GY21 to support Black and Latina/Hispanic women who provide HIV services in the era of COVID-19 and to incorporate lessons learned in future RWHAP Part A programming. The Recipient has developed and offered a racial equity training for RWHAP Part A contracted providers since 2018. These trainings will continue in GY21, and will be done virtually in response to the COVID-19 pandemic. The Recipient will also evaluate eSHARE data to aid in assessing where each priority group is being served in the RWHAP Part A portfolio and to identify gaps in the HIV care continuum.	Increase the quality and responsiveness of services offered to priority populations disproportionately affected by HIV in the NY EMA RWHAP Part A portfolio; decrease inequities identified in priority populations across the HIV care continuum; and improve general health outcomes across priority populations in the NY EMA.	The vast majority of RWHAP Part A clients are Black and Hispanic/Latino in the NY EMA. Given the VS inequity between these populations and White PWH the Recipient will work to improve the quality of care and services offered, with the goal of reducing new diagnoses, unsuppressed VL, and preventable mortality among Black and Latino/Hispanic PWH in the NY EMA.

⁹ However, the YWMSM VS proportions are more labile given that their numbers are also small (<100 in the denominator in each year, as compared with >400 YBMSM and >300 YLMSM in each year).

Challenges/Barriers	Proposed Resolutions	Intended Outcomes	Current Status for RWHAP Part A/ Care Continuum
Addressing the Needs of PWH with Disabilities Under federal, state, and local law, health providers are required to provide reasonable accommodations to individuals with a disability. A 2016 survey of RWHAP Part A providers in the NY EMA identified major challenges to the provision of care for people with disabilities, including: time constraints, lack of resources, lack of funding, and lack of training/education. In 2017, 45% of RWHAP Part A program participants reported having at least one disability at their most recent visit.	Based on a RWHAP provider survey, a review of data in regard to the needs of PWH with disabilities and recommendations from the PC's NAC, the Recipient developed a provider resource guide to aid in better addressing the needs of individuals with various types of disabilities in the NY EMA. Additional efforts include increasing the availability of trainings and TA addressing reasonable accommodations among contracted providers and improved data collection in eSHARE through an update to the disability questionnaire to include more sensitive and inclusive language around disabilities. The resource guide is in final development stages and will be updated as per guidance from the NYC Mayor's Office of Disabilities.	Ensure the provision of reasonable accommodations to PWH with disabilities in order to increase access to and retention in care. Ensure services are delivered in a culturally responsive manner, and are tailored to address provider needs for working with this population.	Work to improve the quality of care and types of services offered to ensure access for all RWHAP Part A participants with disabilities in the NY EMA.
Addressing the COVID-19 pandemic in the RWHAP Part A Portfolio A recent CHAIN survey set out to uncover how participants have been impacted by the COVID-19 pandemic. The results indicated that up to 48% of participants are at a higher risk for serious illness from COVID-19, and 97% had significant increased risk for COVID-19 due to structural inequity indicators, including recent homelessness/housing instability, poverty, and history of incarceration.^{lxxxvi} Furthermore, the findings indicate that up to 49% of participants are experiencing financial hardships and/or are struggling to make ends meet. In addition, a larger proportion of participants (30%) indicated they had been laid off, or had work hours greatly reduced without pay, posing additional barriers for optimal care and treatment.	Enhancements have been made in GY20-21 to provide additional funding to EFA, FNS, and Housing services to address emergent financial needs (which have increased in light of COVID-19), food insecurity, and homelessness/housing instability for PWH in the NY EMA. Additionally, in GY20, the recipient provided flexible service provision standards for RWHAP Part A providers to ensure both provider and client safety while guaranteeing continuity of services during the COVID-19 pandemic. In addition, the recipient authorized a number of changes to contracts, including the provision of remote services, to ensure service continuity for RWHAP Part A clients in the NY EMA, and to prioritize the health and safety of program staff, clients, and communities served.	Ensure RWHAP Part A providers are able to adapt to the current health care landscape, which has shifted both greatly and swiftly in light of COVID-19, and to enable continuity of care and provision of essential support services to PWH in the NY EMA. Additionally, the enhancement made to EFA, FNS, and Housing services will ensure RWHAP Part A participants are not displaced, and are able to continue to adhere to their treatment regimens without the added stressors associated with homelessness, housing instability, or food insecurity.	Continue to provide essential support services to those most impacted by both HIV and COVID-19 to ensure continued progress along the HIV care continuum for RWHAP Part A participants in the NY EMA.

EVALUATION AND TECHNICAL SUPPORT CAPACITY

A. Clinical Quality Management (CQM). The CQM program is a collaborative effort overseen by the RWHAP Part A Project Director and involves BHIV CTP QM/TA and REU, COTA, and Prevention; Housing programs; NYSDOH AI; PHS; PC; consumers; and RWHAP providers.

Through TA, the CQM program seeks to: (1) strengthen RWHAP Part A providers' quality efforts; (2) build providers' capacity for QM while also providing guidance in program model implementation; and (3) improve care across the continuum. The objectives of the CQM program are to: build capacity for QM among RWHAP Part A providers; increase collaboration between RWHAP and Medicaid-funded providers; provide opportunities for peer learning among RWHAP Part A providers; and ensure the continuation of high-quality services for PWH. These objectives are consistent with national goals for increasing the capacity of HIV systems of care that include diverse service providers.

Several processes are in place to provide TA and capacity-building assistance. The CTP QM/TA team members, under the supervision of the CTP Director of QM/TA, identify gaps in the RWHAP Part A system and develop strategies to address gaps and assess quality. QMSs on the CTP QM/TA team, along with REU evaluation specialists, provide TA to RWHAP Part A providers with an emphasis on using data and QI tools to improve care. More specifically, through the CQM program, the grantee develops and implements trainings for RWHAP Part A providers to improve service quality and support QM activities. In August 2019, QM/TA started releasing quarterly memos to advise service providers of updates or clarifications about service definitions and standards, service reporting, documentation, deliverables, and training expectations. The quarterly memos are part of the grantee's plan to improve the quality of TA services by organizing and coordinating the distribution of information.

As part of the CQM program, the NY EMA QM Committee updates and implements the QM plan. The most recent update was completed in July 2019. The committee includes key stakeholders from CTP, the PC (both consumers and staff), NYSDOH AI, Tri-County Region, Housing, HIV Prevention, COTA, and other areas as needed. The plan outlines the CQM program's activities in five domains: consumer engagement, collaboration and coordination, capacity building, service engagement, and service quality. In 2020, the Committee added a new health equity domain, with the objective of improving systems to reduce inequities in health outcomes driven by structural racism. Adding a domain in this area is also consistent with NYC HD's emphasis on addressing racism as a driver of health inequity and poorer health outcomes.

Some CQM efforts are shared with the COTA program to increase coordination between the RWHAP Part A program and non-RWHAP Part A-funded outpatient ambulatory care services. CTP meets regularly with BHIV colleagues in COTA, who are evaluating HIV primary care facilities in NYC to assess client characteristics, clinical and support service capacity, and HIV care outcomes. COTA is also conducting in-person TA visits to support facilities in meeting the NYS ETE initiative's goals. The CQM program uses data from COTA's evaluation and TA to determine how RWHAP Part A services may better support clinical services, including health care settings that receive RWHAP Part A funding through subawards. COTA also coordinates closely with the NYSDOH AI on RWHAP Part B and Medicaid clinical organizational assessments. CTP, Prevention, and COTA and the NYSDOH AI collaborate on shared jurisdictional initiatives including: *New York Knows*, which works to increase HIV testing and linkage; the NYLinks program to increase retention and VS through cross-RWHAP-Part collaboration; and the ETE borough-based and Lower Hudson Valley steering committees which support implementation of the NYS ETE Blueprint and are providing input into the NYC EHE plan.

NYC HD REU staff are responsible for analyzing eSHARE data, as well as consumer survey and supplemental evaluation data, to produce and present portfolio-wide and service category- and agency-level quality performance indicators. Additional analyses (e.g., HIV care continuum measures and mortality rates disaggregated by service category or by client demographic, clinical and/or psychosocial characteristics) help identify inequities in HIV-related health outcomes that may be addressed through program planning and QM/TA efforts.

CTP draws on the expertise of the NYSDOH AI to provide peer learning support through the annual Power of QI Conference. In November 2019, the sixth annual Power of QI conference was held with the theme, *Using Unexpected Results to Improve Performance*, which emphasized that trial and error are essential to the process of improving systems. The Consumers Committee of the PC welcomed conference attendees during the opening plenary and conducted a workshop focusing upon meeting needs for oral health services. HRSA's RWHAP Center for Quality Improvement and Innovation also conducted a workshop about quality improvement through the Project Extension for Community Health Outcomes collaborative. The conference provided a forum for participants to share QM projects through workshops and presentations. Over 250 service providers, consumers, and other stakeholders across the NY EMA attended the Power of QI conference. Bridging Access to Care received the award for best overall project for "*A Look at One HPA Program's Retention Rates and Why Housing Was Lost*" examining and addressing root causes driving housing loss in their program.

1) Use of performance measure data to evaluate inequities in care. Consistent with national goals, BHIV is expanding its efforts to support VS by addressing care quality at the clinic level. The CQM program has collaborated in these efforts by ensuring that RWHAP Part A services support engagement and retention in high-quality clinical care and treatment to achieve and maintain VS. For example, as part of an effort to promote early ART initiation, consistent ART access, and sustained VS, CTP began providing each RWHAP Part A provider agency with client-level reports, known as TSRs, in 2014. The TSRs are prepared every three months using data reported by RWHAP Part A providers in eSHARE. Reports list clients who do not appear to be virally suppressed, distinguishing whether or not the clients are currently prescribed ART. These client-level, custom reports are used to focus programmatic TA and facilitate communication and coordination between RWHAP support service providers, clients, and their medical providers to promote ART use and adherence. In 2017, CTP launched the RWHAP Part A AVSR, and for each organization receiving funding from the RWHAP Part A program, REU prepared a report showing the proportion of each organization's RWHAP Part A clients who were classified as virally suppressed at their last VL test of the calendar year, for multiple years (thus tracking trends over time). Organizations were also able to see how their annual VS proportion compared to that for all RWHAP Part A clients in NYC. The AVSR uses VL data reported to the NYC HIV Surveillance Registry. CTP released new versions of the AVSR in July 2019, breaking down results for five priority subpopulations (OPWH, Black or Latino cisgender MSM, cisgender YMSM, transgender women, and Black and Latina cisgender women) selected in accordance with the NYC HD's Race to Justice initiatives for advancing racial equity and social justice. The updated, expanded AVSR also provides breakdowns of VS proportions among clients "newly enrolled" and clients "established in services," along with guidance for report interpretation (i.e., lower VS among newly enrolled clients may reflect successful outreach to more vulnerable PWH).

In July 2018, CTP began providing Client Progress Reports (CPRs), client-level reports on VS and care status based on information in the NYC HIV Surveillance Registry. Each report lists all clients in a program's current caseload and categorizes them as needing follow-up for connection to

care and/or for VS, requiring case closure due to death, being virally suppressed at last update, or being stably suppressed throughout the report year. CTP rolled out CPRs first to NYC CCP providers who had been re-awarded CCP contracts under the most recent re-solicitation. For these programs, the CPR was designed to facilitate care team decision-making regarding enrollment of some existing clients in the new contracts and closure (with or without a hand-off to other services) of other existing clients, to make room for new enrollment among people with current high need.

Data collected routinely from RWHAP Part A providers include client-level sociodemographic, psychosocial, and health outcomes information, as well as service utilization information. In support of national goals, these data – particularly when merged with comprehensive laboratory data from HIV surveillance – enable the NY EMA to evaluate a range of inequities in service utilization and care continuum indicators, including those related to race/ethnicity, gender, age, transmission risk category, and geographic location, among other factors (e.g., housing stability, disability status). Over 90% of those served in the RWHAP Part A program identify as Black or Latino/Hispanic, and the vast majority (80%) are also living below 100% of the 2020 FPL. As a result, local RWHAP Part A outcomes do not necessarily reflect conventional/general-population racial, ethnic, or income inequities. However, since the sociodemographic subgroups over-represented in the local RWHAP Part A program tend to experience poorer health outcomes, the NY EMA takes a system-wide approach to improving care and outcomes for those served by the RWHAP Part A program. This approach has included strengthening inter-agency coordination and referral systems and the use of data systems to flag clients in need of timely intervention. Together, these data collection, data sharing, and systems coordination efforts help ensure clients served have the appropriate resources and individualized support to achieve and maintain VS. To further address inequities, the NYC HD ensures subrecipients provide services consistent with CLAS Standards according to a protocol designed by QM/TA staff. The protocol calls for RWHAP Part A-funded organizations to assess their compliance with CLAS Standards and incorporate efforts to improve into their QM plans.

The COVID-19 crisis may temporarily interfere with CTP's ability to use performance data to manage service quality. During NYS's PAUSE order, funded organizations worked to re-organize their service delivery systems. In some cases, this made it challenging for them to consistently report their program activities, including data that CTP uses to evaluate service delivery and prepare reports. According to NYC surveillance data, regular VL monitoring has been disrupted, as health care providers responded to the crisis and shifted to remote modes of service delivery, and as patients followed stay-at-home orders, resulting in declines in blood draws for laboratory testing and in reports to the Surveillance Registry as of April 2020.

2) Use of CQM data to inform service delivery. Trends identified through the CQM program enable key stakeholders to assess RWHAP Part A service quality and fidelity to service model guidance over time. Quality indicators, developed in collaboration with RWHAP Part A-funded providers, are often used to inform provider annual QM plans, which are designed to improve service delivery. The indicator data are reviewed for trends to inform long-range service delivery planning and to review the impact of related QI projects.

Most recently, CQM findings informed changes in how CCP services are reimbursed under the 2017-18 re-solicitation, transitioning from the administratively burdensome per-member-per-day reimbursement to FFS. In an effort to ensure service quality, QM/TA staff in CTP worked with CCP providers on an ambitious project to design a system for VBP, an innovative approach for the NY EMA using the Exploration, Preparation, Implementation, and Sustainment framework, a conceptual model of evidence-based practice implementation. In 2019, QM/TA staff invited representatives from CCP programs and other key stakeholders to participate in the design of a

system for VBP for program services. Over the course of four meetings, stakeholders collaborated to consider measures for VBP and payment benchmarks. Using exercises inspired by nominal group technique, stakeholders expressed preferences for types of measures and benchmarks. The grantee will test the new VBP system for CCP comparing the new program data and the program data from the previous GY before implementing in 2021.

ORGANIZATIONAL INFORMATION

A. Grant Administration. Through the rigorous monitoring and accountability measures described below, the NY EMA ensures that RWHAP Part A funds are used effectively to address the country's largest and most complex HIV epidemic. Of the NY EMA's GY20 RWHAP Part A contracts, 48% are reimbursed FFS and 38% are reimbursed through a hybrid FFS and/or for achievement of specific deliverables. Managing the portfolio in this way contributes to efficient resource management with timely reallocation of dollars to highly utilized services and minimal carryover. Through multi-pronged efforts, the NY EMA ensures RWHAP Part A serves as the POLR.

1) Program Organization. GY21 will be the NY EMA's 31st year as a RWHAP Part A Recipient and the NY EMA is committed to efficient program administration, aiming to maximize the effectiveness of HIV services. In GY19, the NY EMA spent nearly 100% of its RWHAP Part A formula award (with \$18,525 requested carryover) and more than 99% of its MAI award (with \$79,479 in requested carryover).

a) RWHAP Part A Administration (see Attachment 10). The Mayor of the City of New York serves as the CEO of the NY EMA. The Mayor has designated the NYC HD as the administrative and fiscal agent for RWHAP Part A. As *Attachment 10* illustrates, the NY EMA's RWHAP Part A program is administered by CTP in the NYC HD BHIV. The BHIV is headed by an Assistant Commissioner, who oversees a staff of over 280 people across eight programs, which includes 49.07 full-time equivalents (FTE) under the RWHAP Part A grant.

The Director of CTP (.85 FTE) oversees all staff responsible for service planning, TA, QM, REU, and RWHAP Part A planning and grant administration, as well as RWHAP Part A fiscal oversight, in collaboration with the Director of Administration (.5 FTE). The Director of Program Planning and Operations (1.0 FTE), collaborates with the Senior Grant Manager (1.0 FTE) and program and administrative fiscal staff (2.45 FTE) to ensure adherence to all applicable HRSA grant reporting and monitoring requirements. The Director of Program Planning and Operations (1.0 FTE) oversees and coordinates the activities of three Program Planners (2.7 FTE) and serves as an alternate to the Director of CTP for PC business and communications with HRSA. The Director of QM/TA (0.94 FTE) oversees a total of 8.0 FTE staff including: one Deputy Director, one QM Project Manager, three QMSs, one Behavioral Health Specialist, one Senior QMS, and one QM Liaison. The Director of HIV Health Equity (1.0 FTE) oversees the implementation of health equity practices within planning, quality management, and TA in CTP. The Director of HIV Prevention (in-kind) oversees the TA provided to the EIS providers, in coordination with the HIV Prevention program. The Director of Housing (0.3 FTE) oversees three Housing Coordinators (2.3 FTE) who manage RWHAP Part A housing subrecipient activities to ensure that housing services and resources are monitored and implemented in a coordinated manner with HOPWA across the NY EMA and in compliance with RWHAP Part A requirements. The Director of REU for the Housing Services Unit (0.5 FTE) coordinates with the Director of Housing for housing services monitoring and evaluation. The Director of COTA (0.2 FTE) oversees 0.26 FTE in TA and training for health care providers. The Director of Administration (0.5 FTE) oversees human resource staff as well as the Deputy Director of Business Systems (0.8 FTE), who manages contract

administration and procurement, including eSHARE data system implementation across Prevention and Care funded with 5.24 FTE for RWHAP Part A (additional FTE is covered with other funds).

RWHAP Part A funds 9.75 FTE in the CTP REU, overseen by the Director of REU (0.7 FTE). Using multiple methods, including merged analyses of provider-reported, HIV surveillance, and survey data, REU staff evaluate RWHAP Part A client and program needs, service utilization, and health outcomes. REU staff track progress on NYS *Integrated HIV Prevention and Care Plan* goals, analyze and prepare eSHARE data for site visits and provider meetings, report on QM performance indicators at the portfolio-wide, service category and agency levels, elicit consumer input through surveys and focus groups, and improve Ryan White Services Report completeness.

The PC Director (1.0 FTE) reports to the NYC HD Deputy Commissioner for Disease Control and oversees a total of 4.9 FTE staff who support the planning and administrative functions of the PC. The PC and Recipient meet weekly to coordinate planning activities and ensure work is conducted in alignment with the MOU approved by HRSA in 2019. The Senior Policy Analyst (0.36 FTE) informs the PC and Recipient of health policy developments and their effect on the NY EMA system of care. The Epidemiologic Liaison (0.4 FTE) works with the PC and HIV Surveillance to provide epidemiological data necessary for PC decision-making.

Temporary Assignment of State and Local Personnel during a Public Health Emergency. In the midst of the COVID-19 response a number of RWHAP Part A supported staff have been activated to assist with response activities including: contact tracing, public information, COVID-19 health equity, and communications. Activated staff report their time dedicated to the response in the City Time system which allows all time dedicated to the response to be charged to the Office of Emergency Management. Given this ability to track staff time during the emergency response, there has been no cost to RWHAP Part A associated with the COVID-19 activation. Given the City's ability to track and assign costs associated with the response, the Recipient has not needed to request permission from the Secretary of HHS for temporary assignment of RWHAP Part A funded staff.

There are currently several vacant Recipient positions: the Assistant Commissioner of BHIV, the Director of COTA, a Health Equity Coordinator, a QMS, an HIV/HCV Evaluation Specialist, an Evaluation Specialist, the Director of Housing, the Senior Grant Analyst, and the Contract Manager. The Assistant Commissioner of BHIV and the Director of COTA positions were only recently vacated, and the rest of the positions are posted and in progress. Candidates are generally named within 90 days of when a job is posted and usually start 6-12 weeks after being named; however, as the City experiences reductions in tax revenue, there is a hiring freeze affecting all vacant positions. The Director of CTP will advocate for hiring of essential grant positions and update the NY EMA's HRSA Project Officer on a regular basis. The NYC HD has an emphasis on recruiting and hiring candidates that are racially and ethnically diverse and more reflective of the NYC population across all roles and levels of leadership. This priority has increased the number of channels in which the NYC HD advertises and recruits for positions. Positions may remain open in order to give hiring managers the opportunity to meet with a diverse candidate pool.

b) Staffing, SOW, and evaluation of contractor or fiscal agent. PHS, the NYC HD's Master Contractor, assists in the administration of the RWHAP Part A program in the NY EMA. The Master Contract was recently re-solicited and PHS was awarded a new nine-year term which is currently being negotiated. Under the direction of the Chief Strategy Office (CSO) and Vice President for CAMS, and four Directors – Senior Director for Programs and Contract Management, Director of Finance and Operations, Director of Business System, and Director of Informatics – PHS administered 144 RWHAP Part A-funded contracts in GY20. PHS employs 19.51 FTE monitoring staff, 2.95 FTE contract administration staff, and 11.61 FTE planning and administrative

staff for a total of 34.07 FTE. The CSO ensures PHS adheres to terms of the Master Contract with the NYC HD and has ultimate responsibility for all operations. Senior Director for Programs and Contract Management oversees programmatic and fiscal monitoring of subrecipients and develops procedures, policies, and standards for contract negotiation and monitoring of subcontractor program performance. Director of Informatics is responsible for: development and management of PHS's information systems, developing policies and procedures for data collection, and ensuring data integrity for contract payment and monitoring. Director of Finance and Operations is responsible for: developing, implementing, and monitoring fiscal policies, administrative procedures, and the portfolio's fiscal compliance. Director of Business Systems is responsible for guiding the procurement process, leading the coordination of cross-unit project management, and continuous QI efforts to ensure compliance with all relevant regulations and terms of the Master Contract.

PHS, under direction from NYC HD, manages the procurement process for RWHAP Part A funds, contract administration including development of subrecipients' contract scopes and budgets, compliance monitoring, TA, subrecipient payment including performance-based reimbursement, fiscal and data management, and external reporting. NYC HD facilitates a monthly coordination meeting and Data Work Group with PHS, to ensure compliance with contractual and HRSA policy requirements, address challenges in the administrative mechanism, including procurement and contracting, and to facilitate communication between NYC HD and PHS leadership.

Monitoring of Master Contract. The Master Contractor reports directly to BHIV on all aspects of its administrative and fiscal processes as outlined in the contractual agreement. BHIV monitors the Master Contractor for compliance with the contractual agreement by conducting site visits, tracking receipt of required reports, and reviewing performance via the Program Progress Report.

BHIV's program and fiscal monitoring staff conduct a minimum of two site visits per contract period for the Master Contract. The site visits consist of a program and fiscal review for a sample of subrecipients. The Master Contract site visits include an entrance interview to discuss changes since the last site visit and the procedure for the current site visit, as well as an exit interview to discuss findings from the current site visit. BHIV reserves the right to conduct additional site visits or adjust site visit dates if necessary, currently all site visits are conducted virtually.

NYC HD Master Contract Subrecipient Sampling Methodology. BHIV staff review at least 10% of RWHAP subrecipients, and BHIV staff review all subrecipients that were on a contract status ("concern," "corrective," or "conditional"), during the site visit review period. If the number of subrecipients on contract status is less than 10% of all subcontracts, then the remaining subcontracts are randomly selected to complete a 10% sample of all subcontracts.

The program and fiscal monitoring staff evaluate documents and files to ensure contractual requirements are being met by the Master Contractor. The program and fiscal monitoring staff complete a site visit report that identifies the material reviewed, compliance with contractual requirements, and if applicable, findings and recommendations to the Master Contractor to remedy findings identified during the site visit.

2) Grant recipient accountability. The NY EMA's multi-faceted contract monitoring process includes monthly electronic data submissions, comprehensive semi-annual reviews, site visits, documentation reviews, frequent telephone and email contact, and other meetings as necessary. Beginning in GY20 PHS and the Recipient initiated a plan to streamline visits as a result of HRSA HAB's GY18 site visit recommendations so that subrecipients receive no more than one site visit per contract per year. However, these face-to-face visits are currently suspended due to COVID-19; alternative fiscal and compliance monitoring is occurring through virtual site visits. All RWHAP Part A providers are required to maintain standardized client-level data records with de-

identified client-level extracts reviewed monthly by PHS for reimbursement and by the NYC HD for service utilization analysis. Using eSHARE, subrecipients finalize client-level data entry by the 15th of each month, the point at which PHS and the NYC HD consider subrecipient-reported data to be ready for assessment for reimbursement and performance. In addition, PHS requires the submission of a monthly Program Narrative Report, which details successes and challenges of the previous month and identifies staff vacancies and changes in program operations. These reports are reviewed by PHS in advance of reimbursement. PHS Contract Managers (CMs) review spending levels for cost-based contracts and total drawdown of reported services data for performance-based contracts and withhold reimbursement if subrecipients fail to submit required monthly programmatic reports, external audit reports, and/or if reports are incomplete or contain unapproved services as well as unbudgeted or unallowable costs.

PHS CMs are responsible for both fiscal and programmatic contractual monitoring, ensuring that costs and service activities are allowable and conform to the contract's budget and scope of services. In addition, providers are assigned a NYC HD QMS with expertise in the relevant programmatic content. QMSs provide one-on-one TA and guidance in QM and convene provider meetings to facilitate peer-led discussions of lessons learned. CMs and QMSs meet at least twice a year per service category to share data on contract performance, review qualitative information on services, and develop action plans to address challenges. While QMSs focus on QM and program development and implementation, CMs monitor contract deliverables and service documentation, conduct fiscal monitoring, and ensure compliance with relevant eligibility and administrative requirements, including client-level reporting.

QMSs and CMs collaborate to ensure that consistent guidance is provided to RWHAP Part A subrecipients through joint site visits. Site visit findings that are successfully addressed post site visit may not lead to formal corrective action. Each RWHAP Part A contract specifies the nature of services to be delivered, eligibility requirements for clients, licensing or other staff qualifications, and contractual expectations. Contracts specify the number of clients to be served and service delivery targets. Each subrecipient providing RWHAP Part A services must have operational grievance procedures in place (including whistleblower policies) and a mechanism for consumer input. Each subrecipient must collect and maintain client-level data in accordance with the NY EMA's reporting requirements for enrolled clients.

i) Common program and fiscal subrecipients' monitoring findings and corrective action process. The three most common fiscal and program monitoring findings are documentation issues, data inaccuracies, and insufficient service levels. Documentation issues, including the need for information consistent with standards of a service type or model as well as missing or incomplete documentation of services, may result in recoupment for services and low service levels. TA is provided within a targeted timeframe, usually three to six months, to facilitate improvement. For providers with persistent performance concerns, PHS implements a progressive process for corrective action in coordination with NYC HD. The process starts with targeted TA in an expected timeframe; should improvement not result, corrective measures are implemented which require a written plan with timeframes for specific metrics of required performance.

Due to the impact of COVID-19, many subrecipients were required to transition to virtual services while maintaining contract compliance. For example, one subrecipient came up with a novel approach to outreach efforts in the absence of site/community-based visits. The COVID-19 pandemic forced the agency to rethink traditional outreach approaches such as neighborhood outreach, home visits, and accompaniments. Many of the agency's clients often have no phone, access medical care sporadically, and unpredictably present to the clinics for urgent visits. To meet

this need during the pandemic, agency Navigators and Care Coordinators developed a relationship with on-site clinic staff to catch clients as they walked into the clinic for unscheduled visits. On-site nurses and medical assistants now immediately reach out to the agency team via cell when a lost-to-care client presents for care. This allows the agency team an opportunity to do a phone visit with the patient while they wait in an exam room.

ii) *Process for ensuring compliance with the single audit requirement.* Consistent with the HHS Uniform Administrative Requirements (45 CFR 75), RWHAP Part A subrecipients are contractually required to submit a single audit report, when applicable, within 30 days after its completion, but no later than nine months after the end of the audit period. A subrecipient is deemed out of compliance if it fails to submit its audit reports by the required due date. Written notification of the delinquency is sent to the subrecipient and payments may be placed on hold pending full compliance. If a single audit is not applicable, the subrecipient must submit a letter of explanation from its auditor or Chief Executive Officer. The letter of explanation must be accompanied by a list showing all of the subrecipient's federal grant revenue and expenses in order to support its claim that it is exempt from preparing the single audit report. PHS communicates any material changes in federal and state audit requirements as they occur, to ensure compliance with up-to-date audit rules. In GY19, PHS contracted with 85 subrecipients; however, only 76 audit packages were required to be submitted since several RWHAP subrecipients are part of larger consortiums and their financials are consolidated into one audit package. All but one of the 76 audit packages were submitted in GY19. The audit package for one subrecipient was submitted during GY20. Of all audit packages received, 44 (58%) were submitted late. The reasons for late submission of the audits vary but included among them are turnover of key staff in the subrecipients' finance area and delayed start of the audits. PHS retains the right to hold payment for failure to submit audit packages and did so during GY19 for several subrecipients. During GY19, the subrecipient payment holds were released upon submission of their audit packages. PHS's Fiscal Manager (FM) and Fiscal Analyst (FA) ensure audit reporting compliance of all subrecipients, conduct a detailed review of audits, follow up on findings identified in the audit, and submit a management letter, if issued. Satisfactory responses from subrecipients are a condition of ongoing compliance, and in some instances, their ability to draw down funds.

iii) *Addressing subrecipient audit findings.* In GY19, 24% of the NY EMA's RWHAP Part A subrecipients' audit reports contained issues noted. Issues ranged from general observations to auditor recommendations, some of which were unrelated to the RWHAP Part A programs or the agencies' infrastructure. Of the issues noted, only 9% were identified as material weaknesses. Issues cited included: lack of written methodology for expenses allocated to government grants; lack of full compliance with federal and Office of Management and Budget guidelines; lack of an updated financial policy and procedures manual; lack of time and effort record keeping; insufficient back-up documentation supporting purchases; lack of accounts analysis and bank reconciliation performance; inadequate segregation of duties; deficiencies in internal controls; and net assets deficits. For subrecipients with audit findings, PHS requests semi-annual updates on corrective measures. In cases where management provides an inadequate or lack of response, the agency may be placed on corrective or conditional status. PHS will then request a corrective action or compliance plan to resolve the audit deficiency; during this time, the agency's reimbursements are placed on hold. None of the agencies with material weakness noted in audit reports were placed on corrective or conditional status. PHS was satisfied with the agencies' responses and action taken to resolve the material weaknesses, which typically follow the audit recommendations.

b) *Third party reimbursement.* During GY19, the NY EMA continued its robust process to ensure all RWHAP Part A funds serve as the POLR. As previously mentioned, the PC undertakes a comprehensive analysis of all available resources and service delivery systems in the process of establishing priorities and allocations for funding. The PC uses an objective priority-setting tool, with one of four criteria being “POLR/Alternate Providers of Service.” This tool helped the PC to design the GY20 RWHAP Part A Spending Plan to address gaps, especially those in Medicaid.

Beginning in GY11 and continuing through GY20, the Recipient and PC staff have implemented the National Monitoring Standards and ongoing monitoring of the changing health care landscape. This includes review and analysis of resources released by HRSA/HAB (e.g., policy notices) and the NYS Medicaid Redesign Team, as well as attending the RWHAP all-recipients conference, which support implementation of POLR. This information was shared with stakeholders through presentations to committees of the PC and Recipient staff, including the monthly Recipient report issued to the PC. Information gleaned through these efforts was incorporated into the *POLR Tool*. The NY EMA requires agency certification to bill Medicaid in all applicable service categories (MCM, MH, Oral Health, and Medical Transportation).

i) *Monitoring third party reimbursement.* Contractual provisions define RWHAP Part A reimbursement as “last dollar funds pursuant to federal law,” mandating that payments cannot duplicate reimbursement that has already been made or can reasonably be expected to be made by other payers. Contracts require subrecipients to carefully monitor third-party reimbursement. As mandated in the RFP and in the eventual contract, all RWHAP Part A providers must participate in applicable NYS Medicaid programs for those services reimbursed by Medicaid. In addition, the NY EMA generally prioritizes non-Medicaid covered services and individuals in service design and planning. Hence, the history of applying for the CMS waiver.

As described on *p. 36*, the Recipient conducted an analysis in GY19 resulting in the creation of updated POLR guidance for service providers and a review tool for contract oversight staff to use during site visits at agencies with contracts in applicable service categories (able to bill Medicaid). During contract negotiations, PHS and subrecipients identify all potentially reimbursable services and explore sources of third-party payment. Contracts that include services potentially reimbursable by Medicaid and other payers are subject to a review of all billing records associated with a patient visit. This review forces coordination between grants management and Medicaid billing staff.

ii) *Documentation of client screening and ensuring POLR.* All subrecipients are required to document the screening of every client for Medicaid, Medicare, the NYS health insurance exchange, or other third-party insurance eligibility and to help eligible clients apply at intake and reassessment, every six months. eSHARE requires input of insurance status for both new and continuing clients, prohibiting submission of reporting forms until such questions are answered. The reporting software captures insurance provider type at time of assessment and reassessment.

Many PWH with incomes between 138 and 500% of the FPL are eligible for discounted premiums for plans on the NY State of Health insurance exchange, resulting in more PWH with health insurance. All service providers who provide benefits counseling and enrollment services are required to become Certified Application Counselors, as training capacity allows, or establish a referral relationship with designated navigator agencies. This helps to ensure that PWH who are eligible for other sources of assistance access those resources before the RWHAP Part A care system, and that PWH are receiving enrollment assistance from application counselors who understand the HIV care system.

iii) *Tracking and use of program income.* The NYC HD and PHS require subrecipients to establish a sliding fee schedule and caps-on-charges policy. Subrecipients are required to track and

report program income for all service categories. In addition to reporting program income earned, programs also report how they have or will use the income to improve RWHAP Part A programs. The most common use of program income is to pay for administrative costs that were not covered under the 10% administrative cap. Due to the safeguards intended to ensure that RWHAP services are designed in light of other local resources, RWHAP Part A funds remain the POLR, with very few instances when a program might earn program income from RWHAP activities. To improve tracking of program income, contract language regarding 340B program income was added to all contract documents in FY19 to ensure that subrecipients are aware that if they are using their RWHAP Part A subrecipient status for 340B eligibility, 340B program income must be reported to the recipient on a yearly basis. A letter highlighting contract language and addressing frequently asked questions was also sent to all subrecipients.

c) Fiscal oversight.

i) Fiscal staff accountability. The NY EMA ensures the efficient use of funds for their intended purpose through fiscal monitoring and accountability protocols. Fiscal staff is supervised by senior managers at PHS and the NYC HD. Spending is recorded and tracked in the PHS data and payment management systems, which are reconciled with the PHS financial accounting system on a quarterly basis. PHS staff prepare and submit detailed quarterly spending reports to the NYC HD, which in turn, the department uses to report by service category to the PC. On a quarterly basis, NYC HD staff prepare service category spending reports to the PC to review and discuss the NY EMA's spending rate. Unobligated balances are tracked continuously, and funds are reprogrammed as necessary in order to maximize services and spending by redirecting funds to services in accordance with the PC-approved reprogramming plan. At the end of the contract term, subrecipients must report the aggregate amount of program income generated and costs covered by it. The Director of Finance and Operations and Assistant Comptroller at PHS manages fiscal tracking and reporting and reports directly to the CSO and Chief Financial Officer, who are part of PHS's senior management team. At the NYC HD, the Grant Fiscal Administrator and the Director of Program Planning and Operations of CTP, all overseen by the Director of CTP and the Director of Administration in the BHIV, are responsible for fiscal oversight and reporting on the RWHAP Part A grant, including implementation of the HRSA/HAB National Monitoring Standards.

Roles and responsibilities of fiscal staff. With the NY EMA's use of performance-based reimbursement, PHS's organizational fiscal monitoring of programs is a combination of efforts that includes agency on-site fiscal review by the CM who is responsible for fiscal monitoring of cost-based contracts and who verifies expenditures are adherent to subrecipients' approved budgets and the Contract Coordinator (CC) who verifies the appropriateness of documentation for services for which the subrecipient received performance-based payment. The CM and CC's work is supervised by a PM. The FM and FA conduct an additional review of the subrecipient's audited financial statements and single audit reports.

NYC HD fiscal staff and the Director of Program Planning and Operations of CTP, in collaboration with the Master Contractor, prepares and submits the following information to HRSA: administrative budgets, allocation and expenditure tables, the SF424A and the Federal Financial Reports, unobligated balance and carryover requests, and other fiscal documents required under the conditions of award. In addition, PHS fiscal staff and the Director of Program Planning and Operations of CTP interpret and summarize the fiscal monitoring standards into policies and procedures for the NY EMA, seeking clarification from HRSA as necessary.

Coordination of program and fiscal staff. The assignment of a CM for RWHAP Part A contracts ensures that a single staff member develops an understanding of each contract's program and fiscal

operations. In addition to site visits, CMs review expenditure reports for cost-based contracts and services data for performance-based contracts as well as authorize and process payments into PHS' accounting system. In addition, semi-annual reviews of the portfolio for compliance with contract terms is conducted which include the audit review, so that CMs and their supervisors are aware of organizational findings that may affect RWHAP Part A contracts.

ii) *Tracking funds.* The NYC HD separately tracks Formula, Supplemental, MAI, and Carryover funds through PHS data and accounting systems, PAMS and Intacct, and AMS Advantage. In standard quarterly reports, PHS reports expenditures to the NYC HD in each funded service category, outlines funding commitments per service category, and summarizes spending rates. The reports are combined with separately tracked NYC HD program fiscal spending data and presented to the PC to monitor expenditures, allocate funding for next year's spending plan, and develop a carryover plan for unspent funds at closeout.

iii) *Subrecipient reimbursement.* PHS reimburses subrecipients monthly and the contract management system logs and time-stamps receipt of monthly reports and automatically uploads expenditure data. The NYC HD extracts data from the client-level database (eSHARE) on the 16th of each month, transmitting it to PHS for payment processing and compliance monitoring.

CMs review reports to determine payment. For cost-based contracts, reported expenditures must be consistent with approved budgets and allowable per the RWHAP program. For performance-based contracts, client-level data correspond to approved service types for payment. Services exceeding approved amounts for each class are disallowed unless a contract is modified to shift projected services between service types or a request for enhancement funding is approved. In addition, many services have utilization restrictions for payment (i.e., frequency limits, minimum group size, or prerequisites). When possible, these rules are enforced electronically, through the payment system database, others are found only through site visits. PHS and the NYC HD developed and provided subrecipients with the *Guide to Requirements for Services: Payability and Data Reporting*, which PHS updates routinely. This Guide provides guidance on submitting data for performance-based contracts. The current version is available on the PHS website.

In the second half of each month, PHS emails subrecipients an electronic report called the Master Itemization Report, which summarizes and itemizes all services recognized by the systems to date. Particular services may be flagged for a number of reasons, including incomplete data entry, duplicate client entries, and failure to meet programmatic requirements. Such problems are identified through a combination of automated data checks and site visits by CMs and CCs. Some problems may be correctible while others may result in recoupment during closeout.

Reimbursements may be withheld despite complete monthly reports. Reasons for withholding include expired insurance policies, delinquent reports, or previously identified disallowances in excess of outstanding contract balances. All withheld reimbursements are discussed with supervisory staff and documented in subrecipient files and the PHS contract management database.

The PHS contract management database computes the payment and notes any disallowances. CMs generate payment authorization reports, validate them, enter the payment into the accounting system, and attaches the payment documents to the entry in the accounting system. The payment is then reviewed by the PMs, who supervise the CMs, for final review and approval ensuring back-up documents support payment. Upon approval, the PHS Accounts Payable Department issues payments once a week, via check or electronic transfer (as selected by the subrecipient). Staff log payment dates in the payment system and reconcile all payments with the accounting system. PHS pays subrecipients within 30-45 days of receipt of all required reports, with the exception of payment withheld pending receipt of any delinquent report.

In addition, over-performing performance-based contracts may be eligible for enhancements to reimburse them for services if unobligated funding is available and modified service category allocations adhere to the PC's reprogramming plan. The GY19 reprogramming plan has allowed for reallocation between service categories up to 20%. Such enhancements reimburse subrecipients for any incremental costs associated with the provision of additional services.

The NYC HD working closely with PHS develops standardized reimbursement rates for performance-based contracts. To ensure reimbursement rates can cover subrecipients program operating costs, the NYC HD and PHS develop rates that are inclusive of the following: 1) current market salaries for service staff, 2) salary costs of support staff, 3) average Fringe Benefit Rate, 4) costs of other than personnel services (OTPS), 5) Indirect Costs/Overhead (capped at the legislative amount), and 6) a markup for missed client appointments. The NYC HD and PHS create a mockup program and associates costs to test the feasibility of the reimbursement rates.

Maintenance of Effort (see Attachment 11).

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EXHIBIT B



New York State's Integrated HIV Prevention and Care Plan 2022-2026





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Section I: Executive Summary of Integrated Plan and SCSN

1. Executive Summary of Integrated Plan and SCSN

A. Approach

New York State's Integrated HIV Prevention and Care Plan 2022-2026 (Integrated Plan) stands on a foundation of many years of hard work by the New York State Department of Health AIDS Institute (NYSDOH AI), New York City Department of Health and Mental Hygiene (NYCDOHMH), and Nassau County Department of Health (NCDOH) and partners and stakeholders across the state, including the Nassau-Suffolk HIV Health Services Planning Council, New York City HIV Planning Group (NYC HPG), HIV Health and Human Services Planning Council of New York, and New York State HIV Advisory Body (NYS HAB). Because of this integrated, coordinated work, New York State (NYS) is poised to end the HIV epidemic by 2024.

NYS was on track to meet core goals for ending its HIV epidemic by the end of 2020, with outcomes measuring Ending the Epidemic (ETE) progress available by December 2021. However, NYSDOH AI, NYCDOHMH, NCDOH, and partners on the frontline spent the majority of 2020 and 2021 responding to the unprecedented COVID-19 pandemic. Providers adapted to the new landscape and found innovative ways to deliver services and support consumers. Still, the public health emergency delayed the achievement of ETE goals. Since the start of the COVID-19 pandemic, there have been increases in HIV diagnoses in certain parts of the state, significant reductions in HIV testing and laboratory reporting, and decreases in the number of New Yorkers accessing PrEP. As a result, NYS is revising its ETE timeline and pledges to reach ETE goals by the end of 2024, with outcomes measuring ETE progress available by December 2025.

The Integrated Plan reflects feedback from HIV planning groups, providers, people with HIV, stakeholders, and affected communities collected through a wide range of community engagement and planning activities. The goals and specific populations presented in the Integrated Plan align with other national initiatives, including the National HIV/AIDS Strategy: 2022-2015 (NHAS) and the Ending the HIV Epidemic in the U.S. (EHE) initiative. The Integrated Plan also aligns with existing statewide efforts, including the ETE initiative and the [2015 *Blueprint: Plan to End AIDS in New York State* \(The Blueprint\)](#), as well as the work of the two Ryan White HIV/AIDS Program (RWHAP) Part A-funded eligible metropolitan areas (EMA) located in NYS: the New York EMA, which includes New York City and Putnam, Rockland, and Westchester Counties, and the Nassau-Suffolk EMA, which includes Nassau and Suffolk Counties.

In many ways, the current HIV landscape in NYS is very different than the one that gave rise to the first Integrated Plan in 2017. The COVID-19 pandemic impacted NYS efforts to end the HIV epidemic by the end of 2020 and key data points still have not returned to pre-pandemic levels. For example, electronic reporting of HIV-related laboratory tests (e.g., HIV antigen-antibody, CD4, viral load) decreased 66% from March to April 2020. In 2020, the number of reports submitted monthly remained at levels averaging approximately 24% lower than in 2019 and, to date, have not returned to 2019 levels. HIV testing conducted through NYSDOH AI-funded sites

averaged well over 2,500 tests per month in 2019 but dipped below 500 tests per month in April 2020 and did not reach 2,000 tests in any given month until July 2021.

Despite these challenges, NYS has met its goal of “bending the curve” of its HIV epidemic. HIV prevalence in NYS decreased in 2019 and in 2020. The most recent data demonstrate a continued decrease in HIV incidence (an estimate of the number of new infections) from 2,813 in 2013 to 1,467 in 2020, a 48% decrease. NYS also saw a continued decrease in new HIV diagnoses, from 3,391 in 2013 to 1,933 in 2020, a 43% decrease.

COVID-19 also gave focus to health disparities. COVID-19 had a significantly disproportionate impact on communities of color, especially Black and Hispanic/Latino New Yorkers. NYS has reinforced its commitment to health equity, reducing racial and ethnic health-related disparities, and addressing the social determinants of health (SDOH) experienced within communities of color as we work to end the HIV epidemic. This commitment is integrated into the broader work of NYSDOH AI, NYCDOHMH, and NCDOH. In July 2022, NYS Health Commissioner Dr. Mary T. Bassett announced the creation of a new Office of Health Equity and Human Rights to address health disparities and work to improve diversity, equity, and inclusion within NYSDOH. Led by Deputy Commissioner Johanne Morne, the new office will house NYSDOH AI and the Office of Minority Health and Health Disparities Prevention and Language Access and the Office of Gun Violence Prevention. With this change, Joseph Kerwin became the Acting Director of NYSDOH AI.

HIV Epidemic in NYS

HIV-related data and other data inform community engagement and planning activities and are also used to measure progress in achieving NYS’s ETE goals.

The Epidemiologic Snapshot, described in greater detail in Section III, provides a summary of the HIV epidemic in NYS, highlighting epidemiologic trends and progress since the start of the ETE initiative, using 2013 as the baseline year, and providing a snapshot of HIV epidemiology in 2020. Among the topline results:

- **Overall.** Since the peak of NYS’s HIV epidemic in the 1990s, the number of people newly diagnosed with HIV and the number of deaths among people with diagnosed HIV have declined, while linkage to care and rates of viral suppression have steadily increased. Despite these successes, disparities related to race and ethnicity, age, and geographic regions persist in HIV diagnoses and care outcomes.
- **Aware of HIV Status.** It is estimated that over 90% of NYS residents are aware of their HIV status, increasing from 91% in 2013 to 94% in 2020.
- **PrEP.** The number of people who filled a prescription for pre-exposure prophylaxis (PrEP) increased drastically from 3,388 in 2014 to nearly 40,000 in 2020.
- **STIs.** HIV often occurs simultaneously with other sexually transmitted infections (STIs). Gonorrhea rates have increased steadily for six years in NYS, and congenital syphilis rates have increased for four years. In 2020, the number of chlamydia and early syphilis cases in NYS declined for the first time in five years, as a result of access to services during COVID-19.
- **Hepatitis C.** In 2020 in New York State (excluding New York City), 4,131 newly diagnosed cases of hepatitis C were reported to the NYSDOH, of which 3,945 were

chronic, 181 were acute, and five were perinatal. An additional 3,001 newly diagnosed cases of hepatitis C were reported to the NYCDOHMH (2,810 chronic, 185 acute, and six perinatal). The number of newly reported hepatitis C cases declined in both jurisdictions since 2019.

- **Syringe Services.** To aid in the prevention of infectious disease transmission, NYS expanded its syringe services program (SSP) substantially in the past ten years, with the number of participants served increasing from 21,456 in 2012 to 35,409 in 2021.
- **Overdose Prevention Centers in NYC.** On November 30, 2021, NYC authorized the opening of the first overdose prevention centers (OPC) in the U.S. The OPCs are privately funded, not funded by governmental or public resources, and they are situated within harm reduction programs in East Harlem and Washington Heights in Manhattan, two neighborhoods with high burdens of fatal overdose. As of April 3, 2022, OPC services have been used over 14,000 times by more than 1,000 individuals, and staff have averted over 230 overdoses.
- **Newly Diagnosed with HIV.** From the initiation of ETE in 2014 to 2019, the number of people newly diagnosed with HIV in NYS decreased by 31%. HIV diagnoses decreased by 19% from 2019 to 2020. This large yearly decrease likely reflects a continued decline in transmission but also effects of the COVID-19 pandemic, including reduced availability and uptake of HIV testing and prevention services, delays in diagnosis of HIV, and reduced frequency of laboratory monitoring for HIV.
- **Demographics of Newly Diagnosed.** Among all NYS residents newly diagnosed with HIV in 2020, 80% were male (sex at birth), 46% were non-Hispanic Black, 30% were Hispanic/Latino, 33% were aged 20-29, and the most frequently reported transmission risk was a history of male-to-male sexual contact (48%).
- **Linked to Care and Viral Suppression.** Alongside the steady decrease in new diagnoses since the onset of the ETE initiative, linkage to care and viral suppression outcomes have continued to improve. The percentage of people linked to care within 30 days of diagnosis increased from 69% in 2013 to 83% in 2020. Additionally, the percent of individuals achieving viral suppression (<200 c/mL) within three months of diagnosis more than doubled, from 23% in 2013 to 54% in 2020.
- **Persons Living with Diagnosed HIV.** In 2020, there were 105,610 persons living with diagnosed HIV (PLWDH) in NYS, maintaining an annual 2% decrease observed since 2017. Reflecting demographic trends seen amongst people newly diagnosed with HIV, 72% of PLWDH were male (sex at birth), 45% were non-Hispanic Black, 29% were Hispanic/Latino, and the most frequently reported transmission risk was a history of male-to-male sexual contact (45%). The majority of PLWDH were aged 50-59 years old (30%), while most people newly diagnosed with HIV were aged 20-29 years. In 2020, 86% of PLWDH were in care, an increase from 81% in 2013. Seventy-five percent of PLWDH were virally suppressed, compared to 66% in 2013.
- **Deaths among Persons with Diagnosed HIV.** The number of deaths among persons with diagnosed HIV has decreased since the mid-1990s, though in 2020 there was an increase in deaths consequent to the COVID-19 pandemic. The percent of deaths related to HIV decreased from 36% in 2013 to 24% in 2019.
- **Eliminating Disparities.** NYS has realized many gains in the prevention and treatment of HIV and continues to prioritize efforts to eliminate disparities. From 2013 to 2020,

non-Hispanic Black and Hispanic/Latino people accounted for the largest percent of new HIV diagnoses in NYS. These individuals represented 73% of new diagnoses, but only 33% of the NYS population in 2020. In contrast to non-Hispanic Black and Hispanic/Latino people, non-Hispanic White and Asian-American/Native American/Multi-Race individuals newly diagnosed with HIV represented a lower proportion compared with their representation of the NYS population.

- **Demographic Measures of Linkage to Care and Viral Suppression.** Linkage to care within 30 days of diagnosis varied by race and ethnicity, with 73% of non-Hispanic White individuals, 66% of non-Hispanic Black individuals, and 69% of Hispanic/Latino individuals in care in 2013. This increased to 85% of non-Hispanic White, 80% of non-Hispanic Black, and 85% of Hispanic/Latino individuals in 2020, with disparities still remaining. Similar patterns were seen in viral suppression among those in care. Of those in care, 91% of non-Hispanic White, 77% of non-Hispanic Black, and 81% of Hispanic/Latino PLWDH were virally suppressed in 2013. This increased to 93% of non-Hispanic White, 84% of non-Hispanic Black, and 88% of Hispanic/Latino PLWDH by 2020.

Approach to Ending the HIV Epidemic

Partnerships and collaboration with other government agencies are essential to plan and achieve ETE goals. NYSDOH AI, NYCDOHMH, and NCDOH, as the recipients of Ryan White HIV/AIDS Program (RWHAP) Part A and Part B funding, shared a collaborative process to develop this Integrated Plan. NYSDOH AI works closely with governmental partners in NYC and Long Island, as well as in all NYS regions, to prioritize, plan, and implement HIV prevention and care efforts statewide. This ongoing collaboration aims to increase efficiency in programming and funding allocation, maximize information sharing, coordinate planning, ensure community program alignment, and facilitate innovative strategies to address the HIV epidemic in NYS.

Ongoing, data-informed community engagement and planning activities are designed to ensure that strategies employed at the state and local level are responsive to service gaps, barriers to access, service-delivery challenges, and the needs of specific populations. In addition, the Integrated Plan is framed around key overarching elements.

Health Equity. As defined by Centers for Disease Control and Prevention (CDC), health equity is achieved when every person has the opportunity to “attain his or her full health potential” and no one is “disadvantaged from achieving this potential because of social position or other socially determined circumstances.” Additionally, “health inequities are reflected in differences in length of life; quality of life; rates of disease, disability, and death; severity of disease; and access to treatment.” Efforts to enhance health equity address SDOH, the many issues that can impact health and limit access to care. Health equity also recognizes intersectionality, how factors like race and ethnicity, class, gender, sexual orientation, and physical ability overlap and are interdependent, making it necessary to recognize all the reasons a person may be marginalized.

Stigma Reduction. Reducing stigma has long been a priority of NYSDOH AI. While primarily focused on HIV, stigma-reduction efforts in NYS also focus on racism, homophobia, transphobia, and other stigmas that people affected by HIV may experience.

Status Neutral Approach. The status neutral approach emphasizes sustained engagement in high-quality care, regardless of HIV status. The status neutral approach aims to improve both HIV care and prevention outcomes by embedding HIV prevention and care into routine care. The “whole-person” approach aims to advance health equity, reduce HIV-related stigma, and drive down disparities.

Undetectable=Untransmittable (U=U). In 2017, NYSDOH AI was the first state health department in the U.S. to sign on to the Prevention Access Campaign U=U Consensus Statement. This statement affirms that people with HIV who have achieved and continue to maintain an undetectable viral load do not sexually transmit HIV. U=U aligns with NYSDOH AI’s efforts to destigmatize HIV and to support innovative biomedical and social efforts to improve the health and well-being of people with HIV.

NYSDOH AI provides robust support to providers across the state to offer the best services possible, especially services that support these overarching elements. Guidelines address optimum care. Evidence-based interventions are encouraged, and technical assistance is available to support implementation. NYSDOH AI regularly conducts statewide quality improvement activities, with each RWHAP Part A jurisdiction having complementary quality management plans and activities.

Ongoing/Emerging Needs

For the most part, needs are identified at the local level and planning groups identify and prioritize strategies to meet these needs. Ongoing community engagement activities (e.g., regional and theme-based listening sessions, population- and issue-specific advisory groups, surveys) allow consumers, providers, stakeholders, and at-risk communities a voice in the process.

As mentioned above, Black and Hispanic/Latino people face significant health inequities and are disproportionately impacted by HIV. Black and Hispanic/Latino men who have sex with men (MSM) and Black and Hispanic/Latina cisgender women are two of the Integrated Plan’s specific populations. Another specific population identified within the Integrated Plan is people aging with HIV. Fifty-six (56) percent of people with HIV in NYS are over 50. People aging with HIV may experience aging-related conditions/co-morbidities at an earlier age. Also, aging is a time of transition. HIV treatment advances have led to improved health outcomes for so many people with HIV and have opened up new pathways to sustaining health over a long life. However, for people who are aging, their income may diminish, social networks may shrink, and there may be physical decline such as loss of mobility or the ability to carry out daily tasks. As people with HIV age, services need to be added or modified to address the needs related to aging. The HIV care system is in need of additional resources to innovate models of care to address comorbidities of people aging with HIV, such as issues related to memory, mobility, nutrition, physical exercise, vision, hearing, and mental health.

Another significant challenge NYS faces is current and expected workforce shortages, especially in critical areas such as public health and mental health, exacerbated by the COVID-19 pandemic. Unpublished preliminary data from the RWHAP-funded Northeast/Caribbean AIDS Education and Training Center (NECA AETC) in spring 2022 indicate that retirement may significantly reduce the HIV workforce in NYS. The purpose of this study was to evaluate the

number of current practicing healthcare providers prescribing HIV antiretroviral medication (for emergency post-exposure prophylaxis (PEP), PrEP, and/or antiretroviral treatment (ART)) and the number of care providers projected to continue to provide HIV-related care over the next five years. The study focused on prescribing HIV clinicians and pharmacists. The decline in the number of infectious disease physicians with a specialty in HIV medicine is notably impacting service delivery. (Results are described in Section IV: Situational Analysis.)

As the Integrated Plan is being written (summer/fall 2022), NYSDOH AI is responding to the domestic monkeypox virus (MPV) outbreak. NYS will continue to be transparent in its approach to respond to emerging issues such as MPV and how these issues are impacting efforts to achieve the goals of the Integrated Plan. Furthermore, NYSDOH AI remains committed to ensuring community engagement and input remains central to the response. For example, NYSDOH AI held two virtual community focus groups on sexual health messaging regarding MPV in August 2022, with over 75 individuals in attendance. Other activities have included the release of MPV clinical guidance and sex positive and stigma-mitigating messaging, and the launch of equity-focused MPV vaccine pilot initiatives.

Integrated Plan Goals

The goals in the Integrated Plan are aligned with the four EHE pillars—diagnose, treat, prevent, respond. In addition, the Integrated Plan includes goals that focus on two fundamental aspects of health equity:

Inclusive. Invite and incorporate input from the specific populations, people with lived experience, partners, and other stakeholders.

Equitable. Address the unique needs and circumstances of affected populations, increase quality services where needed, and seek to address disparities (e.g., access to PrEP).

Incorporating inclusion and equity components into the other goals strengthens the overall Integrated Plan and NYS's commitment to racial equity and inclusion by identifying tangible and actionable steps that will be integrated throughout NYS's effort to achieve the goals.

2022 – 2026 Integrated Plan Goals	
 Diagnose • Increase the percentage of persons living with HIV who know their serostatus to at least 98%. • Increase the percentage of New Yorkers who tested for HIV in the past 12 months. • Reduce the number of new HIV diagnoses by 55%.	 Treat • Increase the percentage of persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%. • Increase the percentage of persons living with diagnosed HIV who receive HIV medical care to 90%. • Increase the percentage of Black persons living with diagnosed HIV who

	receive HIV medical care with suppressed viral load to 95%. • Increase the percentage of Hispanic/Latino persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%. • Reduce current disparities in median CD4 among persons living with diagnosed HIV.
 Prevent • Increase the number of individuals filling prescriptions for PrEP to 65,000. • Reduce current disparities in PrEP utilization rates (defined as the number of individuals on PrEP/100,000) across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS. • Reduce current disparities in statewide SSP service utilization across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS.	 Respond • Analyze surveillance data monthly to identify HIV transmission clusters and outbreaks to facilitate prompt public health response. • Re-engage 75% of persons identified as out of care within six months. • Reduce current disparities in the reengagement rate of persons living with diagnosed HIV identified as out of care within six months across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS.

Monitoring Progress

As stated above, community engagement and planning activities allow NYS to continually monitor for service gaps, barriers to access, service delivery challenges, and the needs of specific populations. Planning groups can select the most appropriate strategies based on local conditions and these can be modified to address emerging issues and trends in the HIV epidemic.

To monitor progress toward achieving our ETE goals, NYS uses epidemiologic and other data to measure improvement. These data are made available on the [ETE Dashboard](#), which integrates various data sources to provide key metrics for tracking ETE progress.

NYSDOH AI uses several methods to communicate with partners, people with HIV, stakeholders, and communities, including by email using a regularly updated listserv. Information on progress toward achieving ETE goals and local needs flows both ways between NYSDOH AI and planning bodies. Regional, topic-specific, and population-focused listening sessions are held across NYS. These provide an opportunity to disseminate updates on progress toward ETE and Integrated Plan goals and obtain input from participants. The annual *Call to Action* letter ([updated in 2022](#)) for partners and stakeholders presents progress updates, priorities, and emerging issues.

How the Plan was Developed

Integrated Plan development and review are a result of the input and work of over 1,000 stakeholders. A guiding principle for NYS's continuum of services is that effective program development must be informed by input from the community. NYSDOH AI coordinates with colleagues at NYCDOHMH and NCDOH and with the Interagency Task Force on AIDS. The NYDOH AI convenes the NYS HIV Planning Body Coordinating Group comprised of RWHAP Part A and the NYS HAB members to synergize planning efforts across jurisdictions. At the statewide level, NYSDOH AI receives input on an ongoing basis from a variety of groups, including the NYS AIDS Advisory Council (AAC), the AAC ETE Subcommittee, expert clinical committees and consumer committees, the Uninsured Care Program Advisory Council, consumer groups, advocacy organizations/groups, other ad hoc work groups, and the 40-member NYS HAB, which was formed through integration of the Prevention Planning Group and the Statewide AIDS Services Delivery Consortium. Within the EMAs, input is also received from the RWHAP Part A planning councils (the HIV Health and Human Services Planning Council of New York and the Nassau-Suffolk HIV Health Services Planning Council) as well as the New York City HIV Planning Group. In addition, focus groups and other forums are held on specific policy or program issues. Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, a variety of HIV-related programs, community leaders, government representatives, advocates, researchers, and other stakeholders. Consumers are represented in all groups; for example, 29% of the NYS HAB members are people with HIV.

The Integrated Plan is also informed by the development of *The Blueprint* and *Ending the Epidemic (ETE) Beyond 2020 Addendum Report*. NYSDOH AI provides ongoing data updates to planning groups to inform their decision making and collects qualitative data through listening sessions and from advisory groups. In 2020, NYSDOH AI held 13 regional sessions, eight theme-based sessions, and two sessions for medical providers; in June 2022, NYSDOH AI held two additional statewide virtual listening sessions. Fifteen population-focused and topic-specific advisory groups have produced reports with recommendations (2018-2020). The Integrated Plan was posted for public comment in October 2022. Letters of concurrence were received from New York State HIV Advisory Body (NYS HAB), HIV Health and Human Services Planning Council of New York, New York City HIV Planning Group (NYC HPG), and the Nassau-Suffolk HIV Health Services Planning Council. This highly collaborative process has been instrumental in creating an HIV prevention and care system across the state that supports efforts to achieve ETE and Integrated Plan goals.

B. Documents Submitted to Meet Requirements

The Integrated Plan closely aligns with and builds on NYS ETE efforts contained in *The Blueprint* and the *ETE Beyond 2020 Addendum Report*, as well as the National HIV/AIDS Strategy: 2022-2026. The Integrated Plan is closely informed by the EHE initiative that includes the New York City 2020 Ending the HIV Epidemic Plan (NYC 2020 EHE Plan) submitted as a deliverable for CDC PS19-1906. The Integrated Plan is also informed by the discussions and results from NYCDOHMH- and NCDOH-led community listening sessions in 2020.

All required documents are included in the Integrated Plan and are summarized in the checklist provided at the conclusion of the plan.

Section II: Community Engagement and Description of Jurisdictional Planning Processes

Overview

A foundation of the NYSDOH AI overall planning strategy – and one of its primary strengths – is a commitment to work with and obtain input from partners, consumers, and other stakeholders throughout the planning, implementation, and monitoring process. These partnerships – with people with HIV, other consumers, service providers, community leaders, advocacy groups, research entities, and federal, state, and local government agencies – have made ETE planning and programming successful in NYS. Partnerships inform the design and implementation of ETE policies and programs, and the partners are fully invested in and committed to working together to achieve the shared goals of the ETE initiative.

Table II.1 lists the community engagement activities conducted by NYSDOH AI that contributed to the Integrated Plan. These activities reflect the breadth and inclusiveness of NYSDOH AI efforts to engage all partners and stakeholders in the planning and prioritization process. Table II.2 lists the community engagement activities conducted by NYCDOH and NCDOH, which have informed their planning processes for HIV prevention, care, and treatment funding and programs.

In this Section:

- NYS approach to planning process
- Engagement of key jurisdictions, community members, and stakeholders
- Meeting programmatic requirements (i.e., SCSN, Part A and B requirements, CDC requirements)

Table II.1: Statewide Community Engagement Activities for Integrated Plan

Activity	Date	Participants	Process
NYS HIV Planning Body Coordinating Group	May 16, 2022	Representatives of Nassau-Suffolk HIV Health Services Planning Council, NYCDOHMH, New York City HIV Planning Group, HIV Health and Human Services Planning Council of New York, NYSDOH AI, and NYS HIV Advisory Body	Representatives reviewed Integrated Plan goals and discussed process for prioritizing strategies.
Listening Sessions (conducted virtually)	June 1 and June 7, 2022	The June 1 session was attended by 53 participants. The June 7 session was attended by 18 participants.	Participants took part in a facilitated discussion addressing barriers to prevention and care, key resources, unmet needs, important allies/partners in carrying out HIV-related activities, inequity and health disparities,

			systemic/structural issues, and the impact of COVID-19. The listening sessions were promoted through use of existing listservs consisting of all previously engaged community partners, funded providers, and longstanding advisory groups. Additionally, ETE Regional Committees were asked to encourage additional individuals who were not previously engaged in ETE conversations to attend. Communication was drafted with background information on the purpose of the sessions and need for community input and shared with funded providers and advisory group members as well as other identified stakeholders. The NYS HIV Planning Body Coordinating Group also informed their members. Findings from the listening session are captured in Section III.4 of the Integrated Plan and informed prioritization of strategies.
Prioritization of Strategies to Support Goals	June 2022	The survey participants/respondents were gathered from the advisory bodies (NYS HAB, HIV Health and Human Services Planning Council of New York, NYC HIV Planning Group, and the Nassau-Suffolk HIV Health Services Planning Council). Members provided the initial responses to proposed strategies and were then asked to prioritize what was	The goal of the survey was to rank strategies based on agreed-upon criteria for implementation. An additional goal was to ensure that all responses/strategies are included in an intentional way to prioritize review and implementation. Respondents were given three weeks to complete the prioritization survey. Respondents were invited to participate by email. Two reminders of the deadline were

		submitted within each area of focus. Respondents are representative of communities served and stakeholders engaged in service delivery. Respondents are residents of all NYS regions and are diverse in representation of populations affected by HIV.	sent, and the deadline date was extended to increase the number of responses.
NYS HIV Planning Body Coordinating Group	July 25, 2022	Representatives of Nassau-Suffolk HIV Health Services Planning Council, New York City Department of Health and Mental Hygiene, New York City HIV Planning Group, HIV Health and Human Services Planning Council of New York, New York State AIDS Institute, and New York State HIV Advisory Body	Representatives discussed: prioritization of goals; outcome of community engagement listening session findings; resource inventory update.
Stakeholder and Community Review of Draft Plan (public comment period)	October 2022	The invitation to review the draft Integrated Plan went out to all members of the NYS HIV Planning Body Coordinating Group as well as to all NYSDOH AI stakeholders that received the Call for Documents. This includes all funded providers, all advisory body members, and other identified stakeholders. The draft plan was posted on the NYSDOH AI website for stakeholders to review.	Stakeholders and community members received an email that notified them that the public comment period was open, provided a link to where the document was posted, and contained instructions on how to submit comments by the due date. Results were summarized and included in the Integrated Plan document.

Letters of Concurrence	October/November 2022	Letters (attached in Section VII) were received from: Nassau-Suffolk HIV Health Services Planning Council New York City HIV Planning Group HIV Health and Human Services Planning Council of New York New York State HIV Advisory Body (NYS HAB)	Letters of concurrence were received from all required planning bodies.
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Table II.2: EMA Community Engagement Activities

EMA	Community Engagement Activities
New York City and the New York EMA (which includes New York City and Putnam, Rockland, and Westchester Counties)	Listening Sessions. Between June and December 2020, NYCDOHMH facilitated nine virtual listening sessions, drawing a total of 308 participants. In planning the sessions, NYCDOHMH partnered with agencies (across the Bronx, Brooklyn, Manhattan, and Queens) and stakeholders serving members of the specific populations identified in the NYC 2020 EHE Plan and worked to enlist new voices into the planning process. Additionally, the NYC EHE team held monthly meetings with NYSDOH AI Planning leadership to coordinate the EHE and NYS ETE planning efforts in anticipation of the Integrated Plan. Community Survey. The community survey, in English and Spanish and English, took place in September and October 2020, with 619 respondents. The survey was disseminated through community-based organizations (CBOs) serving the specific populations, including both HIV- and non-HIV-specific CBOs; local stakeholders, including community leaders, advocates, and staff at organizations; local government agencies; the New York City HIV Planning Group, HIV Health and Human Services Planning Council of New York, and other HIV planning bodies and community advisory boards; and other traditional and non-traditional partners across the city. In March 2022, NYSDOH AI staff attended New York City HIV Planning Group and HIV Health and Human Services Planning Council of New York meetings to provide an overview of the process for developing the Integrated Plan and gather feedback on the process and on components of the NYC 2020 EHE Plan to incorporate into the Integrated Plan. The Planning Council's Consumers Committee hosted three additional virtual sessions to gather additional feedback on the Integrated Plan.

Nassau-Suffolk EMA	Consumer Needs Assessment Surveys. The Nassau-Suffolk EMA engages consumers through needs assessment surveys. Over 450 consumers participated in the 2019 survey, which was administered online, in person at RWHAP Part A provider locations, and by telephone. The survey was offered in both English and Spanish. Training was provided to peers who were enlisted to assist with the survey administration. Topic-specific consumer needs assessments are also conducted (e.g., newly diagnosed, out-of-care, women of color). Committees. The Strategic Assessment and Planning Committee of the Planning Council is instrumental in engaging stakeholders and the community. They host annual community forums and hold population-specific focus groups to elicit feedback on services and to assess needs and identify gaps. This committee also conducts a consumer and provider survey every two years. Consumer Involvement Committee members also serve as facilitators for the community forums since peer-to-peer interactions often result in better community feedback and engagement. The Clinical Quality Management (CQM) Committee of the Planning Council engages key stakeholders, including providers and people with HIV, to obtain feedback on quality-related issues and disparities. The CQM Committee relies heavily on consumer feedback and shared experiences related to accessing care to determine quality improvement activities.
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1. Jurisdictional Planning Process

Partnerships and collaboration with other government agencies are essential to ongoing planning activities and achieving ETE goals. The NYSDOH AI, the NYCDOHMH, and the NCDOH, as recipients of RWHAP Part A and Part B funding, worked together to develop the *Integrated HIV Prevention and Care Plan, 2022-2026* for NYS. Other partners and stakeholders also contributed to the Integrated Plan.

The NYSDOH AI works closely with governmental partners in NYC and Nassau-Suffolk Counties and all other regions in NYS, to prioritize, plan, and implement HIV prevention and care efforts statewide. This ongoing collaboration increases efficiency in programming and funding allocation, maximizes information sharing, promotes coordination, ensures community programs are aligned, and facilitates adoption of innovative strategies to address the HIV epidemic statewide.

a. Entities Involved in the Planning Process

A wide range of stakeholders are critical to the success of the Integrated Plan. Beyond our state regional partners, the NYSDOH AI involves a wide array of partners in the planning and implementation of New York's HIV-related activities. The Integrated Plan development and review is a result of input from over a thousand stakeholders. **Table II.3** lists the various participants that took part in the development of the Integrated Plan. This includes people with HIV, other consumers, HIV service providers, advocates, community representatives,

government agencies, and other involved parties. The Integrated Plan aligns with New York State's ETE efforts, as well as the NHAS and the EHE initiative.

Overview of the Planning Process. Below is a brief description of the key steps of NYS's planning process.

Table II.3. HIV Prevention and Care Planning Participants

- NYSDOH AI, NYCDOHMH, NCDOH (RWHAP Part A and B recipients)
 - New York State HIV Planning Body Coordinating Group
 - New York State HIV Advisory Body (NYS HAB)
- Part A planning councils (the HIV Health and Human Services Planning Council of New York and the Nassau-Suffolk HIV Health Services Planning Council as well as the New York City HIV Planning Group)
 - New York State AIDS Advisory Council (AAC)
 - AAC ETE Subcommittee
 - RWHAP Part C and Part D recipients
 - ETE Regional Committees
 - Interagency Task Force on AIDS
- Expert clinical committees and consumer committees convened by the AIDS Institute Office of the Medical Director, including HIV Quality of Care Clinical Advisory Committee and Consumer Advisory Committee
 - Uninsured Care Program Advisory Council
 - Consumer groups
 - Advocacy organizations/groups
 - Ad hoc work groups

- **Coordination of Planning.** NYSDOH AI, NYCDOHMH, and the NCDOH program teams are responsible for coordinating the plan development, including developing and providing tools for facilitating the work of planning bodies, updating the Epidemiologic Snapshot for NYS, completing the Resource Inventory, gathering data/plan segments from all entities, and writing the Integrated Plan. The HIV Planning Coordinating Group is responsible for reporting back to their home planning body on progress and interim milestones and bringing information and concerns to bi-monthly meetings. The HIV Planning Coordinating Group identifies goals and strategies for inclusion in the Integrated Plan. Members include representatives from Nassau-Suffolk HIV Health Services Planning Council, NYCDOHMH, NYC HPG, HIV Health and Human Services Planning Council of New York, NYSDOH AI, and NYS HAB. The members of the HIV Planning Coordinating Group convened six times during the planning year (virtually) to develop the Integrated Plan and will meet at least twice a year after submission to review progress and ensure that the jurisdictional planning processes are well-coordinated and responsive to statewide needs and priorities.
- **Planning Bodies/Councils Input.** Statewide HIV planning bodies and planning councils contribute information to develop the Integrated Plan narrative, identify goals, strategies, and activities, and support stakeholder involvement.

- **Stakeholder Input.** Stakeholders participate in surveys, focus groups, listening sessions, and other forums throughout the process to identify service and resource gaps and barriers, monitoring and evaluation efforts, and jurisdictional follow-up actions.
- **Additional Methods of Providing Input.** Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, staff from HIV-related programs, community leaders, government representatives, advocates, researchers, and other stakeholders. Consumers are represented in all groups. For example, 29% of the NYS HAB members are people with HIV.

Development of NYS's ETE Plan. The 64-member ETE Task Force developed the *Plan to End AIDS in New York State*, also known as *The Blueprint*, based on almost 300 recommendations received from the community via statewide stakeholder sessions, online forums, conference calls, and widely disseminated surveys. *The Blueprint* was presented to planning bodies, advisory groups, other state and local agencies, and community representatives.

The ETE Task Force's advisory work continues through the AAC ETE Subcommittee. Ongoing regional and population specific ETE discussions include more than 500 participants. Since its release, NYS has worked collaboratively with all partners to implement the recommendations included in *The Blueprint* and monitor their implementation. Further input continues, such as the convening of several advisory groups to develop specific implementation strategies in support of *The Blueprint* recommendations.

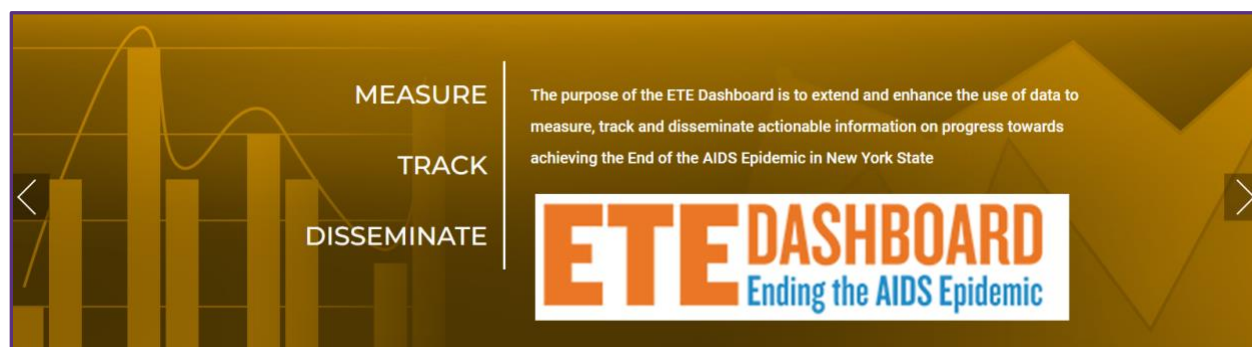
Role of Planning Committees and Stakeholders. Planning committees and stakeholders were vitally important in developing the recommendations for the Integrated Plan (and in other NYSDOH AI planning activities). This input can take the form of suggesting recommendations or reviewing and synthesizing them once they are developed. More information on the needs assessment process and how findings are used to make these recommendations can be found in Section III.

Use of Data in Planning Process. The NYSDOH AI's planning activities are informed by a range of data and other sources, including epidemiological data, research, and evaluation studies.

- Studies utilizing epidemiologic data to examine trends as well as specific objectives, such as linkage to and retention in care and viral suppression.
- Medicaid and contract/program data, including Early Identification of Individuals with HIV/AIDS (EIIHA) data.
- Input from providers, consumers, and other community representatives obtained through a variety of forums, such as regional listening forums, frequent stakeholder meetings, and other planning meetings.
- Input from advisory bodies, such as the New York State AIDS Advisory Council, the NYS HAB, the Interagency Task Force on HIV/AIDS, the AAC Ending the Epidemic Subcommittee, and consumer and provider advisory committees.
- Program, epidemiologic, Medicaid, and quality data are used to capture and address gaps (e.g., gaps in the continuum of care, including people with HIV who are unaware of their status, people with HIV not in care, and people with HIV who are not virally suppressed).

- HIV care continuum data are used to assess ETE progress and assess gaps.

In addition, evaluation of the overall ETE initiative is aligned with milestones and key metrics tracked to monitor *The Blueprint* and published on the [ETE Dashboard](#).



The goals in the Integrated Plan align with these metrics.

Role of Issue-Specific Advisory Groups to Address Structural and Social Factors.

There are many structural and social factors that place communities at risk for HIV, hepatitis C, opioid overdose, and STIs. To ensure that key issues related to ETE and the voices of those whose lives are impacted by these issues are not lost, the NYSDOH AI convenes 15 population and issue-based advisory groups to develop tailored strategies for communities disproportionately affected by HIV. The advisory group members are diverse in terms of age, gender, lived experience, geography, and racial and ethnic diversity. The goals of the advisory groups are to:

- Develop specific implementation strategies in support of *The Blueprint*;
- Optimize impact on identified communities in NYS; and
- Ensure that healthcare and treatment needs are prioritized and met.

The [advisory groups](#) that developed implementation strategies focused their recommendations on the following key groups or topics: Native American; Asian and Pacific Islander; transgender and gender non-conforming individuals; older adults; women; expanding employment opportunities; Black MSM; Hispanic/Latino gay and bisexual men; young adults; STIs; data; pharmacy planning and partnerships; drug user health; non-English speaking, migrant, seasonal farm workers and new immigrants; and sentinel events such as injection drug use.

Considering Social/Structural Issues

Structural Factors: community, cultural, economic, legal, organizational, physical, and policy aspects of the environment that impede or facilitate efforts to prevent and effectively treat HIV.

Social factors: economic and social determinants that influence the health of both people and communities. These include racism, sexism, homophobia, transphobia, stigma, trauma (multigenerational and episodic), conditions for early childhood development, education, employment, income and job security, food security, health services, access to services, housing, social exclusion, and stigma.

b. Role of the RWHAP Part A Planning Councils

Part A EMAs are required to convene planning councils that conform to specific RWHAP requirements. For example, at least 33% of members must be unaligned (i.e., not affiliated with a service provider) and be living with HIV. Responsibilities of Part A planning councils include:

- Setting funding priorities for the allocation of federal HIV/AIDS service dollars under Part A of the RWHAP;
- Conducting consumer needs assessments and identifying the needs of people with HIV in the region;
- Developing a comprehensive service plan for delivering HIV services; and
- Evaluating how efficiently the providers of HIV services are selected and reimbursed through the administrative mechanism.

Given these responsibilities, the work of these planning councils directly aligns with integrated planning at the state level.

As noted above, development of the Integrated Plan is facilitated by the NYS HIV Planning Body Coordinating Group. It is composed of the leadership of all the state's HIV planning bodies (HIV Health and Human Services Planning Council of New York, Nassau-Suffolk HIV Health Services Planning Council, NYS AIDS Advisory Council, NYC HIV Planning Group, NYCDOHMH and NYSDOH AI).

NYC 2020 EHE Planning Process. Local and state ETE planning efforts originated with community leadership and have encompassed broad engagement and collaboration among community leaders, advocates, health and supportive service providers, researchers, and government representatives, including NYCDOHMH staff. NYCDOHMH worked with community members who reflect the diverse and complex NYC HIV epidemic to review the status of *The Blueprint* recommendations and 2015 NYC ETE Plan strategies, last updated in 2020; gather broad input on successes, gaps, and unmet needs; and further develop the existing plans to address persistent HIV-related health inequities.

The NYC 2020 EHE Plan development and data collection involved an iterative dialogue of community engagement and feedback, conducted through nine NYCDOHMH listening sessions, seven NYSDOH AI listening sessions, and a community-wide survey that generated 619 responses.

- **Listening Sessions.** Between June and December 2020, NYCDOHMH facilitated nine virtual listening sessions, drawing a total of 308 participants. Each session was well-attended, with anywhere from 11 to 93 participants, with an average of 35 participants across all sessions. In planning the sessions, NYCDOHMH sought to partner with agencies and stakeholders serving members of the specific populations identified in the NYC 2020 EHE Plan and worked to enlist as many new voices as possible in the planning process. Partner organizations were evenly distributed across the Bronx, Brooklyn, Manhattan, and Queens, and helped recruit participants for their respective listening sessions.

- **Community Survey.** NYCDOHMH launched the community survey in English and Spanish on September 1, 2020 and accepted submissions through October 16, 2020. During development of the survey, NYCDOHMH collected feedback from community members and planning bodies, including on the wording of the survey's demographic questions, the literacy level of survey questions, and overall length of the survey. Based on this feedback, NYCDOHMH revised the survey to expand the age ranges and include immigration status. The survey was designed to be completed within 15 to 20 minutes and was disseminated through CBOs serving NYC 2020 EHE Plan priority populations, including both HIV- and non-HIV-specific CBOs; local stakeholders, including community leaders, advocates, and staff at organizations; local government agencies; the NYC HPG, HIV Health and Human Services Planning Council of New York (Planning Council), and other HIV planning bodies and community advisory boards; and other traditional and non-traditional partners across the city. In total, 619 participants responded to the feedback portion of the survey.
- **Key NYC 2020 EHE Plan Partners.** NYCDOHMH has a long history of collaborating with local HIV prevention and care planning bodies to identify needs, prioritize services, allocate resources, and develop comprehensive service directives. The NYC HPG and Planning Council operate as NYCDOHMH's primary HIV community planning bodies. Both are comprised of community members, service providers, government representatives, and advocates, as well as community members affected by HIV but unaffiliated with the HIV service delivery system. In addition, NYCDOHMH collaborates with NYS HAB, which provides input on and support for HIV prevention and care activities statewide.
 - NYC HPG works to inform NYCDOHMH's HIV prevention efforts. Appointed by the NYCDOHMH Commissioner, members fully reflect communities affected by HIV in New York City. Among NYC HPG's 25 members in 2021, 56% are Black, Indigenous, People of Color (BIPOC), 64% are ages 20 to 39 years, 16% identify as people with HIV, and 45% identify as gay and/or MSM or women who have sex with women. Further, 8% are transgender and 4% identify as gender nonconforming.
 - The Planning Council uses a systematic, evidence-driven, representative, and inclusive planning process to prioritize services and allocate RWHAP Part A funding across service categories for the New York EMA, which includes New York City and the Tri-County Region (Putnam, Rockland, and Westchester Counties). Among the Planning Council's 50 members in the 2020-2021 planning cycle, people with HIV constituted 38% of members, and at the beginning of the planning cycle, one-third of members were people with HIV not affiliated with a RWHAP Part A-funded agency. A majority (81%) of the Planning Council's non-affiliated people with HIV are BIPOC.
 - NYCDOHMH has long-standing relationships with state and local government agencies, community bodies, healthcare facilities, and CBOs, which facilitate communication, collaboration, and coordination of HIV prevention and care efforts. Collaborative partners include hospitals, community health centers, federally qualified health centers (FQHCs), and CBOs, some of which receive funding through NYCDOHMH; Designated AIDS Centers; SSPs; LGBTQ+ health centers; NYSDOH

Quality of Care networks; institutions of higher education; faith-based organizations; NYC Department of Education and its School-Based Health Centers; New York City Administration for Children's Services and affiliated foster care agencies and juvenile justice facilities; New York City Health + Hospitals (H + H), the City's public hospital system; and New York City Mayor's Office to End Domestic and Gender-Based Violence.

- NYS HAB is an advisory body to the NYSDOH AI, drawing on the expertise and experiences of consumers, providers, and community members to provide guidance on service needs, affected populations, and emerging issues related to HIV prevention, healthcare, and supportive services throughout NYS. NYS HAB membership has equal representation of men and women, and 60% identify as LGBTQ+, 80% are BIPOC, and 11% are people with HIV.

Nassau-Suffolk HIV Health Services Planning Council. The Nassau-Suffolk HIV Health Services Planning Council was formed in 1992 and is an all-volunteer member body appointed by the county in which each member resides. Members include service providers, those with lived experience, consumers, and other stakeholders.

Community input is integral to the EMA's planning process and is incorporated into the Priority Setting Resource Allocation (PSRA) process at various stages. People with HIV are involved in the PSRA planning process through membership in the Strategic Assessment and Planning Committee, Finance Subcommittee, and the Planning Council. All meetings are open and community participation is encouraged. To ensure people with HIV can fully participate in the PSRA process, training is provided. People with HIV also gain understanding through attendance of committee meetings and participating at all levels of the needs assessment and planning processes. The Strategic Assessment and Planning Committee hosts annual community forums and population-specific focus groups to gain feedback on services and to assess needs and gaps. This serves as an opportunity for the community to provide input regarding the Part A-supported services they need and utilize and to help shape the service system. The qualitative data gathered reflect direct consumer experiences. Additional input on consumer experience comes from the Consumer Involvement Committee (CIC). It has a standing agenda that addresses barriers, gaps in services, and any service utilization issues as reported by consumers affiliated with the different consumer advisory boards at provider agencies.

Other examples of community engagement and information exchange include:

- Ongoing recruitment efforts of the membership subcommittee and CIC to increase unaligned consumers on the planning council and committee membership;
- United Way of Long Island regularly sends out a weekly mailing of HIV-related information as a resource to both consumers and providers within the community, which includes a link to the planning council website;
- Sharing of information on the planning council website, Twitter page, and United Way's Facebook page; and

- Observance of World AIDS Day by hosting an annual event that is open to the community.

c. **Role of Planning Bodies and Other Entities**

The NYS HAB plays a key role in leading and coordinating planning across the state. The NYS HAB is an integrated care and prevention advisory body to the NYSDOH AI. It identifies and addresses prevention and healthcare needs with an emphasis on linkage, retention, and viral suppression.

The NYS HAB focuses on integration, synergy, and efficiency in responding to jurisdictional needs and federal requirements. Its mission is to provide recommendations and guidance on service needs, affected populations, and emerging issues related to HIV prevention, healthcare, and supportive services throughout NYS. It uses recommendations from *The Blueprint*, the NHAS and the *NYS Integrated HIV Prevention and Care Plan* to guide its work.

NYS HAB membership is comprised of 33-40 people drawn from 11 designated regions of the state. Up to three members are appointed to the NYS HAB from each region of the state. NYS HAB membership reflects the people served in terms of race/ethnicity, sexual orientation, age, risk category, gender identity, and other identified criteria. Twenty-nine (29) percent of the current NYS HAB membership are people living with HIV. Full NYS HAB meetings are open to the public.

There are four co-chairs: two community co-chairs and two governmental co-chairs. The executive committee and by-laws committee are charged with overall governance of the NYS HAB. The NYS HAB has standing committees that address HIV prevention, healthcare, and supportive service needs. Each committee reviews available epidemiological, evaluation, behavioral and social science, cost-effectiveness, and needs assessment data to determine HIV needs and to make recommendations about how these needs can best be met. Three additional standing committees are:

- **Best Practices Committee:** Identifies cutting-edge healthcare issues and prevention/intervention strategies and recommendations related to needs and gaps to maximize effective HIV prevention, supportive services, and service coordination of programs across all NYS regions and populations with an emphasis on identification of new cases, rapid linkage to care, retention, and viral suppression.
- **Emerging Issues Committee:** Identifies, examines, and provides information and recommendations related to developing trends about HIV prevention, healthcare, and supportive services throughout NYS. Monitors national trends and changes that impact NYS.
- **Social Determinants Committee:** Identifies specific populations and communities (statewide and regionally) disproportionately affected by HIV and makes recommendations to address health disparities and SDOH that impact their overall health and well-being.

d. **Collaboration with RWHAP Parts**

The Integrated Plan update includes an updated Statewide Coordinated Statement of Need (SCSN). The SCSN is an integral component of this Integrated Plan. The purpose of the SCSN is

to provide a collaborative mechanism to identify and address the most significant HIV-related needs of people with HIV and to maximize coordination, integration, and effective linkages across all RWHAP Parts.

Participation and input into the SCSN process by all RWHAP recipients, HIV planning bodies, HIV service providers, and other interested organizations throughout NYS was requested in a formal communication to over 1,000 stakeholders in March 2022. It asked for planning documents, local needs assessments, and proposals. These documents and data were used in the state-level planning process.

e. Engagement of People with HIV

As mentioned above, NYSDOH AI has a long history of engaging people with HIV in the planning and design of HIV-related activities/services. NYSDOH AI engaged people with HIV and community stakeholders throughout the entire process to develop the Integrated Plan and will continue to engage them on an ongoing basis as the plan is implemented. People with HIV contributed to development of the plan in many ways.

- Membership of each planning body participating in the development of the Integrated Plan.
- Input in developing *The Blueprint*.
- Participation in numerous regional forums/listening sessions, focus groups, community calls, online portals, and ongoing needs assessments to inform annual planning and priority setting.
- Regular structured consumer surveys.
- Four sessions with the Consumer Committee of the NY EMA Planning Council to gather input on each section of the Integrated Plan led by Committee leadership with NYSDOH AI and NYCDOHMH staff in attendance.

Facilitating Engagement/Participation of People with HIV

- Best practices in cultural competence and cultural appropriateness are emphasized.
- Meeting schedules are posted online and promoted through traditional and social media.
- Efficiency of meetings is emphasized to respect the time commitment required of participants.
- Presentations and planning-related documents present complex information in an understandable way.
- Interpretation services are available for people who do not speak English and the deaf and hard of hearing as necessary.
- There are options to provide input and recommendations online and via conference calls.

The people involved in developing the Integrated Plan reflect the people affected by the HIV epidemic in NYS. Memberships of the various planning bodies and their committees/task forces reflect the local epidemic in terms of race/ethnicity, gender, transmission risk, and geography.

f. Priorities

Key priorities were identified through the planning and community engagement processes. The persistent racial and ethnic disparities in new HIV diagnoses and rates of HIV viral suppression are the highest identified priority areas of need and form the basis for many of the priorities identified. Our thorough discussion of the priorities is included in the needs assessment (Section

III) and the situational analysis (Section IV). These priorities are reflected in the goals and priority strategies of the Integrated Plan.

Key priorities identified in *ETE Beyond 2020 Addendum Report* are listed below. These were identified through the input of advisory committees (population and topic specific), listening sessions (2020), and a statewide survey.

- Ensure access to adherence, treatment, and prevention services.
- Increase efforts to engage specific populations in healthcare services.
- Increase community engagement/outreach and partnerships/collaborations.
- Address mental health and substance use by utilizing a trauma-informed care approach.
- Increase technology resources and telehealth services.
- Develop strategies to address resource deficiencies and barriers to care.

In addition, NYSDOH AI continues to identify emerging issues that have an impact on achieving the goals of the Integrated Plan. Most recently, these were identified in the 2022 NYSDOH AI Call to Action.

As stated in a March 2022 Dear Colleague letter from then-NYSDOH AI Director, Johanne E. Morne, ***“We must have the courage to look clearly at these disparities and have the integrity to ask ourselves a series of difficult questions about how we will prioritize our efforts to prevent new cases of HIV among Black New Yorkers, and work to eliminate racial disparities in rates of viral suppression.”***

Addressing Racial Disparities: Key Priorities

Priority #1: Take decisive action to address persistent disparities in new HIV diagnoses and HIV viral suppression rates for BIPOC New Yorkers. Ensure every Request for Application NYSDOH AI releases beginning in 2022 has a health equity component and evaluative criteria specific to health equity. Make the following resources and trainings available:

- Guidance tool for applying a health equity lens in the work of an agency.
- Standardized SDOH screening integrated into the AI Reporting System (AIRS).
- Provider training on how to conduct SDOH screening in a consumer-centered, affirming manner.
- Healthcare organization considerations in support of health equity.
- Health equity competencies for healthcare providers.
- Regional training/networking sessions on racism as a root cause of inequitable health outcomes.

Response: Beginning in 2022, NYSDOH AI contract managers will dialogue with funded agencies to identify specific actions, consistent with the funding stream, to prioritize innovative, culturally appropriate HIV prevention services, and to refine models of HIV care, treatment, and support services to reduce racial and ethnic disparities in new diagnoses, linkage to care, and viral suppression.

Priority #2: Take action in accordance with NYS's Hepatitis C Elimination Plan. On November 17, 2021, NYS released its Hepatitis C Elimination Plan. The plan is rooted in four guiding principles: health equity; harm reduction; trauma-informed care; and engagement of people with lived experience. The plan is comprised of nine recommendations related to prevention; 12 related to testing and linkage to care; six related to care and treatment access; and 14 related to SDOH.

Priority #3: Stem the increasing tide of congenital syphilis. The number of congenital syphilis cases in NYS has more than doubled over the last five years. Congenital syphilis, which results from untreated maternal syphilis infection in pregnancy, is entirely preventable. Each case represents a failure of the public health and healthcare systems. To reduce missed prevention opportunities, NYS needs sustained, consistent, equitable, and timely access to high-quality prenatal care for all people, including transgender people. The NYSDOH AI is calling on all healthcare providers in NYS to:

- Screen people for syphilis as recommended;
- Determine pregnancy status of all people of reproductive capacity diagnosed with syphilis;
- Make sexual health discussions a routine part of every prenatal visit; and
- Screen all pregnant people at least three times during their pregnancy, including at the time pregnancy is first identified, between 28 and 32 weeks, and upon delivery.

Response: The NYSDOH AI-supported Clinical Education Initiative's Sexual Health Center will prioritize training on these important topics.

Priority #4: Meet the needs of older adults with HIV.

NYS will advance efforts on several fronts including:

- **Enhanced Data Analysis.** NYSDOH AI staff will analyze data to determine the extent to which AI-funded providers and direct services programs are serving older adults at risk for, or living with, HIV to identify disparities and work to modify existing programming and to identify new programming possibilities.
- **Uninsured Care Programs (UCP) Outreach to Older Adults.** UCP will provide outreach to participants in adult day programs, senior service programs and other settings to discuss available services, including PrEP Assistance Program and AIDS Drug Assistance Program (ADAP) Plus Insurance Continuation. The program will develop written materials for its Medicare consumers to educate individuals on the benefits of utilizing the UCP in conjunction with other health insurance like Medicare.
- **Develop a Continuing Education Concentration on HIV and Aging for Certified Peer Workers (CPW).** CPWs will be trained to conduct age-related screenings that will help connect older adults with HIV to needed services related to reduced mobility, memory, and frailty.

Priority #5: Expand access to harm reduction services and mental health services. In 2021, legislation provided new tools to combat the opioid crisis, including expanding access to substance use disorder treatment in NYS prisons and county jails. This historic legislation reminds us that all health and support services providers should take every opportunity to

promote access to harm reduction services, treatment for substance use disorder, access to naloxone, and safety planning to reduce opioid overdose. Our systems should work to destigmatize mental health services and strengthen our capacity to make effective referrals for needed services. Using a harm reduction model to address the intersection of health, mental health, and substance use must be a priority for 2022.

g. Updates to Other Strategic Plans Used to Meet Requirements

The Integrated Plan closely aligns with NYS ETE efforts, as well as the NHAS and the EHE initiative that includes New York City's ETE plan. *ETE Beyond 2020 Addendum Report* included the findings from both regional virtual listening sessions and theme-based listening sessions, held in 2020. It also included the results of a statewide survey conducted from December 2020 to January 2021. In addition to these data from the *ETE Beyond 2020 Addendum Report*, the Integrated Plan incorporates findings from two listening sessions held in June 2022.

NYC ETE Plan. The NYC ETE plan reflects and builds upon *The Blueprint*. The NYC ETE Plan employs an HIV status-neutral approach to reduce the number of new HIV infections to non-

epidemic levels; improve the health and well-being of people with HIV and people vulnerable to HIV; and eliminate HIV-related health inequities.

The NYC ETE Plan aligns with NYS ETE priorities and goals. In 2020, NYSDOH AI released the *ETE Beyond 2020 Addendum Report*, which describes how NYS will build on *The Blueprint* to take the ETE initiative beyond 2020. The report includes key themes and outcomes informed by feedback received from stakeholders throughout 2020, and summarizes NYS's ETE planning process, essential partnerships that support the ETE initiative, statewide ETE metrics, progress to date, and community-identified emerging priorities.

NYC ETE Plan: Strategies for Ending the HIV Epidemic

- Strategy 1: Increase the number of people who know their HIV status by diagnosing HIV infection as early as possible, promoting routine testing within healthcare facilities, and scaling up testing options in non-clinical settings.
- Strategy 2: Prevent new HIV acquisition by increasing access to effective prevention interventions, including pre-exposure prophylaxis (PrEP), emergency post-exposure prophylaxis (emergency PEP), condoms, harm reduction, and supportive services.
- Strategy 3: Improve viral suppression and other health outcomes for people with HIV by optimizing medication adherence and access to care, improving coordination of clinical and supportive services, and increasing access to immediate antiretroviral treatment (iART).
- Strategy 4: Enhance methods to identify and intervene on HIV transmission networks to better support individuals and communities at increased risk of exposure.
- Strategy 5: In all NYC ETE strategies, utilize an intersectional, strengths-based, anti-stigma, and community-driven approach to mitigate racism, sexism, homophobia, transphobia, and other systems of oppression that create and exacerbate HIV-related health inequities.



Section III: Contributing Data Sets and Assessments

1. Data Sharing and Use

NYSDOH AI provides and shares a wide range of data to support community engagement and planning activities. Data sharing from the HIV epidemiology system is achieved through project-specific data use agreements as allowed by existing HIV epidemiology security and confidentiality protocol, [NYS public health laws](#) and applicable [CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention \(NCHHSTP\) data security and confidentiality guidelines](#). Currently, HIV epidemiology data are shared electronically with staff conducting Partner Services; select staff in NYSDOH AI communicable disease registries for co-morbidity assessment (e.g., tuberculosis (TB), STI, etc.); healthcare providers for the purposes of linkage and retention in medical care using the HIV/AIDS Provider Portal; NYCDOHMH for epidemiology and partner services as outlined in a memorandum of understanding; the AI Office of Medicaid Policy and Programs, for sharing with Medicaid Managed Care Plans to improve viral load suppression. Matching is conducted with the NYSDOH AI Reporting on an ongoing basis for a variety of HIV prevention-related monitoring and evaluation. NYC and NYS have established direct lines of programmatic collaboration to ensure that a comprehensive prevention and care program exists in NYS. This extends to both the prevention and epidemiology work portfolios. For example, the AI funds 100+ providers in NYC to deliver a range of evidence-based prevention programming. NYS and NYC epidemiology units have data sharing agreements in place to ensure HIV epidemiology data for people who migrate across the NYS/NYC border are available to both jurisdictions. NYCDOHMH supports NYSDOH AI activities through letters of agreement to ensure an equitable distribution of federal resources to the whole state, keeping in mind the maintenance of shared infrastructure and other responsibilities that fall solely to NYS, the symbiosis of the epidemiologic data systems, and the programming based on these systems.

In this Section

- Data Sharing and Use
- Epidemiologic Snapshot
- HIV Prevention, Care, Treatment Resource Inventory
- Needs Assessment

Epidemiologic Data. HIV epidemiologic data are used on an ongoing basis for planning and targeting interventions. They are available in the [NYS HIV/AIDS Surveillance Annual Report](#) and through the [ETE Dashboard](#).

Slide Sets to Support Community Engagement and Planning. Every year, NYSDOH AI makes tailored presentations at and/or provides data sets for regional, topic-specific, and population-focused listening sessions. Among the information provided are updates on progress to ETE and Integrated Plan goals, in general and related to the topics/populations.

Data Collected through Community Engagement/Needs Assessment Activities.

NYSDOH AI uses various methods to share data collected through community engagement and needs assessment activities. For example, the *ETE Beyond 2020 Addendum Report* included the

findings from both regional virtual listening sessions and theme-based listening sessions, held in 2020. It also included the results of a statewide survey conducted from December 2020 to January 2021. In addition to these data from the *ETE Beyond 2020 Addendum Report*, the Integrated Plan incorporates findings from two listening sessions held in June 2022.

Data Sharing Agreements. As stated above, NYS and NYC epidemiology units have data sharing agreements in place to ensure HIV epidemiologic data for people who migrate across the NYS/NYC border are available to both jurisdictions.

2. Epidemiologic Snapshot

Introduction

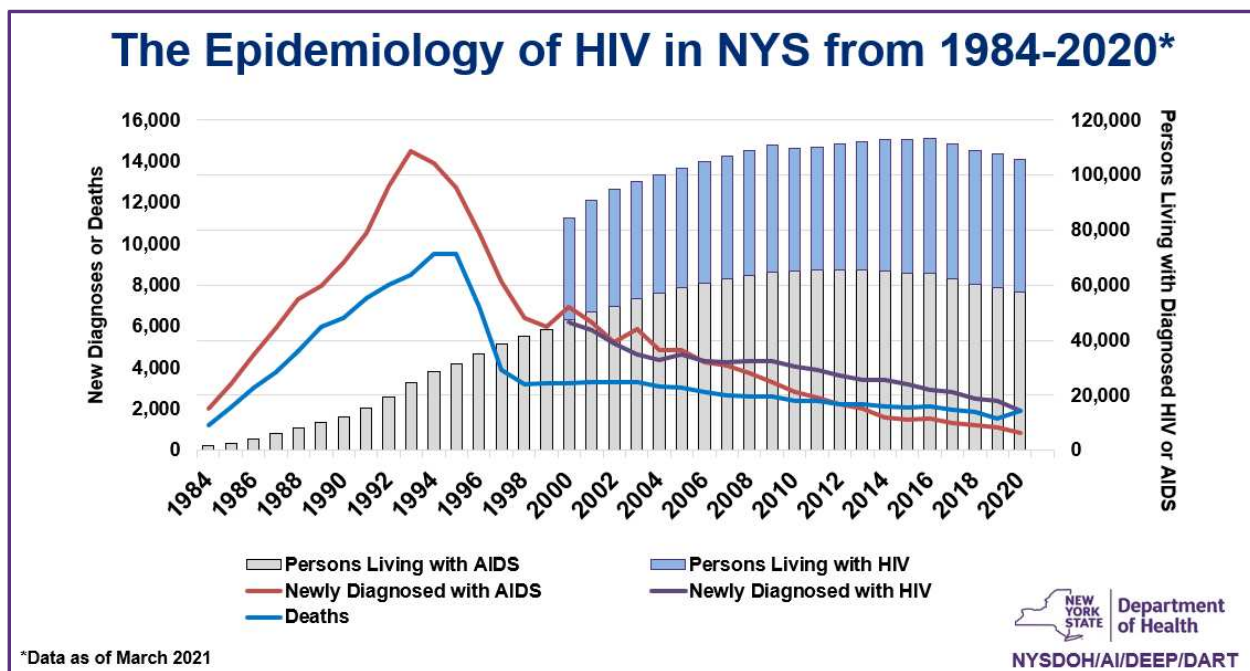
As the state public health authority, the NYSDOH is responsible for maintaining the NYS Registry of confirmed and suspected HIV/AIDS cases.

On June 29, 2014, NYS announced the Ending the Epidemic (ETE) Initiative, a plan to move the state closer to the end of the HIV epidemic. The three-point plan aims to: 1) identify persons with HIV who remain undiagnosed and link them to healthcare; 2) link and retain persons diagnosed with HIV in healthcare to maximize virus suppression so they remain healthy and prevent further transmission; and 3) facilitate access to PrEP to prevent the acquisition of HIV. ETE will maximize the availability of lifesaving, transmission-interrupting treatment for HIV, saving lives and improving the health of NYS residents. The plan will help NYS overcome its historical burden of the worst HIV epidemic in the country and work towards a future where new infections are rare and those living with HIV are able to live normal lifespans with minimized complications.

This Epidemiologic Snapshot provides a summary of the HIV epidemic in NYS, highlighting epidemiologic trends and progress since the start of the ETE Initiative, and additionally provides a snapshot of HIV epidemiology in NYS during 2020. Completeness of 2020 data may be affected by the COVID-19 pandemic and subsequent public health response, known as NY PAUSE. Reported HIV-related laboratory testing result volume and clinician reports of persons with diagnosed HIV were lower compared to prior years. Additionally, HIV surveillance activities in NYS were delayed, potentially resulting in an inaccurate count of persons with diagnosed HIV.

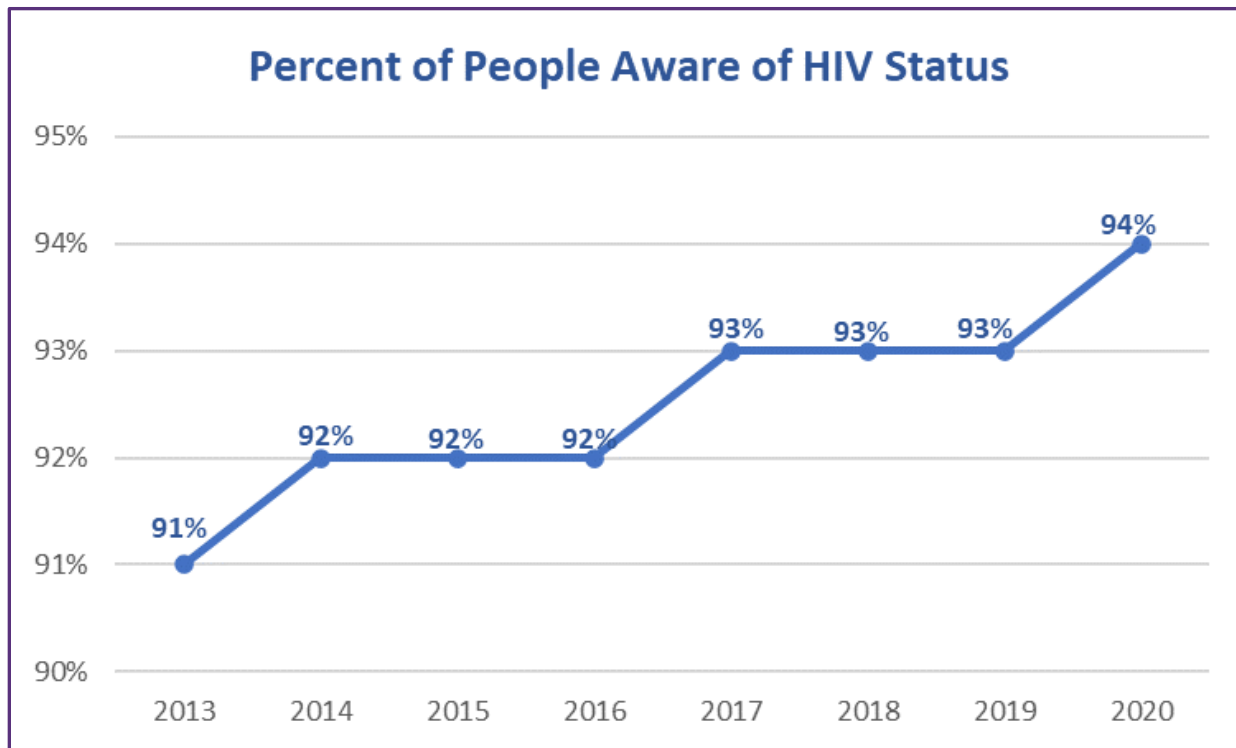
Background

Since the peak of NYS's HIV epidemic in the 1990s, the number of persons newly diagnosed with HIV and the number of deaths among persons with diagnosed HIV have declined, while linkage to care and rates of viral suppression have steadily increased. Despite these successes, disparities remain among race/ethnicity, age, and geographic regions in HIV diagnosis and care.



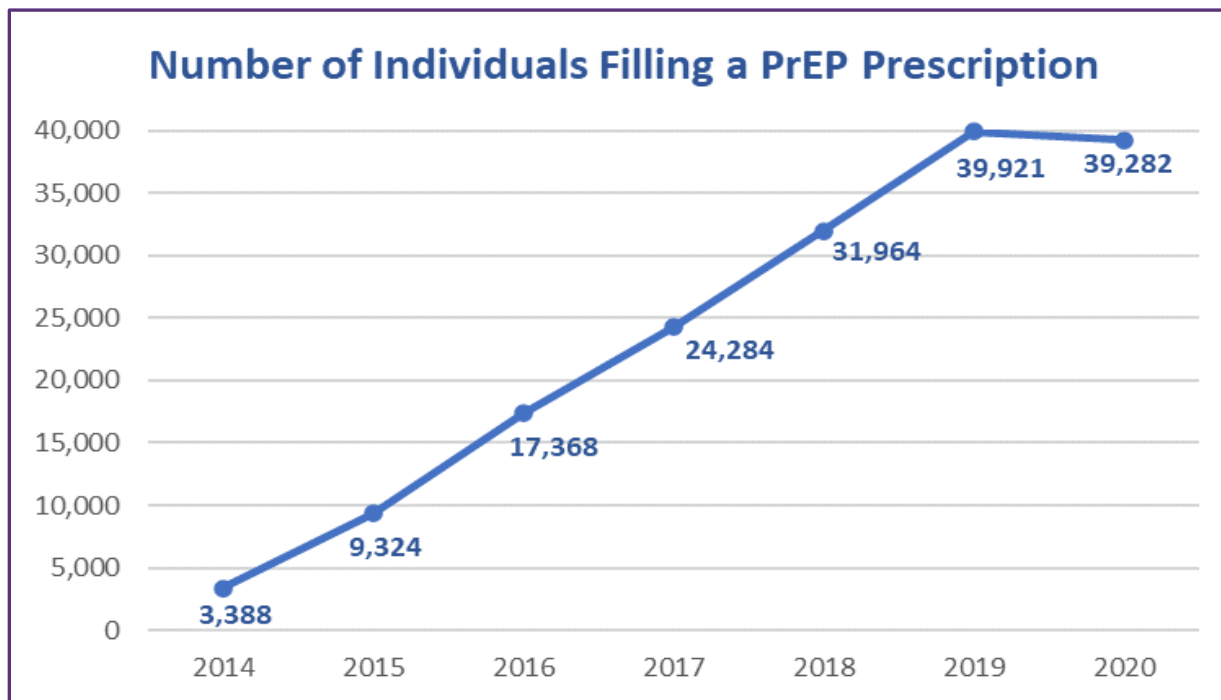
HIV Prevention

It is estimated that over 90% of NYS residents are aware of their HIV status, increasing from 91% in 2013 to 94% in 2020.

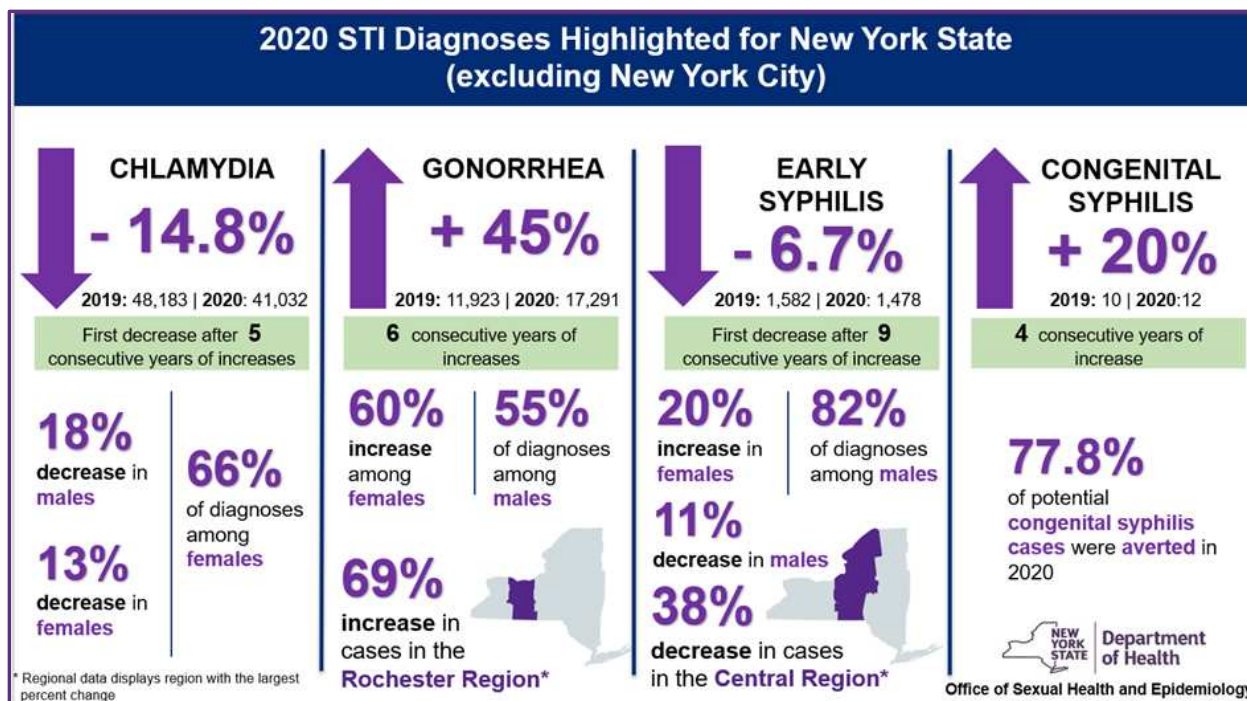


Awareness of HIV status is one pillar of ETE aimed at preventing HIV transmission. Another prevention goal is increasing PrEP access throughout the state. The number of individuals who

filled a prescription for PrEP increased dramatically from 3,388 in 2014 to nearly 40,000 in 2020.

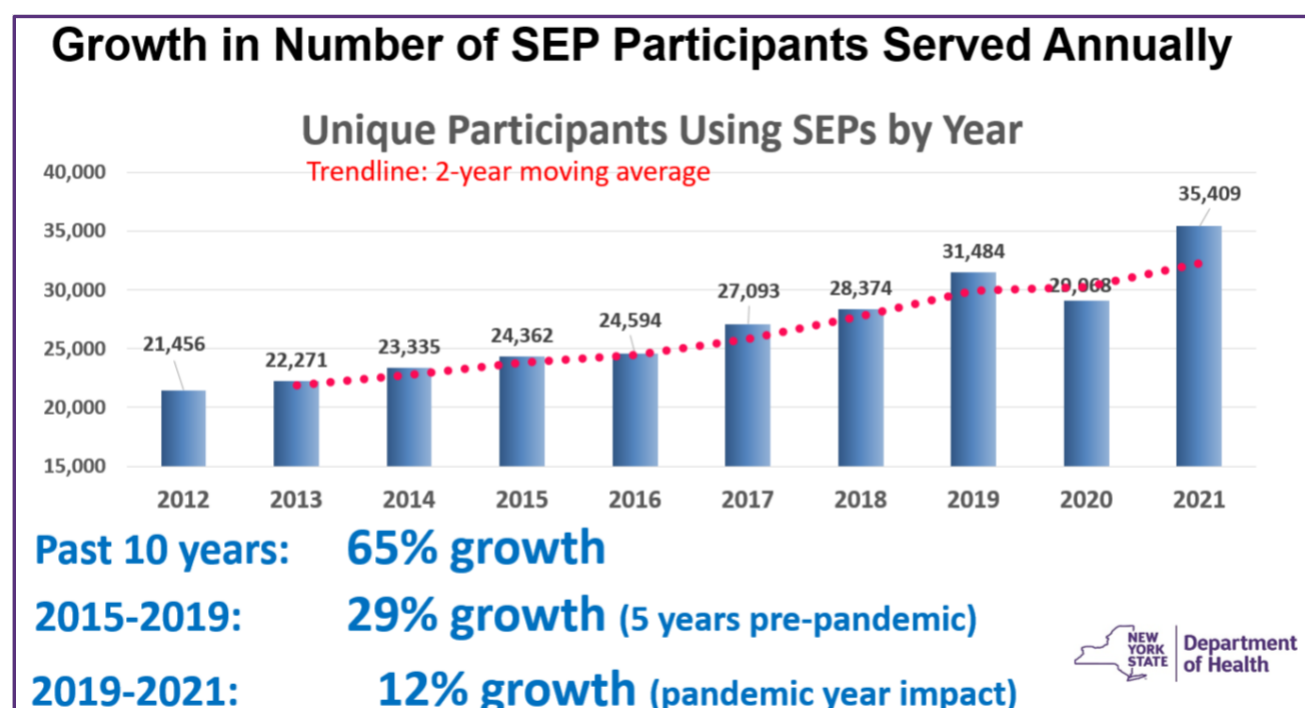


HIV often occurs simultaneously with other sexually transmitted infections. Gonorrhea rates have increased steadily for six years in NYS, and congenital syphilis rates have risen for the past four years. In 2020, the number of chlamydia and early syphilis cases declined for the first time in five years, as a result of access to services during COVID-19.



In 2019, 6,175 newly diagnosed cases of hepatitis C were reported to the NYSDOH AI, of which 5,911 were chronic, 253 were acute, and 11 were perinatal. The number of newly reported hepatitis C cases declined in NYS overall but increased in New York City (NYC). The majority of newly reported cases were chronic, indicating that infection happened in the past. The number of acute cases was low in 2019 but was higher than in the previous year. In 2019, the rate of newly reported hepatitis C was highest amongst those aged 25-34 years. Sixty (60) percent of females with newly reported hepatitis C were of reproductive age (ages 15-44).

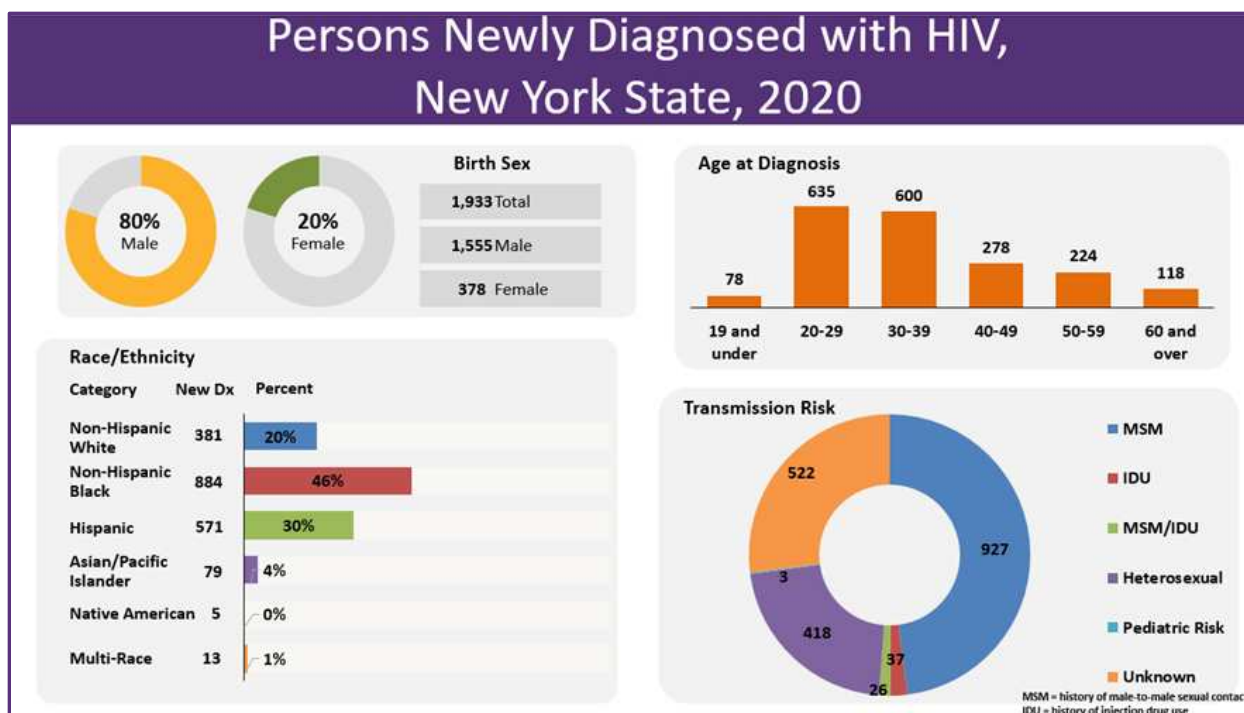
Aside from sexual transmission, HIV can be transmitted through the sharing of needles and “works” associated with injection drug use. To prevent transmission of HIV via this mode, NYS has established a syringe services program. This program has expanded substantially in the past ten years, with the number of participants served increasing from 21,456 in 2012 to 35,409 in 2021.



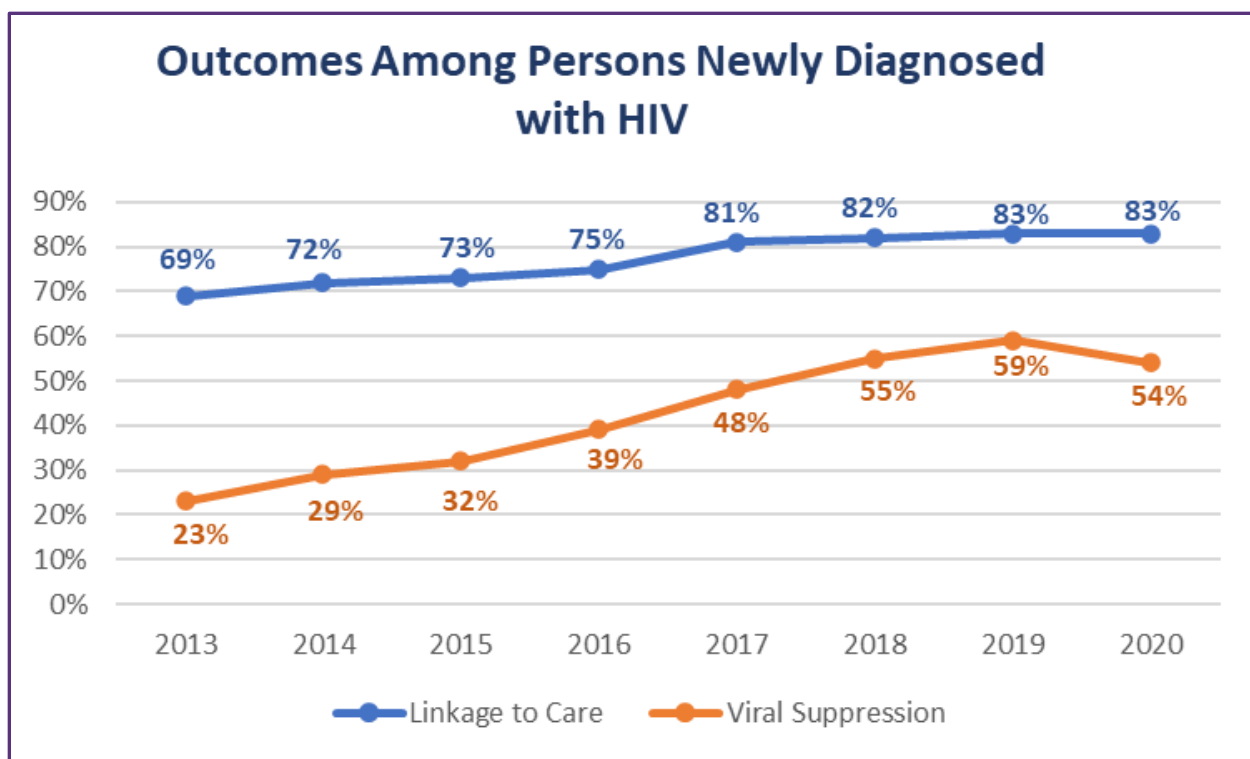
New HIV Diagnoses

From the initiation of ETE in 2014 to 2019, the number of persons newly diagnosed with HIV in NYS decreased by 31%. HIV diagnoses decreased by 19% in 2020 compared to 2019, perhaps indicating a continued decline in transmission but also possibly reflecting a lack of testing or delayed reporting as a result of the COVID-19 pandemic.

Among all NYS residents newly diagnosed with HIV in 2020, 80% were male (sex at birth), 46% were non-Hispanic Black, 30% were Hispanic/Latino, 33% were aged 20-29, and the most frequently reported transmission risk behavior was a history of male-to-male sexual contact (48%).

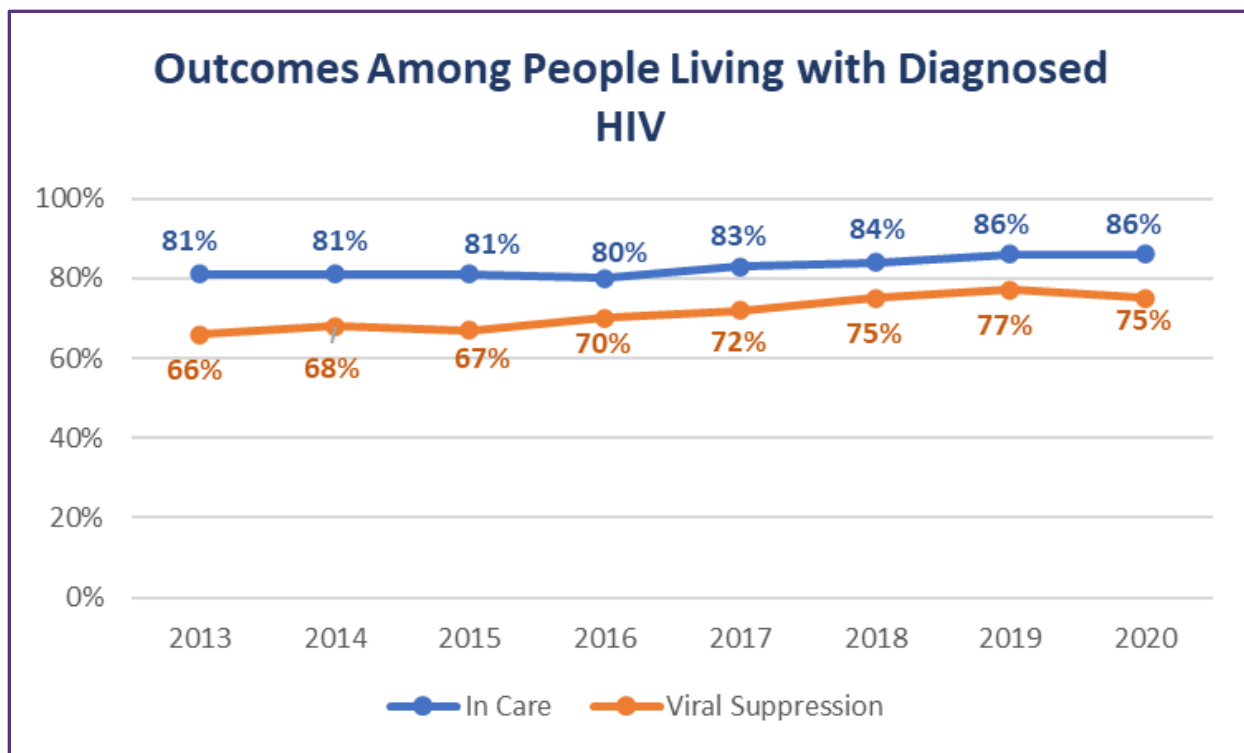


Alongside the steady decrease in new diagnoses since the onset of the ETE initiative, linkage to care and viral suppression outcomes have continued to improve. HIV care is defined as a CD4, viral load, or genotype test result reported to NYSDOH AI. The percentage of persons linked to care within 30 days of diagnosis increased from 69% in 2013 to 83% in 2020. Additionally, the percent of individuals obtaining viral suppression (<200 c/mL) within three months of diagnosis more than doubled, from 23% in 2013 to 54% in 2020.



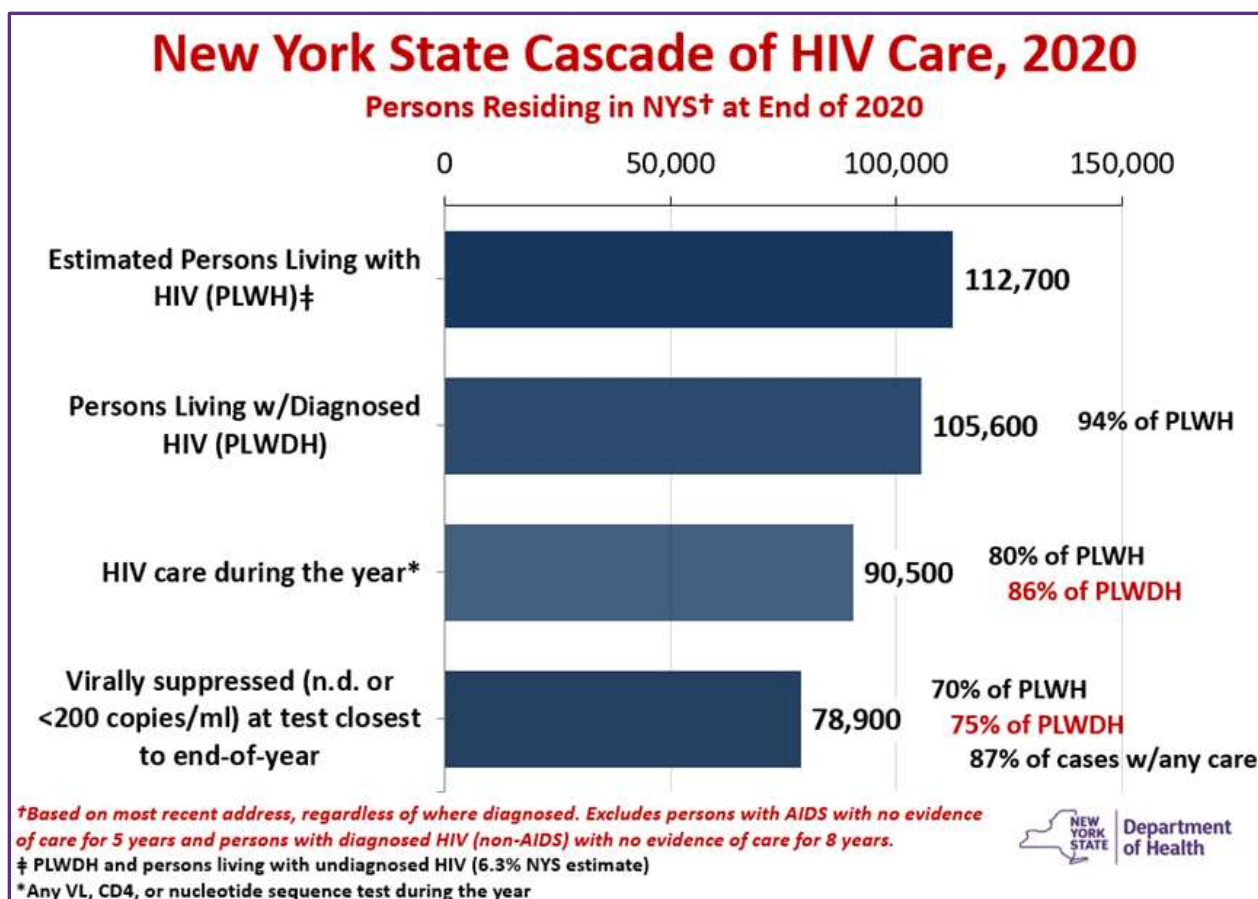
Persons Living with Diagnosed HIV (PLWDH)

In 2020, there were 105,610 PLWDH in NYS, maintaining an annual 2% decrease observed since 2017. Reflecting demographic trends seen among persons newly diagnosed with HIV, 72% of PLWDH were male (sex at birth), 45% were non-Hispanic Black, 29% were Hispanic/Latino, and the most frequently reported transmission risk was a history of male-to-male sexual contact (45%). The majority of PLWDH were aged 50-59 years old (30%), while most persons newly diagnosed with HIV were aged 20-29 years. In 2020, 86% of PLWDH were in care, an increase from 81% in 2013. Seventy-five (75) percent of PLWDH were virally suppressed, compared to 66% in 2013.



HIV Care Cascade

The HIV Care Cascade presents a snapshot of engagement in care among all persons with HIV in NYS at one point in time, across the continuum of care from transmission through diagnosis, participation in care, and success of care.

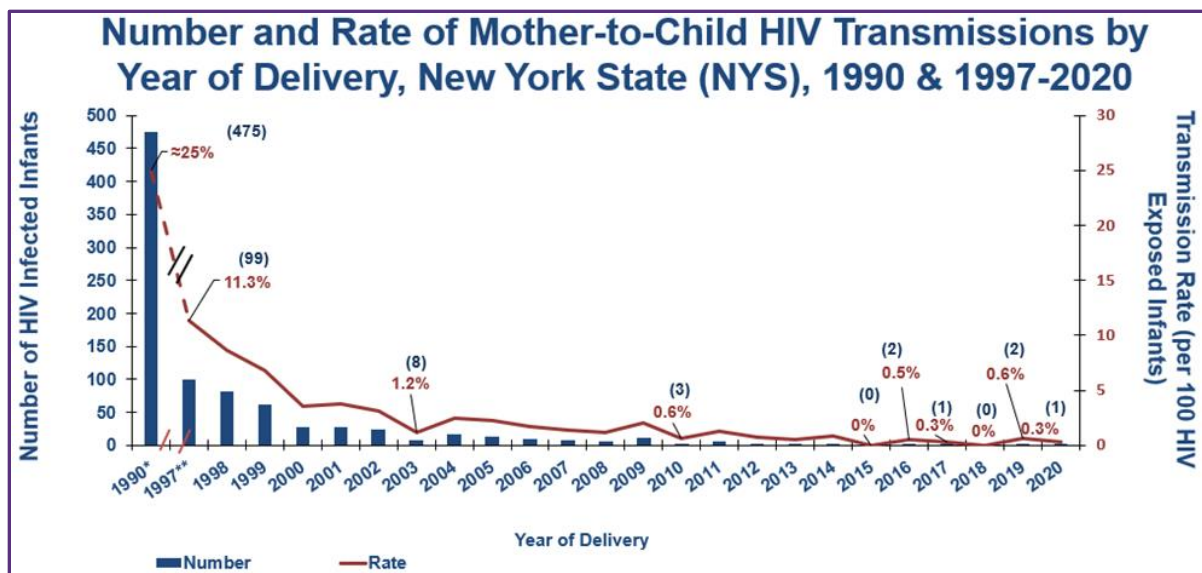


Deaths among Persons with Diagnosed HIV

The number of deaths among persons with diagnosed HIV has decreased since the mid-1990s, though in 2020 there was an increase in deaths consequent to the COVID-19 pandemic. The percent of deaths related to HIV decreased from 36% in 2013 to 24% in 2019.

Mother-to-Child HIV Transmission (MTCT)

At the height of the HIV epidemic in 1990, nearly 2,000 women with diagnosed HIV gave birth in NYS. That year, the HIV MTCT rate was estimated to be 475 – 760 infected infants per 100,000 births, indicating a transmission rate of approximately 25-40%. In 2020, there was a MTCT rate of 0.3% among HIV-exposed infants with known status and 0.48 HIV-infected infants per 100,000 live births. The CDC defines “elimination” of MTCT as a transmission rate of less than one percent of HIV-exposed infants and less than one case of MTCT per 100,000 live births. Based on these criteria, NYS has successfully eliminated MTCT for the sixth consecutive year and seventh year overall (2013 and 2015-2020).



HIV Cluster Detection and Response

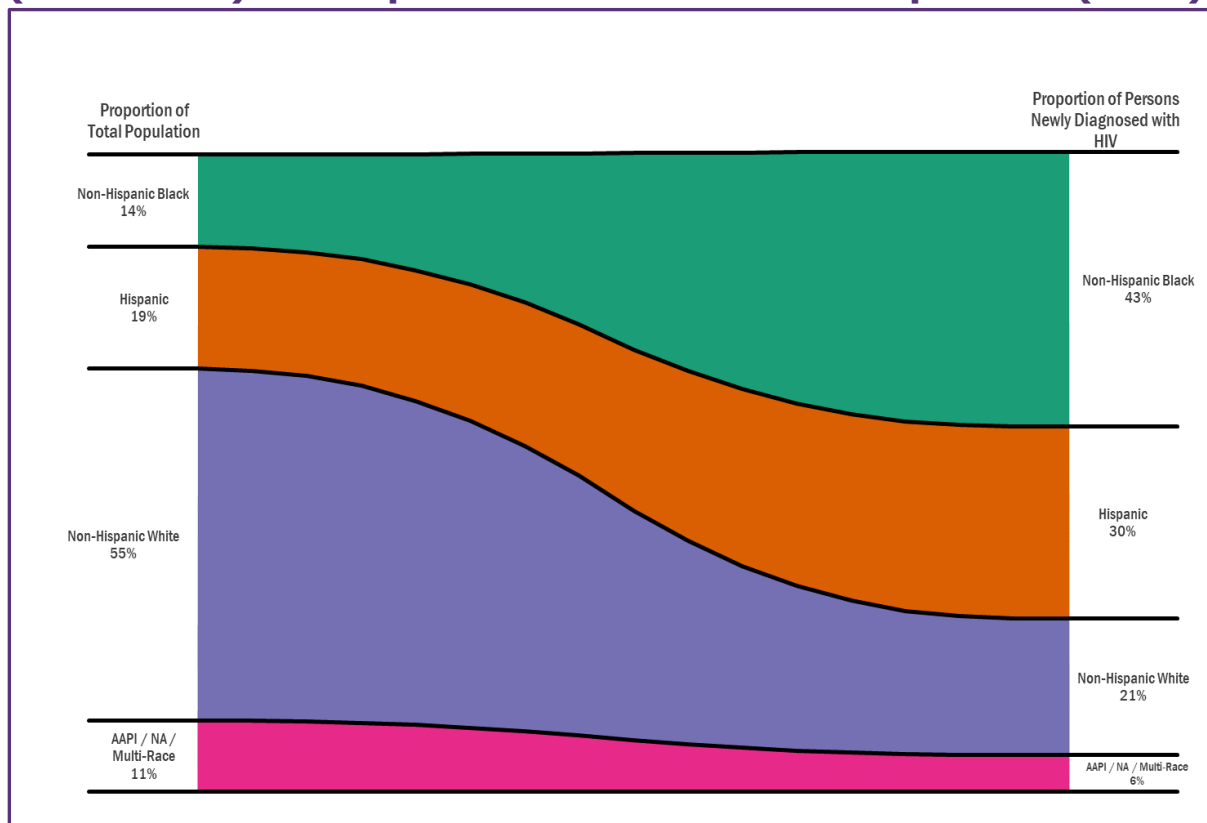
Cluster detection and response involves identifying risk networks or geographic areas that show increased transmission of HIV. The overarching goal of cluster detection is to use available data to help focus proven, but resource limited, HIV prevention tools and interventions where they are needed most. A cluster is defined as an increase in the number of persons newly diagnosed with HIV in a particular geographical area over a specific time period.

A health advisory was issued in October 2020 after elevated numbers of new diagnoses were observed in the spring and summer of 2020 in Monroe County. NYS activated the NYSDOH AI Outbreak Response, which included bi-weekly meetings with key partners from epidemiology, prevention, healthcare, and drug user health programs to actively respond to the increases in new diagnoses. A listening session was held on October 30, 2020, where Monroe County community providers helped to identify potential strategies and recommendations to address the emergent situation.

Disparities in HIV-related Outcomes by Demographic

NYS has made many gains in the prevention and treatment of HIV and continues to prioritize efforts to eliminate disparities. From 2013-2020, non-Hispanic Black and Hispanic/Latino individuals accounted for the largest percent of new HIV diagnoses in NYS. These individuals represented 73% of new diagnoses, but only 33% of the NYS population in 2020. Non-Hispanic White and Asian American/Native American/Multi-Race individuals represented a greater proportion of the NYS population than the population newly diagnosed with HIV.

Race/Ethnicity Composition of Persons Newly Diagnosed with HIV (2011-2020) in Comparison with the General Population (2020)



Note that the number of persons newly diagnosed with HIV in NYS was 3,971 in 2011 and 1,933 in 2020.

Linkage to care within 30 days of diagnosis varied by race/ethnicity with 73% of non-Hispanic White individuals, 66% of non-Hispanic Black individuals, and 69% of Hispanic /Latino individuals in care in 2013. This increased to 85% of non-Hispanic White, 80% of non-Hispanic Black, and 85% of Hispanic/Latino individuals by 2020, with disparities still remaining. Similar patterns were seen in viral suppression among those in care. Of those in care, 91% of non-Hispanic White, 77% of non-Hispanic Black, and 81% of Hispanic/Latino PLWDH were virally suppressed in 2013. This increased to 93% of non-Hispanic White, 84% of non-Hispanic Black, and 88% of Hispanic/Latino PLWDH by 2020.

Impact of COVID-19 and Monkeypox (MPV) on PLWDH

NYS was the epicenter of the COVID-19 and Monkeypox (MPV) outbreaks. NYS has prioritized understanding the impact of the COVID-19 pandemic as well as MPV on PLWDH. A recent study found that from March 1-June 7, 2020, 2,988 PLWDH were diagnosed with COVID-19, a rate of 27.7 per 1,000 PLWDH, which was higher than among persons living without diagnosed HIV (19.4 per 1,000) in NYS. Further research identified that about 30% of PLWDH had not received a dose of a COVID-19 vaccine as of October 24, 2021.

As of July 2022, there were 88 persons diagnosed with MPV in NYS outside of NYC. Of these 88 individuals, 33%, or 29 individuals, had been previously diagnosed with HIV.

Epidemiologic Snapshot References

Data are available at the follow links to further explore the metrics in this report.

HIV

[Ending the Epidemic – Measure, track, and disseminate information on progress towards achieving the End of the AIDS Epidemic in New York State \(etedashboardny.org\)](https://etdashboardny.org)

[HIV/AIDS Statistics in New York State - New York State Department of Health \(ny.gov\)](https://ny.gov)

Hepatitis B and C

[Communicable Disease Annual Reports and Related Information \(ny.gov\)](https://ny.gov)

STI

[Sexually Transmitted Infections Data and Statistics \(ny.gov\)](https://ny.gov)

HIV and COVID

Tesoriero JM, Swain CE, Pierce JL, et al. COVID-19 Outcomes Among Persons Living With or Without Diagnosed HIV Infection in New York State. JAMA Netw Open. 2021;4(2):e2037069. doi:10.1001/jamanetworkopen.2020.37069

Tesoriero JM, Patterson W, Daskalakis D, et al. Notes from the Field: COVID-19 Vaccination Among Persons Living with Diagnosed HIV Infection — New York, October 2021. MMWR Morb Mortal Wkly Rep 2022;71:182–184. DOI: <http://dx.doi.org/10.15585/mmwr.mm7105a4>

HIV, STI and Monkeypox

Curran KG, Eberly K, Russell OO, et al. HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1141–1147. DOI: <http://dx.doi.org/10.15585/mmwr.mm7136a1> September 9, 2022 / 71(36);1141–1147

3. HIV Prevention, Care, Treatment Resource Inventory

To compile this resource inventory, NYSDOH AI worked directly with partners at the NYCDOHMH and NCDOH to collect accurate information across all NYS programs from the most up to date sources available. In some cases, information for CDC, Substance Abuse and Mental Health Services Administration (SAMHSA) and other grant funding was obtained via internet research. The fiscal year information is noted with each source for reference.

i. Funding Source	ii. Funding Amount (\$)	% of Total Funding	iii. Funded Service Provider Agencies/Contracts	iv. Services Delivered	v. HIV Care Continuum Step(s) Impacted
Statewide					
New York State Medicaid Expenditures Statewide (SFY20-21)	\$2,500,692,797	69.44%	N/A	Outpatient/Ambulatory Health Services, Substance Abuse/Mental Health Services, Oral Health, Other Outpatient/Community Based Primary Medical Care Services, Home/Community Based Support Services, Counseling and Testing, Prescription Medications	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Ryan White HIV/AIDS Program (RWHAP) Part C (EIS) (FY 2020)	\$2,925,411	0.08%	37	EIS, core medical services, support services, quality management, and administration.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Ryan White HIV/AIDS Program (RWHAP) Part D (WICY) (FY2020)	\$626,986	0.02%	14	Medical services, clinical quality management, support services, and administrative costs.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Community Based Dental Program (FY2021)	\$588,509	0.02%	2	Increasing access to oral health care for people with HIV.	Retained in Care
HRSA Ryan White HIV/AIDS Program (RWHAP) Part F (FY2016)	\$4,636,222	0.13%	17	Assists accredited dental schools, post-doctoral dental programs, and dental hygiene education programs with uncompensated costs incurred in providing oral health treatment to patients with HIV infection.	Retained in Care
HRSA Ryan White Special Projects of Significance (SPNS) (FY2020)	\$2,205,000	0.06%	5	Support innovative demonstration projects that test and respond to the challenge of HIV/AIDS service provision to underserved and vulnerable populations.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Ryan White Special Projects of Significance (SPNS) (FY2022-2024)	\$2,250,000	0.06%	5	Support innovative demonstration projects that test and respond to the challenge of HIV/AIDS service provision to vulnerable populations of Aging with HIV.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA AIDS Education and Training Centers (AETC) Program (2021)	\$3,845,677	0.11%	1	Trains health care providers to treat people living with HIV/AIDS through a network of regional centers and associated sites.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
CDC HIV Prevention and Surveillance Programs (FY2016) - Directly Funded Service Providers	\$90,065,427	2.50%	N/A	Activities include Comprehensive High-Impact HIV Prevention Projects for Community Based Organizations	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
National Education and Training Centers Program (2017)	\$247,697	0.01%	1	Capacity building for HIV Physician's Assistant training program	Prescribed ART
SAMHSA (FY2022)	\$109,863,380	3.05%	N/A	SAMHSA funding includes funding for the Center for Mental Health Services (CMHS), the Center for Substance Abuse Prevention (CSAP), and the Center for Substance Abuse Treatment (CSAT).	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HOPWA (FY2016)	\$49,742,018	1.38%	17	HOPWA provides housing assistance and related support services for low-income persons with HIV/AIDS and their families.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
New York State DOH/AIDS Institute Financial Resources Inventory					

i. Funding Source	ii. Funding Amount (\$)	% of Total Funding	iii. Funded Service Provider Agencies/Contracts	iv. Services Delivered	v. HIV Care Continuum Step(s) Impacted
Ryan White HIV/AIDS Program (RWHAP) Part B (FY2022) Base and Emerging Communities	\$32,847,831	0.91%	N/A	Medical case management services (including treatment adherence), Case management (non-medical), Food bank/home-delivered meals, Health education/risk reduction, Psychosocial support services, quality management, evaluation.	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Ryan White HIV/AIDS Program (RWHAP) Part B Minority AIDS Initiative (MAI) (FY22)	\$1,432,810	0.04%	N/A	Increase enrollment in Health Care Services, ADAP, Medicaid or other health care coverage.	Linked to Care
Ryan White HIV/AIDS Program (RWHAP) Part B (FY2022) ADAP Earmark	\$92,321,794	2.56%	N/A	ADAP medications, Insurance Continuation	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Other ADAP State funding (FY 2019)	\$20,000	0.00%	N/A	Expenditures support the HIV Uninsured Care Program which includes; ADAP Medications, HIV primary care services, Home Care, Insurance continuation.	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Estimated Drug Rebates	\$223,271,069	6.20%	N/A	Expenditures support the HIV Uninsured Care Program which includes; ADAP Medications, HIV primary care services, Home Care, Insurance continuation, Behavioral Health Education, Nutrition Health Education, Medical case management services (including treatment adherence), Case management (non-medical)	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Ryan White Part B Supplemental (FY2019)	\$9,985,945	0.28%	N/A	ADAP Medications	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Ryan White HIV/AIDS Part B COVID Response (FY 2020)	\$1,500,000.00	0.04%	N/A	Provides onetime funding to support preventing, preparing for, and responding to coronavirus disease 2019 (COVID19), as outlined in the Coronavirus Aid Relief and Economic Security Act (P.L. 116-136).	Retained in Care
NY State Appropriations (FY2021)	\$175,273,292	4.87%	361 grants	HIV/STD/Hep C Prevention & Support Services, HIV Health Care, HIV Uninsured Care Services (ADAP, ADAP Plus, Home Care, APIC), PrEP/PEP, HIV Testing, Criminal Justice Initiative, Housing, Nutrition Health Education, Legal Services, Medical case management services (including treatment adherence), Case management (non-medical), Syringe Exchange, Drug User Health, Education & Training, Quality of Care, LGBT Health, Management & Administration, Epidemiology, Surveillance & Partner Notification, Viral Hepatitis	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
CDC HIV/AIDS, Viral Hepatitis, STI and TB Prevention-Component A and B	\$16,082,708	0.45%	7	Component A: Integrated HIV Surveillance and Prevention Program for the NYS Department of Health Component B: High Impact Prevention and Surveillance Project (HIPS) Prevention model research	At-Risk, High-Risk, Diagnosed, Linked to Care,
CDC HIV/AIDS, Viral Hepatitis, STI and TB Surveillance	\$1,323,369	0.04%	9	Emerging Infections Program, Medical Monitoring Project and Behavioral Surveillance	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed

i. Funding Source	ii. Funding Amount (\$)	% of Total Funding	iii. Funded Service Provider Agencies/Contracts	iv. Services Delivered	v. HIV Care Continuum Step(s) Impacted
New York City DOHMH Financial Resources Inventory					
Ryan White Part A - New York EMA (FY2022) Grant year: 1/1/2022 - 12/31/2022	\$93,341,502	2.59%	131	AIDS Drug Assistance Program, Oral Health Care, Early Intervention Services, Mental Health Services, Medical Case Management (incl. Treatment Adherence), Substance Abuse Treatment - outpatient, Case Management (non-Medical), Food Bank/Home-Delivered Meals, Health Education/Risk Reduction, Housing Services, Legal Services, Medical Transportation Services, Psychosocial Support Services	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
ETE Ryan White Parts A and B- New York EMA (FY2022) Grant year: 3/1/2022 - 2/28/2022	\$13,110,582	0.36%	14	Engagement and Re-Engagement in Care, Initiation of iART, Evidence-Based Interventions in Priority Populations including E-VOLUTION, Golden Compass, and Project nGage; HIV Testing, Enhanced Patient Navigation for HIV-Positive Women of Color, Transgender Women Engagement and Entry to Care, Improved Protocols for Data to HIV Care Activities	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Prevention-CDC HIV Cooperative Agreement (PS18-1802) (FY2022) Grant year: 1/1/2022 - 12/31/2022	\$31,121,885	0.86%	4	Community-level services for HIV Prevention, Community Mobilization Interventions, Condom Distribution Services, Demonstration Projects for Innovative Prevention Strategies, HIV Testing Services, Structural-level Change Support Services, Sexual and Behavioral Health Services	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Prevention-CDC (PS20-2010) (FY2022) Grant year: 8/1/2021 - 7/31/2022	\$7,988,289	0.22%	18	HIV Testing, Outreach, Status-Neutral Prevention and Care Coordination, HIV Prevention Navigation	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Surveillance - CDC HIV Cooperative Agreement (PS18-1802) (FY2022) Grant year: 1/1/2022 - 12/31/2022	\$5,061,982	0.14%	4	HIV Surveillance Activities	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Prevention- City Tax Levy (FY2022) Fiscal Year: 7/1/2021 - 6/30/2022	\$36,859,944	1.02%	56	Condom Distribution, Faith-based services, Hepatitis prevention and treatment services, Ending the Epidemic, Health Literacy for Seniors, Supportive Counseling, Training, Baby-Friendly Hospital Designation, Buprenorphine Access, Injection Drug Users harm reduction programs	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Prevention- City Council (FY2022) Fiscal Year: 7/1/2021 - 6/30/2022	\$19,380,640	0.54%	147	Condom Distribution, Faith-based services, Hepatitis prevention and treatment services, Ending the Epidemic, Health Literacy for Seniors, Supportive Counseling, Training, Baby-Friendly Hospital Designation, Buprenorphine Access, Injection Drug Users harm reduction programs	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HOPWA (FY2022) Grant year: 4/1/2021 - 3/31/2022	\$41,777,058	1.16%	N/A	Supportive Housing and Tenant Based Rental Assistance for PLH in the NYC EMSA	Retained in Care
Housing-City Tax Levy (FY 2022) Fiscal Year: 7/1/2021 - 6/30/2022	\$1,999,830	0.06%	N/A	CTL dollars for Subgrantees to utilize for COLA, Indirect Costs and MOCS Indirect Increase	Retained in Care
HRSA Capacity Building Grant Fiscal Year 2022	\$681,000	0.02%	3	Expanded capacity for expand HIV prevention, testing, and treatment services at health centers	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed

i. Funding Source	ii. Funding Amount (\$)	% of Total Funding	iii. Funded Service Provider Agencies/Contracts	iv. Services Delivered	v. HIV Care Continuum Step(s) Impacted
Nassau Suffolk EMA Financial Resource Inventory					
Minority AIDS Initiative (MAI) (FY 2022)	\$441,892	0.01%	7	Mental Health, Medical Case Management and Medical Transportation	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Ryan White HIV/AIDS Program (RWHAP) Part A (FY 2022)	\$5,212,688	0.14%	30	Outpatient/Ambulatory Health Services, Medical Case Management, Medical Transportation, Mental Health Services, Medical Nutrition Therapy, Early Intervention Services, ADAP, Emergency Financial Assistance	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
CDC HIV Prevention and Surveillance Programs (FY 2021)	\$378,562	0.01%	1	Capacity Building Initiative for SA and HIV Prevention for At-Risk Racial/Ethnic Minority Youth and Young Adults , HIV Testing, Outreach, and Care Coordination	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HOPWA (FY 2021)	\$2,265,552	0.06%	5	HOPWA provides housing assistance and related support services for low-income persons with HIV/AIDS and their families. Long Island only uses funds for bricks and mortar.	Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA AIDS Education and Training Centers (AETC) Program (2021)	\$330,000	0.01%	1	Trains health care providers to treat people living with HIV/AIDS through a network of regional centers and associated sites.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Ryan White HIV/AIDS Program (RWHAP) Part C (EIS) (FY 2021)	\$375,528	0.01%	1	EIS, core medical services, support services, quality management, and administration.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
HRSA Ryan White HIV/AIDS Program (RWHAP) Part D (WICY) (FY 2021)	\$1,667,675	0.05%	2	Medical services, clinical quality management, support services, and administrative costs.	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
SAMHSA (FY 2021)	\$16,538,622	0.46%	16	SAMHSA funding includes funding for the Center for Mental Health Services (CMHS), the Center for Substance Abuse Prevention (CSAP), and the Center for Substance Abuse Treatment (CSAT).	Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Suffolk County Dept. of Health Services (FY 2021)	\$20,000	0.00%	1	HIV labs	Retained in Care, Prescribed ART, Virally Suppressed
Nassau County Dept. of Health (FY 2020)	\$207,928	0.01%	1	HIV medications	Retained in Care, Prescribed ART, Virally Suppressed

i. Funding Source	ii. Funding Amount (\$)	% of Total Funding	iii. Funded Service Provider Agencies/Contracts	iv. Services Delivered	v. HIV Care Continuum Step(s) Impacted
Nassau County Dept. of Health (FY 2020)	\$81,266	0.00%	1	Methadone Maintenance Treatment Program	Retained in Care, Prescribed ART, Virally Suppressed
HRSA Capacity Building Grant Fiscal Year 2022	\$325,000		1	Expanded capacity for HIV prevention, testing, and treatment services at health center	At-Risk, High-Risk, Diagnosed, Linked to Care, Retained in Care, Prescribed ART, Virally Suppressed
Suffolk County Dept. of Health Services (FY 2021)	\$93,856	0.00%	3	Methadone Maintenance Treatment Program	Retained in Care, Prescribed ART, Virally Suppressed
TOTAL	\$3,601,009,223				

a. Strengths and Gaps

Strengths. The ongoing community engagement and planning processes allow for regular reassessment of needs and prioritization of resources across the state.

Gaps. While there are always opportunities to improve access to services and how they are delivered, NYSDOH AI has confidence that services are in place to support the care cascade and that these are available across all jurisdictions in the state, while taking into account the needs of specific populations. Gaps are identified through ongoing community engagement and planning processes, as described elsewhere in this report.

b. Approaches to Partnerships

Partnering opportunities. All stakeholders and partners had an opportunity to participate in the planning process, through either community engagement activities (e.g., listening sessions, advisory groups, surveys) or as members of planning bodies. These opportunities are widely promoted by NYSDOH AI, NYCDOHMH and Nassau-Suffolk Counties.

Development of Resource Inventory. As stated above, NYSDOH AI staff, as part of the Integrated Plan workgroup, worked directly with partners in New York City and Nassau-Suffolk Counties to collect accurate information across all NYS programs.

4. Needs Assessment

Achieving the goals of ETE requires addressing inequities and SDOH, such as income and employment instability; access to affordable, quality food, housing, education, and healthcare; economic injustice/poverty; racism; homophobia; transphobia; discrimination; and stigma. Additionally, NYS will plan to integrate the recently adopted National HIV/AIDS Strategy Federal Implementation Plan's five indicators that reflect the multi-dimensional factors of quality of life among people with HIV. The indicators address self-rated health, unmet need for mental health services, hunger/food insecurity, unemployment, and unstable housing or homelessness. These new measures will expand focus beyond clinical measures for people with HIV.

Many ETE efforts, especially outside of EMAs in NYS, are funded by the state through contracted CBOs and providers. The work of many of these organizations seeks to prioritize health equity to promote equal access.

In the Needs Assessment Subsection

- Overarching Needs Assessment Findings
- Services People Need to Access HIV Testing
- Services People with HIV Need to Stay in HIV Care and Achieve Viral Suppression
- Barriers to Accessing HIV Testing, Prevention, and Care and Treatment Services
- EMA and Emerging Communities Need Assessment Activities
- Priorities
- Actions Taken
- Needs Assessment Approach

While equity and health access have been central factors since before development of the ETE plan in 2014, moving forward, NYS must continue to focus on taking the steps necessary to

address mistrust, stigma, and the SDOH that keep people from accessing HIV services and remaining in care. This is reflected in the status neutral approach that is central to this plan. This approach facilitates the integration of prevention and treatment—a unified process from outreach to testing to comprehensive primary care. It addresses the needs of the whole person while mitigating HIV-related stigma and other SDOH.

A large percentage of people with HIV in NYS are aware of their status (94%), in care (80%), and virally suppressed (70%). This is a significant achievement, although the COVID-19 pandemic did impact the state's ETE efforts. An ongoing challenge is that some individuals who remain undiagnosed and outside of care may face significant challenges to testing and engaging in HIV care.

NYSDOH AI has incorporated key approaches related to SDOH into ETE activities. These include status neutral approaches, U=U, and the continuum of HIV care in the state that includes services that address SDOH (e.g., case management, outreach, food and nutrition, housing, transportation, health education, and legal services). These services are designed to meet the needs of specific populations and align with the priorities in *ETE Beyond 2020 Addendum Report* (see below) and the priorities of partners and stakeholders.

- Promote health equity and addressing health disparities and stigma.
- Partner and collaborate with key stakeholders (e.g., policy makers, government, provider, and community partners; consumers; and research entities) to address SDOH.
- Promote services that are responsive to the lived experiences, trauma, and stigma that disproportionately affect communities of color, indigenous populations, LGBTQ+ communities, and transgender and gender non-conforming individuals.
- Assist service providers in implementing trauma-informed practices and policies.
- Promote promising practices that address health disparities. The continuum of HIV care in the state includes services that address SDOH (e.g., case management, outreach, food and nutrition, housing, transportation, health education, and legal services).

There are many overlapping aspects to these outreach and engagement activities; for example, they focus on the same specific populations. As the status neutral approach emphasizes, it is the person, and their life circumstances, that must be considered, not their HIV status. This approach allows NYS to make progress toward ending the HIV epidemic, but more importantly, improve the lives of those specific populations that are engaged in services.

Needs Assessment Activities that Informed Development of Integrated Plan Goals

Ongoing needs assessment activities (described below) informed the development of the Integrated Plan's goals and the strategies prioritized to meet them. The findings of the needs assessment align with and reinforce the state's commitment to health equity and will inform NYS's efforts to continue to reduce disparities and provide more welcoming services. Many of the needs identified are overarching as they relate to systemic issues that impact those vulnerable to HIV, the newly diagnosed, and people with HIV.

Given that this Integrated Plan focuses on the four EHE pillars—diagnose, treat, prevent, respond—the focus areas under which needs fall are indicated. Since ongoing engagement in

care supports achieving viral suppression and those who are virally suppressed cannot transmit the virus, New York considers these activities to also support prevention.

Overarching Needs Assessment Recommendations

- Ensure comprehensive healthcare, with integration of primary care (for HIV, STIs, hepatitis, and other co-occurring conditions) and specialty care for all people, including those who are uninsured or underinsured. *(Pillars: Treat, Prevent)*
- Use a person-centered approach and ensure access to culturally and linguistically appropriate prevention and healthcare services. *(Pillars: Diagnose, Treat, Prevent)*
- Facilitate patient access to their electronic medical records, pharmacy, and laboratory data to empower patients and improve continuity of care and adherence. *(Pillars: Treat, Prevent)*
- Address stigma and discrimination in healthcare services. Expand quality indicators to include stigma and discrimination to provide a baseline for providers and health plans to use to improve a patient's healthcare experience. *(Pillars: Diagnose, Treat, Prevent)*
- Ensure access to care for residents of rural, suburban and other areas of the state. *(Pillars: Diagnose, Treat, Prevent)*
- Address health inequities and social determinants of health. *(Pillars: Diagnose, Treat, Prevent)*
- Improve engagement with specific populations, (e.g., youth, people aging with HIV, incarcerated individuals, people of trans experience). *(Pillars: Diagnose, Treat, Prevent)*
- Assess and address the impact of the COVID-19 pandemic. *(Pillars: Diagnose, Treat, Prevent)*
- Continue telehealth services statewide post COVID-19; address barriers to these services experienced by specific populations (e.g., lack of access to technology; lack of knowledge related to use of technological tools). *(Pillars: Treat, Prevent)*
- Address mental health and substance use by using a trauma-informed care approach and harm reduction. *(Pillars: Diagnose, Treat, Prevent)*
- Address the unique healthcare needs of specific populations, including, but not limited to, LGBTQ+ and Hispanic/Latino communities, incarcerated individuals and those preparing for re-entry, and people with disabilities and multiple health conditions including mental health and substance use. *(Pillars: Diagnose, Treat, Prevent)*
- Educate providers and consumers on healthcare-related topics in relation to specific populations (e.g., LGBTQ+ individuals, people with disabilities, people with multiple medical conditions, youth). *(Pillars: Diagnose, Treat, Prevent)*
- Increase focus on health literacy and health education for younger individuals. *(Pillars: Diagnose, Treat, Prevent)*

Summary of Needs by Region

In addition to there being overarching needs, there are needs specific to geographic regions. The *ETE Beyond 2020 Addendum Report* presented need-related themes by region, which were identified through the needs assessment activities that informed the report.

Table III.1. Key Themes by Region from NYS ETE Beyond 2020 Addendum Report Listening Sessions

Identified Theme	NYC						ROS					
	Upper Manhattan	Lower Manhattan	Queens	Staten Island	Brooklyn	Bronx	Nassau-Suffolk	Hudson Valley	Northeast	Central	Finger Lakes	Western
Additional community outreach and engagement	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Adolescent testing, prevention, and care services			✓	✓	✓			✓				
COVID-19 impact	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Data sharing platforms		✓		✓					✓			
Expanded PrEP/PEP/nPEP access	✓				✓		✓			✓	✓	
Focus on young MSM of color										✓		
Food security	✓				✓	✓	✓	✓	✓		✓	✓
Housing	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Inclusive conversations					✓						✓	✓
Income/Employment security	✓			✓	✓	✓	✓	✓	✓		✓	
LGBTQ prevention and care, with a focus on transgender individuals			✓		✓	✓	✓			✓		
Linguistically, culturally appropriate materials and services			✓			✓				✓		✓
Mental health services	✓			✓	✓		✓	✓	✓	✓	✓	✓
Opioid use, HCV, STI, and HIV links	✓		✓				✓	✓	✓	✓	✓	✓
Provider training, education, and cultural sensitivity		✓	✓	✓		✓	✓	✓	✓	✓		✓
Routine testing outreach and access					✓					✓		
Rural access to testing, prevention, and care services										✓		
Services for individuals over 50	✓		✓			✓					✓	
Sexual health education	✓						✓			✓		✓
Substance abuse treatment						✓	✓	✓	✓	✓	✓	
Syringe exchange											✓	
Technology-related access and education (including Telemedicine and Telehealth, Zoom, Social media)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Transportation		✓					✓	✓		✓	✓	✓
Trauma-informed care approach (TIC)	✓	✓		✓				✓			✓	

Services for People who Need to Access HIV Testing. The 2022 listening sessions identified three needs related to HIV testing.

- Greater availability of rapid HIV testing in nontraditional settings (i.e., many do not have access to or seek primary care where they could receive testing). (*Pillar: Diagnose*)
- Greater availability of home HIV testing. (*Pillar: Diagnose*)
- Incentives for at-risk populations (e.g., immigrants) for HIV testing and linkage to care. (*Pillar: Diagnose*)

Within New York's framework of health equity, NYSDOH AI is working to improve availability and accessibility of HIV testing and address the concerns of specific populations.

An estimated 10,200 people in New York are living with HIV but do not know their status. These individuals must be identified and linked to treatment to improve their health and to reduce the risk of transmission to partners. Specific populations include: MSM; youth, including young MSM; LGBTQ+ people; people who use drugs; Medicaid recipients; people who are uninsured or underinsured; women; communities of color; incarcerated people; and people receiving hospital or primary care, who are required by law to be offered an HIV test. Additionally, individuals who are out of care and those who are not virally suppressed, while not the primary focus of HIV testing programs, are people who should be linked or reengaged in treatment. Populations are addressed based on epidemiologic data related to new diagnoses and risk behaviors. Populations are also addressed based on *The Blueprint* priorities and input and recommendations received through the community engagement and planning process,

specifically recommendations and implementations strategies identified by the ETE Subcommittee and the ETE regional and population- and topic-specific workgroups.

Testing by CBOs and in Other Settings. NYSDOH AI has contracts with community partners so that HIV testing/referral is available in a variety of settings, especially those that serve at-risk individuals. CBOs that provide HIV testing have been advised to ensure their efforts reach specific populations such as Black and Hispanic/Latino MSM, women of color, and transgender men and women. CBOs use evidence-based outreach strategies to address HIV stigma and present knowledge of HIV status as the community norm. Several CBOs are using vans to reach community residents or to make testing available in environments where people engage in risk behaviors. HIV testing is available onsite at NYSDOH AI authorized SSPs.

Testing in Healthcare Settings. Since 2010, NYS Public Health Law (NYSPHL) has required healthcare providers to offer HIV testing to all individuals age 13 to 64 as a routine part of healthcare (see below for more information on laws related to HIV testing). The *Expanded HIV Testing Partnership Model* supports capacity building in healthcare facilities to increase HIV testing in underserved communities. It also created billing standards for reimbursement so that HIV testing is sustainable in these setting. As part of this initiative, two public service announcements (PSA) promote HIV testing and partner services—one targeting providers and the other targeting community members. The PSAs have been distributed on social media, through medical associations, and by CBOs.

Home Testing. To reach individuals who do not access HIV testing in traditional and non-traditional settings, NYSDOH AI and NYCDOHMH offer self-testing through the HIV Home Test Giveaway campaign for individuals at risk for HIV infection who may not be reached in other HIV testing settings. Both state and city campaigns were initiated in 2016 and expanded in April 2020 in response to the COVID-19 public health emergency. The campaigns were further expanded in November 2020 to include cisgender Black women and the LGBTQ+ community.

Services People Placed At-Risk of HIV Need to Stay HIV Negative

While the 2022 listening sessions identified the need for more LGBTQ+ healthcare centers that provide comprehensive healthcare and sexual health services, including access to PrEP and HIV testing for MSM and transgender and gender nonconforming populations. These are not the only needs in this area. As noted above, addressing the systemic issues related to health equity will strengthen New York's services to specific populations.

Also, it is important to note that NYSDOH AI has made a significant effort to increase access to PrEP. This includes the state-funded PrEP Assistance Program (PrEP-AP), which provides PrEP services to people who are uninsured or underinsured and a voluntary PrEP directory that allows people to search for PrEP prescribers based on their location. According to the directory, PrEP prescribers are available in all areas of the state with the highest number of new HIV diagnoses.

As of 2022, there are 25 NYSDOH authorized SSPs and four Second Tier Syringe Exchange Programs with 17 programs across 56 sites in NYC, and 11 programs with 28 locations across the remainder of the state. These programs are designed to reduce the risk of acquiring HIV through injection drug use. The range of services offered varies across the sites. These include

HIV, STI, and hepatitis counseling and testing; peer-based risk reduction counseling; behavioral interventions; mental health counseling; opioid overdose prevention training; aftercare for overdose; and care management.

Services to Link Newly Diagnosed to Care and Treatment

The needs assessment identified two areas for improvement, which are very general.

- Increase linkage to care. (*Pillars: Treat, Prevent*)
- Ensure rapid initiation of ART. (*Pillars: Treat, Prevent*)

As the epidemiologic snapshot indicates, 83% of newly diagnosed individuals are linked to care within 30 days of diagnosis. Across NYS we are working to do better through several initiatives and activities.

Early identification of individuals with HIV/AIDS (EIIHA) is thoroughly integrated throughout the ETE and the Integrated Plan. These activities include:

- Funding linkage and retention initiatives in Medicaid managed care plans to engage the individuals in care and treatment;
- Uninsured Care Programs (UCP) provides universal access to HIV medications and care by bridging the gap between Medicaid and private insurance coverage; and
- Revision of the UCP enrollment process to facilitate same-day enrollment and rapid access to treatment.

NYSDOH AI's policy on rapid initiation of ART states that all new HIV diagnoses are an immediate call to action for every provider who engages with that person, with the goal being rapid initiation of ART. Providers serving people with HIV should strive for same-day initiation of HIV treatment. An updated clinical guideline was published on *When to Initiate ART and Rapid ART Initiation*. The guideline was developed for primary care providers and other clinicians to encourage initiation of ART at the time of HIV diagnosis, ideally on the same day or within 96 hours.

In conjunction with this policy, the Data to Care Rapid Treatment Project was established. It focuses on identifying areas of improvement in the steps of the treatment-to-viral-load-suppression process. Work includes enhanced data collection and detailed data reviews to identify barriers to rapid ART initiation and the development of programmatic interventions to ensure same-day initiation of ART or within four to seven days of diagnosis. Educational materials have been developed to introduce newly diagnosed to the concept of rapid treatment.

Services that People Need to Stay in Care and Achieve Viral Suppression

The needs assessment identified multiple ways to improve retention in care and support consumers in achieving viral suppression.

- Use data to identify HIV-positive people who have not achieved viral suppression and address their support service, behavioral health, and adherence needs. Use client-level data to identify and assist patients lost to care or not virally suppressed. (*Pillars: Treat, Prevent*)

- Monitor performance related to viral suppression by HIV providers, facilities, and managed care plans to improve treatment outcomes across the state. (*Pillars: Treat, Prevent*)
- Use electronic medical record prompts in all settings to identify non-suppressed people in need of re-engagement or other assistance. (*Pillars: Treat, Prevent*)
- Ensure adequate, stable levels of support to people with HIV in housing, transportation, employment, nutrition, substance abuse treatment, mental health services, and/or childcare. (*Pillars: Treat, Prevent*)
- Train and employ people with HIV as peer guides who can help others navigate support systems and offer personal understanding and encouragement to overcome stigma and discrimination that may undermine treatment adherence. (*Pillars: Treat, Prevent*)
- Address gaps in healthcare resources and services for people aging with HIV. (*Pillars: Treat, Prevent*)

The following activities are examples of what is currently being done across the state to support retention and viral suppression.

- Retention and adherence programs that identify people out of care and not virally suppressed and link them to care and treatment.
- Matching epidemiologic and Medicaid data to identify people in Medicaid managed care plans who are out of care and not virally suppressed.
- Expanded partner services, which uses HIV epidemiology data to identify previously diagnosed and reported people with HIV who appear to be out-of-care and uses partner services staff to re-engage these individuals in medical care and notify and test/treat partners.
- Retention and adherence initiatives targeted to specific populations, such as adolescents/young adults, young MSM, young MSM of color, and transgender people.
- Provision of a range of services that address SDOH and facilitate linkage to care and treatment, such as housing services, case management, food and nutrition, transportation, legal services, and benefits counseling.
- Implementation of the Client Progress Report (CPR), which matches AIRS data and HIV Surveillance data to create a consumer level retention and viral suppression status report. This report is distributed to eligible providers to assist in determining the care status of their consumers.
- In NYC, there are also projects underway to facilitate equitable long-acting injectable (LAI) ART awareness, uptake and adherence. The NYCDOHMH Bureau of Hepatitis, HIV, and STI (BHHS) Clinical Operations and Technical Assistance Program is working on the provider detailing side, and the BHHS Care and Treatment Program is working on a National Institutes of Health (NIH) implementation-science grant to identify and pilot test RWHAP medical case management-type support service strategies to facilitate access and adherence to LAI ART. These efforts are directed at the Treat pillar and the goals of viral suppression and health equity.

Barriers to Accessing Existing HIV Testing, Prevention, Care, and Treatment Services

As mentioned above, the needs assessment process identified many overarching needs that, when addressed, will result in a more welcoming, accessible, and empowering healthcare experience. This will hopefully make people more likely to get tested for HIV and engage and stay in care. The needs assessment also identified barriers specific to testing, engagement, retention, and supporting those placed at risk to remain negative.

State Laws and Regulations Related to HIV Testing. NYS has several laws designed to increase access to HIV testing. NYSDOH AI has also enacted policies to support access to testing. Since 1990, the state has supported the integration of HIV testing in healthcare settings via Medicaid and required integrated HIV testing in grant-funded programs. Laws related to HIV testing are listed below.

- Since 2010, NYS Public Health Law (NYSPHL) has required healthcare providers to offer HIV testing to all individuals age 13 to 64 as a routine part of healthcare. In 2014, the state removed the requirement for written consent; in 2015 the requirement was removed in correctional facilities; and in 2016 the upper age limit of 64 was eliminated. Steps are taken to ensure the law is observed such as review of licensed facilities with emergency departments for HIV testing policies and procedures, the review of patient admissions for compliance with the mandatory offer, and a review of FQHCs of NYC to determine if HIV testing was conducted when an individual had an STI and if STI testing was conducted when an HIV test was conducted.
- The NYS Public Health Law was amended to require reporting of acute HIV within 24 hours. This modification supports the identification of people with HIV early in their infection and linking them to treatment. Initiation of treatment during acute HIV infection can improve health outcomes and reduce HIV transmission.
- An amendment to the Public Health Law has been requested to mandate reporting of negative HIV screening results, which will aid in the identification of newly acquired infections through the determination of a seroconversion window. This reporting will be especially critical in facilitating rapid initiation of HIV treatment. It will also assist in targeting testing initiatives.
- Future legislative proposals include modifying state law to allow pharmacists and dentists to conduct HIV testing.

Barriers to Accessing HIV Services (Prevention, Testing, Care, Treatment). New York's statewide approach has been to tailor services to the needs of specific at-risk populations, creating a more welcoming environment. In support of a status neutral approach, New York strives to offer a range of services addressing SDOH regardless of HIV status. These include specialized care centers for adolescents and youth access programs; transgender healthcare programs; prevention and related services for gay men and MSM; SSPs; drug user health hubs; LGBTQ+ health and human services; family-centered care for women; and the Uninsured Care Programs.

Below are just two of many examples of this tailored approach within the NYS.

- Activities specific to MSM include a home HIV testing campaign.

- Activities associated with incarcerated individuals include the Criminal Justice Initiative (CJI). The goal of the CJI is to provide interventions and support services that reduce the spread of HIV/STI/hepatitis C and meet the priority needs of people with HIV and at-risk in the NYS Department of Corrections and Community Supervision system. The goal is to identify new infections and ensure connection to medical care and partner services. The CJI uses peers to deliver HIV/STI/hepatitis C-related information. It is designed to support people with HIV exiting NYS correctional facilities in achieving successful community re-entry, with a focus on addressing barriers to services.

Needs Assessments Statewide, EMAs and Emerging Communities Activities

In addition to statewide activities to assess needs, below are brief summaries of needs identified by EMAs, other NYS communities, and through information gathered from statewide regional listening sessions.

EMA Needs Assessment: New York City. The NY EMA, which includes New York City and Westchester, Putnam and Rockland Counties, continues to have one of the largest HIV burdens in the U.S. During the recent period of concerted efforts to implement *The Blueprint* and NYC ETE Plan (2016-2020, the last year for which data are available), there was a 40% decrease in new HIV diagnoses in the NY EMA from 2016 to 2020.

Based on information provided in the NY EMA Grant Year 2022 RWHAP Part A submission, in 2020, among all people newly diagnosed with HIV in the NY EMA, 78% were men, 47% were non-Hispanic Black, 34% were Hispanic/Latino, 75% were younger than 45, and 59% were MSM, including MSM with a history of injection drug use (MSM-IDU). In the same year, 3% of new HIV diagnoses in the NY EMA were among transgender people, 98% of whom were transgender women. Approximately 91% of newly diagnosed transgender women were Black or Hispanic/Latina, nearly all of whom were between the ages of 20 and 29. In 2020, among people with HIV in the NY EMA, 72% were men, 43% were Black, 33% were Hispanic/Latino, and 59% were MSM, including MSM-IDU. While new diagnoses remain concentrated among people younger than 45 (75%), people 45 and older accounted for more than half of people with HIV in 2020 (69%). These data highlight the already large number of people aging with HIV in the NY EMA and underscore the importance of assessing and addressing their evolving needs.

Equity Framework. The prevalence of HIV is highest among Black and Hispanic/Latino New Yorkers and among people who live in neighborhoods of high or very high poverty. Many people in these communities experience multiple challenges that severely impact health, including racism, stigma, poverty, trauma, mental health issues, food insecurity, and housing instability.

Increased Need for HIV-related Services. As the number of people with HIV has increased and inequities have persisted, demands on the NY EMA's service system and needs along the entire HIV care continuum have grown. Specific actions to address needs include:

- Increase testing to reduce late diagnoses;

- Provide and disseminate information to people at risk for HIV about the importance of early HIV diagnosis;
- Ensure prompt linkage to care following diagnosis;
- Increase outreach among people who have dropped out of care;
- Increase efforts to identify barriers to viral suppression among people with HIV who are in care, particularly among vulnerable populations; and
- Address barriers to care for different populations of people with HIV through specific actions (e.g., ensuring a diverse body of service providers who represent the lived experience of different populations of people with HIV, providing services that are affirming and reflect cultural humility and trauma-informed care, and tailoring information related to HIV testing, care, and treatment to address cultural and linguistic differences).

EMA Needs Assessment: Nassau-Suffolk. The two-county Nassau-Suffolk EMA is located on Long Island—with the population of people with HIV almost evenly split between the two counties. The people with HIV in the EMA are disproportionately Black, Hispanic/Latino, male, and people above the age of 50 when compared to their representation in the general population. New infections among Hispanic/Latino communities continue to grow, making this population the majority of people with HIV in the EMA. People who identify as MSM represented the largest number of newly diagnosed people with HIV. In addition, data indicate that risk factors include substance use; involvement in the legal system; and mental health co-morbidities. The 2022 listening sessions also noted that the political climate of Long Island perpetuates stigma and represents a barrier to HIV prevention and care services.

At-Risk Population. Using various data, the Nassau-Suffolk EMA has identified four at-risk populations: Black, Hispanic/Latino, MSM, and cis and transgender women of color. In addition, HIV testing patterns are reviewed using data provided by NYSDOH AI annually and are reflected in the EIIHA plan with collaborative partners in outreach, early intervention services, and HIV prevention. Specific populations include those more vulnerable to HIV infection for reasons that include engagement in high-risk behaviors, poverty, marginalization by society, and fear of accessing HIV services.

Needs. Nassau-Suffolk EMA needs assessment activities have identified the following needs:

- Services that are culturally and linguistically responsive to a shifting demographic;
- Services that address subsistence needs such as food, housing, and transportation;
- Messages that reach MSM and other targeted groups and services in place to link and keep them in care;
- Affordable housing for people with HIV; and
- Transportation for people with HIV to provide access to primary care, core medical services, and support services (in a context of limited public transportation).

Emerging Communities: Albany, Buffalo, and Rochester. Through RWHAP Part B, NYS receives emerging communities (EC) funding, which is distributed in three regions in NYS: Albany; Buffalo; and Rochester. The Health Resources and Services Administration (HRSA) determines the award amounts and the geographic region of each EC annually. Use of these

funds is responsive to identified needs, as supported by the recommendations and input through the existing planning and community engagement processes.

This funding is used along with all NYSDOH AI resources to ensure geographic parity in access to HIV and status neutral services. It supports one provider in each region. Currently, services are targeted to MSM. They focus on non-medical case management, health education/risk reduction, and psychosocial support emphasizing linkage to and retention in care and treatment. The proposed services are consistent with the local needs assessments, *The Blueprint*, and the Integrated Plan.

a. Priorities

The goals and strategies presented in this plan were drafted and prioritized through New York's ongoing planning and needs assessment processes (See Section II). Further insight into needs was provided by the 2022 listening sessions. In July 2022, planning groups engaged in a process to prioritize specific strategies to support the achievement of this plan's goals. These strategies are presented in Section V.

b. Actions

We have described many of the ongoing activities carried out across the state to achieve the goals of the ETE and this plan. In addition, Section V includes strategies, prioritized by planning groups, that will support achievement of the plan's goals.

c. Approach

Identifying Needs. Needs assessment is ongoing as part of the ETE initiative and public advisory planning process and conducted by the ETE Subcommittee to the NYS AIDS Advisory Council. The Subcommittee identifies needs and recommends implementation strategies to respond to these needs. It is made up of community leaders, advocates, health and social services providers, researchers, government representatives, and consumers. In addition, there are population- and topic-specific advisory bodies that identify needs for specific populations, including but not limited to Asian/Pacific Islanders, Native Americans, Non-English speaking migrant seasonal farm workers, new immigrants, women, Latino gay/bisexual men, Black MSM, young adults, and older adults (50+). There are also regional ETE committees throughout the state that focus on the needs specific to each region. People with HIV participate in all these groups.

2020 Listening Sessions, ETE Beyond 2020 survey. The listening sessions were designed to get feedback and provided opportunities for stakeholder discussions to identify needs and increase the areas of focus for ETE efforts beyond 2020. Each session was attended by an average of 55 participants representing different communities impacted by HIV in NYS.

Each listening session included a trauma-informed care introduction and exercises to acknowledge current realities pertaining to COVID-19, loss, structural racism, and other difficult present-day experiences. The listening sessions were regionally based and representative of counties throughout NYS.

Theme-based listening sessions focused on the following topics: sexual health; trauma-informed care; health equity; aging with HIV; faith communities; and LGBTQ+ Health. Regional sessions, focused on local needs, were conducted for Upper Manhattan, Lower Manhattan, Bronx,

Brooklyn, Queens, Capital District, Buffalo, Rochester, Syracuse, Mid-Lower Hudson Valley, Nassau, Suffolk and Staten Island.

The feedback gathered from the listening sessions was utilized to develop the ETE Beyond 2020 survey that collected quantitative data to complement the qualitative data collected from the listening sessions. Input from advisory bodies, the ETE population- and issue-specific advisory groups, the listening sessions, and the statewide survey were used to develop the ***ETE Beyond 2020 Addendum Report***. Input from advisory bodies, the ETE population and issue-specific advisory groups, the listening sessions, and the statewide survey were used to develop the *ETE Beyond 2020 Addendum Report*. As mentioned above, needs assessment findings presented in the *ETE Beyond 2020 Addendum Report* were used to inform needs assessment activities for the Integrated Plan. The report describes how NYS will build on *The Blueprint* to take the ETE initiative beyond 2020.

Needs Assessment Activities, 2022. In June 2022 NYSDOH AI held two virtual listening sessions to gather stakeholder input on the Integrated Plan. The findings from these sessions are reflected in this plan.

Unmet Need Estimate. As part of the Part B base grant application for FY2022, NYSDOH AI conducted an unmet need analysis using the state HIV epidemiology system. HIV epidemiologic data were combined AIRS data and Uninsured Care Program (ADAP) data. The AIRS and ADAP data represent the number of consumers in the jurisdiction who received any Part B or Part-B related funded service. These data also provide information regarding the care patterns for these individuals. The epidemiologic data includes care status indicators (e.g., viral load and CD4 lab reporting), the ADAP data includes additional information about medical visits, and the AIRS data includes information on medical case management. Combining these data sets provides a more comprehensive picture about the care and services consumers are receiving.



Section IV: Situational Analysis

This section focuses on the strengths, challenges, and identified needs for the jurisdiction. It draws on both quantitative and qualitative data from numerous sources, as well as input from planning groups and community engagement activities (e.g., listening sessions). It describes the specific populations identified by planning groups. It also presents ongoing and emerging challenges, both statewide, in NYC, and in other specific populations/geographic areas; service gaps; workforce issues; and other emerging issues that will impact achievement of the goals of the Integrated Plan.

In this Section

- NYS Response to HIV: Strengths
- Themes Identified by Needs Assessment Activities
- NYS Workforce Issues
- Challenges and Mitigation Strategies
- EMA Situational Analysis
- NYS Specific Population

1. Situational Analysis

Informing the Integrated Plan: Overarching Elements

There are several key elements that form the overarching framework for the Integrated Plan. These key elements are reflected in the goals and strategies of the Integrated Plan.

Health Equity. Health equity emphasizes equal access to healthcare to ensure everyone has the same opportunity to be as healthy as possible. Efforts to enhance health equity address:

- **Social Determinants of Health.** These relate to conditions where a person lives and if healthcare is available and accessible. SDOH focus on many issues that impact people's daily lives: housing; transportation; racism/discrimination; stigma; violence; education and employment opportunities; availability of nutritious food (e.g., food deserts); opportunity for physical activity; and air and water quality. Also considered are language and literacy skills—does the person have the ability to effectively communicate with clinicians. Health literacy focuses on the ability to talk about and understand health issues.
- **Intersectionality.** Race, class, gender, sexual orientation, physical ability, and other factors create an overlapping and interdependent system of discrimination and disadvantage. People have unique experiences related to discrimination, oppression, and stigma. In creating accessible and welcoming services it is important to consider everything that could marginalize a person.

Stigma Reduction. While primarily focused on HIV, stigma-reduction efforts in NYS also focus on racism, homophobia, transphobia, and other factors. These efforts have been underway for several years.

The Stigma and Resilience (STAR) Coalition is a collaboration with NYSDOH AI, NYCDOHMH, NYC HPG, and the HIV Center for Clinical and Behavioral Studies and the NECA AETC, both at

Columbia University. The goal of the coalition is to involve agencies and others who are committed to reducing stigmas that work against optimal HIV prevention, care, and treatment.

The NYSDOH AI supported a statewide, multi-level anti-stigma campaign on billboards, subway cars, healthcare sites, pharmacies, social media platforms/dating sites, and TV PSAs. As part of the ETE initiative, this coalition guided the work of four projects in New York City: *Mapping NYC Stigma-Reduction Initiatives*, *Compendium of Successful Stigma-Reduction Approaches*, *STAR Project Town Hall*, and *Stigma and Drivers*. The provider training, *From Stigma to Affirmation*, identifies steps to address stigma. NYSDOH AI has also encouraged providers to diversify the cultural/ethnic climate within their organizations by hiring staff who reflect the communities they serve.

Status Neutral Approach. This health equity approach to HIV education, testing, and treatment emphasizes treating everyone regardless of their HIV status with similar access to services. This approach integrates prevention and treatment services so that both become part of comprehensive primary care and address the needs of the whole person while mitigating HIV-related stigma. All consumers receiving HIV testing or other services (e.g., STI screenings) are treated the same. Depending on the results of HIV testing, people are referred to either HIV prevention or HIV treatment. Those who are HIV negative are referred to PrEP and condoms. Those who are HIV positive are referred to, or re-engaged in, treatment.

Undetectable=Untransmittable (U=U). In September 2017, the NYSDOH AI became the first state health department in the nation to sign on to the Prevention Access Campaign Undetectable=Untransmittable Consensus Statement. This statement affirms that people with HIV who have achieved and continue to maintain an undetectable viral load do not sexually transmit HIV. U=U aligns with NYSDOH AI's efforts to destigmatize HIV and to support innovative biomedical and social efforts to improve the health and well-being of all people with HIV.

Sexual Health Focus. Borne out of the pioneering work and success of New York City's sexual health clinics, the sexual health focus is embraced statewide to offer comprehensive, affirming sexual healthcare, including STI and HIV testing; stigma free sexual history taking; supportive sex positive environments; PEP; PrEP initiation and navigation; and partner services. NYSDOH AI's Office of Sexual Health and Epidemiology conducts behavioral epidemiology to guide policy and programmatic development. Several sources of primary and secondary data are used to understand risk behaviors in: 1) groups at higher risk of STIs through HIV/STI Partner Services disease intervention activities analytics; 2) localities with higher STI rates through supporting local testing efforts; and 3) the general population through supporting inclusion of a state-added sexual behavior module on the annual statewide Behavioral Risk Factor Surveillance System (BRFSS) survey, coordinated with the NYSDOH Division of Chronic Disease Prevention.

NYS Response to HIV: Strengths

By necessity, NYS has been at the forefront of our nation's response to HIV. These efforts have been guided by the NYSDOH AI, which is committed to eliminating new infections, improving the health and well-being of people with HIV, STIs, and viral hepatitis, and improving LGBTQ+ health and the health of people who use drugs.

Below are the strengths that New York brings to the ETE effort.

- Significant consumer and stakeholder involvement.
- Commitment to health equity, reduction of SDOH, and elimination of stigma.
- Robust local, regional, and state-level planning processes.
- Ongoing needs assessment activities.
- Focus on use of data to track and report progress on ETE goals.
 - This includes creation of the web-based, public-facing ETE Dashboard system that allows users to measure, track, and disseminate actionable information on progress toward ETE goals.
- The NYS Quality of Care (QOC) Program, which is designed to ensure equitable access to HIV care that promotes the health and well-being of all people with HIV in NYS.
 - The program collects data on the performance of HIV providers, uses these data to identify areas for improvement, and supports improvement activities by building capacity for quality management.

Themes Identified by Needs Assessment Activities

Recent needs assessment findings reflect how the COVID-19 pandemic and the social justice movement have had a tremendous impact on communities across the state. In particular, COVID-19 shed greater light on health disparities among Black, Indigenous, and Hispanic/Latino communities in the state. Below we present major themes from needs assessment activities and the EHE pillars that are the focus of the theme. We also present identified challenges and needs that have been identified through needs assessment activities over the past few years. These challenges and needs are addressed by the goals and strategies presented in Section V.

Address Health Inequities and SDOH *(Pillars: Diagnose, Treat, Prevent)*

- Address inequities and disparities among vulnerable populations (e.g., low income, unstable housing, intimate partner violence, people with disabilities).
- Engage communities (e.g., leaders, stakeholders, people with lived experience).
- Better understand intersectionality of demographic factors (e.g., examine data by race/ethnicity).
- Employ strategies to address health inequities that focus on multiple conditions (e.g., HIV, STIs, heart disease, diabetes).
- Assess the educational needs of vulnerable populations.

Needs Assessment Activities

As noted in previous sections, as part of ETE, NYSDOH AI and our partners carried out multiple needs assessment activities in the last few years. The findings have been provided to our planning partners and informed the development of the Integrated Plan. Reports from 15 population- and issue-specific advisory group (most completed 2018 – 2020) were analyzed and included. While the reports have different formats, most include a description of their planning process and specific recommendations.

- 2019 listening sessions held by planning bodies (2019).
- 2020 NYSDOH AI held 13 regional community listening session, eight theme-based sessions, and two sessions for medical providers.
- 2020 and Beyond ETE Survey.
- 2022 Virtual Community Listening Sessions (2).

- Provide non-English educational materials (e.g., Spanish, Chinese, Russian, Italian, French).

Systemic Issues (Pillars: Diagnose, Treat, Prevent)

- Loss of 340B funding
- Criminalization of sex work
- Racism
- Stigma (HIV, homophobia, transphobia)

Access to Adherence, Treatment, and Prevention Services (Pillars: Diagnose, Treat, Prevent)

- Assist consumers in returning to routine care, treatment, and medication adherence.
- Educate providers and consumers on healthcare-related topics pertaining to specific populations (e.g., LGBTQ+, people with disabilities, people with co-morbidities, older adults (50+) with HIV, youth).
- Expand outreach and harm reduction strategies.
- Integrate trauma-informed care (including policies to ensure this strategy is being implemented).
- Implement strategies to prevent re-traumatization. The focus should be “what happened to you?” not, “what is wrong with you?”
- Continue telehealth services, address access issues (e.g., limited internet access) and provide training to consumers.
- Continue home visits to support retention in care.
- Assess effectiveness of service delivery changes resulting from COVID-19 (e.g., delivery of prescriptions, 90-day refills).

Engage Specific Populations in Healthcare Services (Pillars: Diagnose, Treat, Prevent)

- Assess the healthcare needs of underserved populations (e.g., LGBTQ+, Hispanic/Latino, incarcerated/re-entering individuals, people with disabilities, people with mental illness, people with substance use disorder).
- Increase engagement of people with unstable housing to support adherence.
- Increase health literacy/health education, resources, and services for youth/young adults.
- Address gaps in healthcare services for older adults (50+) with HIV.
- Address needs of incarcerated/re-entering individuals.
- Create safe spaces for vulnerable populations (e.g., LGBTQ+, transgender) that will facilitate open communication/interaction with providers.

Community Engagement/Outreach and Collaborations (Pillars: Diagnose, Treat, Prevent)

- Increase coordination across the NYSDOH AI portfolio to improve collaboration with stakeholders.
- Increase collaboration with organizations focused on mental health and substance use disorder.
- Offer HIV testing in non-traditional healthcare settings statewide.
- Identify new ways to work with faith-based communities/organizations.
- Improve data reporting practices and increase access to data for stakeholders.
- Utilize additional social media and virtual platforms to promote HIV services (with input from consumers and stakeholders).

- Increase opportunities for non-traditional community organizations to receive funding/support to engage vulnerable populations.
- Increase partnerships with organizations that address SDOH (e.g., nutrition, housing).
- Work with communities to provide interactive and educational activities in hard-to-reach areas of the state.
- Foster relationships with community leaders and local businesses to address SDOH.

Increase and Enhance Mental Health and Substance Use Disorder Services (Pillars: Diagnose, Treat, Prevent)

- Increase mental health, health education, and harm reduction services to offset barriers to care.
- Assess trends in substance use disorder and mental illness post COVID-19.
- Integrate a trauma-informed approach to treatment.
- Provide more educational materials related to mental health and substance use disorders.
- Address shortage of mental health providers.

Communication and Education (Pillars: Diagnose, Treat, Prevent)

- Campaigns that promote sex positivity tailored to specific communities (e.g., LGBTQ+, people who use drugs, youth, faith-based).

Workforce Issues

The COVID-19 pandemic, starting in March 2020, greatly changed healthcare in profound ways, and New York was again the epicenter. It lay bare the stress and risk that clinicians face, especially in health emergencies. Lives were lost and clinicians left the field due to burnout and other considerations. This exacerbated current and expected workforce shortages.

Workforce-related issues were highlighted in the 2017-2021 Integrated Plan. The previous Integrated Plan included findings from a needs assessment conducted during November 2015-June 2016 by the RWHAP-funded NECA AETC to identify HIV training and technical assistance gaps and priorities in the region covered by the NECA AETC, which includes the states of New York and New Jersey and the territories of Puerto Rico and U.S. Virgin Islands. The assessment echoed other local and national findings—identifying a shortage of trained providers in many parts of the region, which at that time was expected to worsen due to retirement of long-time HIV providers.

Healthcare Providers: Training Needs

- Strategies to address stigma homophobia, transphobia, racism
- Cultural competency
- Trauma-informed care, including resources for trauma management
- Substance use disorder treatment options
- HIV, HCV, and STI treatment options
- Social Justice
- Geriatrics, issues related to aging with HIV (i.e., needs of people with HIV over 50)

Preliminary data (unpublished) from the AETC Program HIV Workforce study conducted in spring 2022 indicate that retirement may significantly reduce the HIV workforce in New York.

The purpose of this study was to evaluate the number of current practicing healthcare providers prescribing HIV antiretroviral medication (for PEP, PrEP, and/or ART) and the number of care providers projected to continue to provide HIV-related care over the next five years. The study focused on prescribing HIV clinicians and pharmacists.

- Twenty-one (21) percent of respondents reported it was VERY likely they would retire from clinical practice entirely within the next five years. An additional 15% said it was somewhat likely they would retire.
- Thirty-four (34) percent said they would be reducing or stopping to see HIV patients within next five years. While the top reason (26%) was too much time spent on documentation, retirement (15%) and burnout (15%) were also cited.
- Thirty-six (36) percent reported the current supply of clinicians providing direct medical care to patients with HIV in their community is unable to meet demand.
- When asked about concern for shortage of various professions over the next five years, the most frequently cited concerns were around mental health providers (92% concerned); dentists (78%); providers treating substance use disorder (74%); and infectious disease specialists (72%).

Three important workforce issues raised in NYSDOH AI's 2022 listening sessions include:

- Workforce reflective of populations served (i.e., more diversity in healthcare workforce);
- Need for more mental health providers; and
- Expanded use of peers in delivery of services (trainings to professionalize peers, advancement opportunities, support as they engage in work).

Training Needs

Training needs, identified through needs assessment activities by NECA AETC and NYSDOH AI, have remained fairly consistent in recent years.

Table IV.1: Training Needs, Topics

NECA AETC November 2015- June 2016 Needs Assessment	NYSDOH AI 2020 Listening Sessions	NECA AETC, 2021- 2022 Needs Assessment
• Strategies for retaining and re-engaging consumers in care • Better integration of mental health and substance use treatment in care • Hepatitis C • HIV and aging	• Strategies to address stigma homophobia, transphobia, and racism • Cultural competency • Trauma-informed care, including resources for trauma management • Substance use disorder treatment options • HIV, hepatitis C, and STI treatment options	• Stigma • Behavioral health • Health equity and racial justice • PrEP • EHE initiatives • HIV and aging • Immediate ART • Oral health

	• Social Justice	<i>(Ranking of topics by likelihood agencies will seek training on the topic)</i>
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These topics identified through needs assessment activities also align with NECA AETC's most frequently requested training topics in 2021-2022. These included: stigma/discrimination; cultural competence/humility; PrEP; motivational interviewing; retention/re-engagement in care; treatment as prevention (U=U); mental health disorders; substance use disorder; and behavioral prevention.

In addition to training HIV providers, as the population of people over 50 with HIV increases, HIV providers are collaborating with chronic disease specialists and geriatricians. These specialists also require training on coordination of care, co-management, drug interactions, and other clinical issues related to aging with HIV. They may also require training in cultural competence, bias and stigma reduction, confidentiality/privacy, and how to create a welcoming environment for people with HIV.

Supporting the HIV Workforce

In this Integrated Plan, there are specific strategies to address workforce issues (See Section V).

- Provide trainings for medical and other providers to assess barriers, increase, promote and expand access to routine HIV testing as per NYS guidelines in medical and nonmedical settings (*Pillar: Diagnose*).
- Increase trainings to build the capacity of the HIV workforce to deliver high-quality care, treatment, and secondary prevention service to ensure effective referrals, follow-up, and engagement for consumers (*Pillar: Treat*).
- Partner with local and state government agencies to leverage and promote workforce development opportunities for people with HIV, and members of specific populations (*Pillar: Treat*).
- Employ peer workers (especially members of specific populations) to support sustained engagement in HIV prevention and care services (*Pillar: Treat*).
- Support peer employment and fair compensation while maintaining their benefits in peer transition to work (*Pillar: Treat*).
- Engage/partner with NYS Clinical Education Initiative (CEI) to establish curriculum, training requirements Continuing Medical Education (CME) credits and evaluation to increase training opportunities to non-HIV specialties (*Pillar: Prevent*).
- Develop status neutral toolkit for providers to increase their ability to communicate with consumers (*Pillar: Prevent*).

Regional partners, people with HIV, providers, and stakeholders will continue to identify workforce issues through needs assessment, planning, and prioritization processes. Moving forward, NECA AETC is available to meet the training needs of clinicians and providers in NYS. Importantly, they have proven themselves able to pivot to address emerging issues as they did during the COVID-19 pandemic. From March 2020-November 2021, NECA AETC held 197 training and capacity building events focused specifically on COVID-19, reaching 6,840

participants. Topics included COVID-19 testing, diagnosis, treatment, clinical trial updates, vaccines, coping with loss and grief, best practices in telehealth, safely reopening clinic space, and the disparate impact of COVID-19 on communities of color. NECA AETC will be an important partner in achieving the goals of the Integrated Plan and ETE.

Prescription Drug Coverage, Costs and the 340B Program

A potential challenge may emerge if disruptive legislative changes are made affecting the 340B federal drug discount program. Preserving access to savings from the 340B program is an important policy and legislative priority for NYS safety net health programs, providers, and consumers. Enacted by Congress in 1992, the 340B program provides discounts on prescription drugs for populations served by eligible entities such as FQHCs, RWHAP recipients, and disproportionate share hospitals. The subsequent savings enable safety net providers to provide medical care to uninsured individuals as well as vital wraparound services like nutrition, transportation, and housing. Safety net providers depend on funds generated from the 340B program to provide care and services to 2.3 million underserved New Yorkers. Approximately 70% of those individuals are people of color and nearly 90% are low-income. The NYS AAC, among other key stakeholders in the Integrated Plan development, place a high priority on safety net providers maintaining full access to these vitally important 340B savings.

Statewide Challenges and Mitigation Strategies

Challenge	Mitigation Strategy
Advance Health Equity and Dismantle All Forms of Oppression Including racism and homophobia and other “isms” and “phobias” that contribute to HIV-related health inequities.	Develop internal and external policies, practices, and partnerships with other state agencies, organizations, and entities.
Increase Community Engagement/Outreach While this is important for all populations, emphasis should be placed on people facing housing instability/homelessness, youth and young adults, LGBTQ+ individuals, people who inject drugs, and older adults with HIV.	Strengthen partnerships and collaboration with other state agencies and CBOs.
Address Barriers to Engaging in Prevention and Care Due to SDOH Especially for populations at increased risk of HIV acquisition for improved linkage to prevention and care services.	Build partnerships with organizations that can help to address these needs. Use evidence-based practices to re-engage people in care.
Increase Training for Providers to Address Equity Topics include cultural competency, implicit bias, stigma, trauma-informed care, health equity, and LGBTQ+ sensitivity.	Promote training opportunities available through NYSDOH AI and NECA AETC.

Sustainable Funding for Community-Based Organizations Especially those that reach individuals at risk for and with HIV and organizations addressing SDOH.	Promote technical assistance through NYSDOH AI and NECA AETC.
Maintain 340B Program Discounts Potential legislative changes to savings program on prescription drugs for populations served by eligible entities such as FQHCs, RWHAP recipients, and disproportionate share hospitals.	Promote efforts to maintain 340B program to continue reimbursing and supporting safety net providers to provide medical care to uninsured individuals as well as vital wraparound services like nutrition, transportation, and housing.
Integrate Trauma-Informed Care Approach into All NYSDOH AI Programming/Initiatives	Promote training opportunities available through NYSDOH AI and NECA AETC for the purpose of integrating trauma-informed care into all NYSDOH AI programming/initiatives.

EMA Situational Analyses

New York City

New York City's four most populous counties – Bronx, Kings (Brooklyn), New York (Manhattan), and Queens – are among the 48 counties designated as part of the EHE initiative. NYCDOHMH coordinates New York City's response to the HIV epidemic, including HIV testing initiatives; prevention, care, and treatment programming; epidemiology; training and technical assistance; policy advocacy; community engagement; social marketing; and racial equity and social justice initiatives. Fundamental to this work is a commitment to racial equity and social justice to dismantle the underlying racism, identity-based stigmas, and other systemic oppressions that drive HIV-related health inequities.

The NYC ETE Plan reflects and builds upon *The Blueprint*. NYC's ETE Plan, first implemented in 2015, employs an HIV status neutral approach to: reduce the number of new HIV infections to non-epidemic levels; improve the health and well-being of people with HIV and people vulnerable to HIV; and eliminate HIV-related health inequities. The NYC ETE Plan includes key strategies, which align with the goals in *The Blueprint*.

NYCDOHMH and planning bodies prioritize, plan, and implement HIV epidemiologic and status neutral prevention and care efforts citywide. This ongoing coordination aims to: increase efficiency and reduce duplication; maximize the volume and accessibility of programming and services; ensure that community input informs the design and implementation of jurisdictional plans to end the epidemic; and facilitate implementation of innovative strategies to address the HIV epidemic. These combined, coordinated HIV planning and program efforts will inform the development and implementation of the Integrated Plan.

NYC Response to HIV: Strengths

- NYCDOHMH supports health promotion and education through sexual health marketing campaigns focused on HIV testing, biomedical prevention and treatment, and stigma.
- Health insurance coverage is widely available to people with HIV in NYS. Medicaid, which NYS expanded to include adults up to 138% of the federal poverty level (FPL)

following the passage of the Affordable Care Act is the primary payer of care for New Yorkers with HIV, and Medicaid supports a full range of healthcare services, medications, and care management services. In addition, insurance coverage is available at no cost to New Yorkers with HIV with an income up to 500% FPL (as of April 2019) through a combination of expanded Medicaid and New York State of Health insurance marketplace plans, and the NYS Uninsured Care Programs provides support for premiums and copays for income-eligible New Yorkers.

- HIV prevention and care services and other healthcare services are available through a wide array of healthcare service delivery sites across NYC and NYS, including Designated AIDS Centers, state-certified, hospital-based programs that serve as hubs for a continuum of hospital and community-based care; hospital-based HIV clinics; and FQHCs and other community health centers located in medically underserved neighborhoods. NYCDOHMH's innovative sexual health clinics and telemedicine hotline offer low- to no-cost services for [sexually transmitted infections \(STIs\)](#), including HIV. Anyone 12 years or older can receive walk-in services, regardless of immigration status. No parental consent is necessary.
- NYC and NYS have been leaders in using a public health approach to injection drug use, including injected heroin and other opioids, to protect individual and community health by preventing transmission of HIV and hepatitis C. NYC has taken specific action in recent years to expand access to harm reduction services including authorizing the opening of two privately funded overdose prevention centers, supporting numerous SSPs, and providing extensive naloxone distribution and services, including through NYCDOHMH's peer-led non-fatal overdose response system (Relay).
- NYC and NYS have a deep network of CBOs that employ a range of funding sources to provide HIV testing, prevention, and care services for New Yorkers affected by HIV. CBOs, including specific population-led grassroots organizations with critical access to underserved populations, engage in individual and system-level advocacy to ensure the communities they serve have access to culturally affirming, comprehensive services.

NYC Areas of Need

Many New Yorkers face complex, challenging environments affecting HIV prevention and HIV-related health outcomes. These issues can include unstable housing, food insecurity, poverty, immigrant status, criminal justice involvement, mental health, substance use, and intimate partner violence, among other factors. Through its planning, programming and partnerships, NYCDOHMH works to address these issues related to social and structural determinants of health and various types of stigma that can drive inequitable access to HIV testing, prevention, care, and treatment services for New Yorkers. NYC and the NY EMA are working to resolve a number of challenges, in collaboration with the Planning Council, consumers, and providers.

New York City Challenges and Mitigation Strategies

Challenge	Mitigation Strategy
Addressing Needs of People with HIV age 50 and Over	The Planning Council's Consumer Committee worked with the NYCDOHMH to create a service directive for referral for healthcare,

More than half the people with HIV in the NY EMA are 50+. Inequities persist among this population in terms of viral suppression rates, with Black and Hispanic/Latino people with HIV experiencing lower rates of viral suppression than White people with HIV. Late diagnoses are higher, especially for women. Death rates for Black and Hispanic/Latino people with HIV are also significantly higher.	supportive services, and outpatient medical services, while improving existing services to ensure responsiveness to the clinical and support needs of people aging with HIV. Additional strategy: to conduct training to increase the clinical capacity of core medical and support service providers to address the needs of this population.
Addressing Health and Racial Equity Across the EMA's Portfolio Racial/ethnic minority subgroups are disproportionately affected by HIV (e.g., cisgender Black women, young Black MSM, Black and Hispanic/Latino older people with HIV).	The Planning Council convened work groups designed to advance racial health equity and make recommendations related to EMA activities. Additional strategy: to conduct focus group project to identify gaps and ways to enhance services; focus group findings will also inform provider training and technical assistance.
Addressing Impact of COVID-19 A survey conducted by NYCDOHMH and described in its Grant Year 2022 RWHAP Part A grant submission indicated many people with HIV were experiencing financial hardship or struggling to make ends meet, including many who had been laid off or had reduced hours.	NYCDOHMH will provide additional support for people with HIV to address financial needs, food insecurity, and homelessness/housing instability. Additional strategies: develop flexible service provision standards to ensure provider/consumer safety and facilitate continuity of services; provide cost-based reimbursement, allowing providers to adjust to evolving healthcare landscape.

Nassau-Suffolk

As of December 31, 2020, according to the NCDOH, 5,302 individuals were living with HIV/AIDS in the EMA. The number of new HIV diagnoses over a 3-year timeframe (2018-2020) fluctuated between 178 and 120 cases per year, with an annual average of 158 cases. A major challenge is late diagnoses. In 2020, 28% of the newly diagnosed had already progressed to AIDS, with the majority of these cases among Black and Hispanic/Latino populations. People with HIV in the EMA are disproportionately Black, Hispanic/Latino, male, and above the age of 50. MSM are the leading transmission risk category (43.0%). Males comprise 69.1% of people with HIV. Racial and ethnic minorities (including people of more than one race) account for close to 63% of all people with HIV in the EMA.

The EMA's approach to HIV prevention and care services aligns with the four guiding goals outlined in the *2017-2021 NYS Integrated HIV Prevention and Care Plan*. These goals are to: 1) reduce new HIV infections; 2) increase access to care and improve health outcomes for people

with HIV; 3) reduce HIV-related disparities and health inequities; and 4) achieve a more coordinated response to the HIV epidemic.

Needs

- Services that are culturally and linguistically responsive to a shifting demographic
- Resources to address subsistence needs such as food and housing
- Transportation (very limited public transportation in a suburban area)
- Messages that reach MSM and other targeted groups
- Services that keep people in care.

Nassau-Suffolk Challenges and Mitigation Strategies

Challenge	Mitigation Strategy
Changing Healthcare Landscape The pandemic thrust consumers, physicians, and other healthcare and service providers onto virtual platforms and other digital technologies at an unprecedented speed.	• Assess consumer satisfaction with virtual services and develop or strengthen a hybrid model that allows consumers to choose how they access healthcare and support services. • Connect consumers to existing resources in the community for assistance with obtaining expanded broadband services, tablets, phones, etc. • Provide consumer training to ease usage of virtual platforms and digital technologies.
Stigma Stigma makes it difficult to identify, link, and retain the newly diagnosed in care.	• Utilize social media, trainings, and peers to increase awareness of HIV and U=U, a campaign that addresses stigma. • Expand access to mental health services and support groups to address needs of individuals dealing with stigma. • Implement best practices learned from the National HIV Challenge to reduce HIV-related stigma and disparities.
Barriers for Populations Experiencing Inequities in Health Outcomes Socioeconomic factors such as income and education often lead to hardships for people with HIV in obtaining healthcare. Structural factors such as racism, misogyny, transphobia also contribute to inequities.	• Collaborate with planning council and subrecipients, and other service providers to broaden efforts to address socioeconomic factors that prevent people with HIV accessing healthcare and/or remaining engaged in healthcare.

	• Improve health literacy, with emphasis on people with limited English proficiency, to ensure understanding of treatment options and the availability of services. • Increase funding for essential supportive services (e.g., transportation, legal) that help keep people with HIV in care. • Facilitate health insurance enrollment through the marketplace, apply for ADAP.
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a. Specific Populations: 2022-2026 Integrated Plan

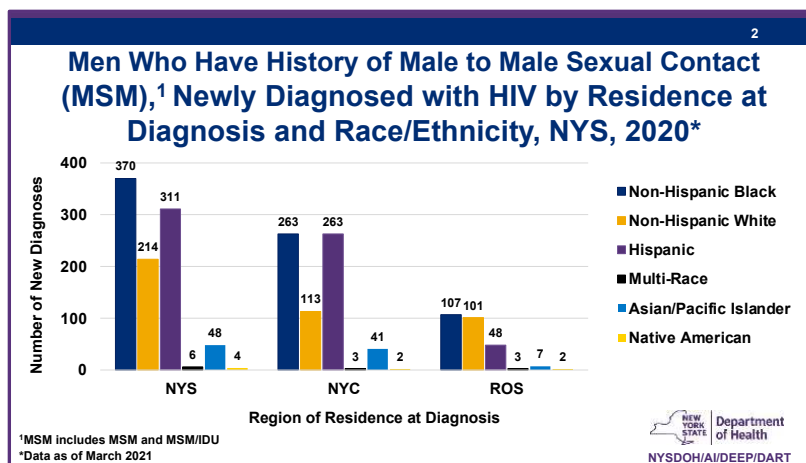
Through planning and prioritizing processes and efforts to identify unmet need, three specific populations have been identified for the Integrated Plan:

- Black and Hispanic/Latino men who have sex with men (MSM);
- Cisgender women of color; and
- People with HIV age 50 and over.

Each of these populations face unique challenges and have specific needs. In addition to the data issues listed below, ETE advisory groups have developed reports for each of these populations.

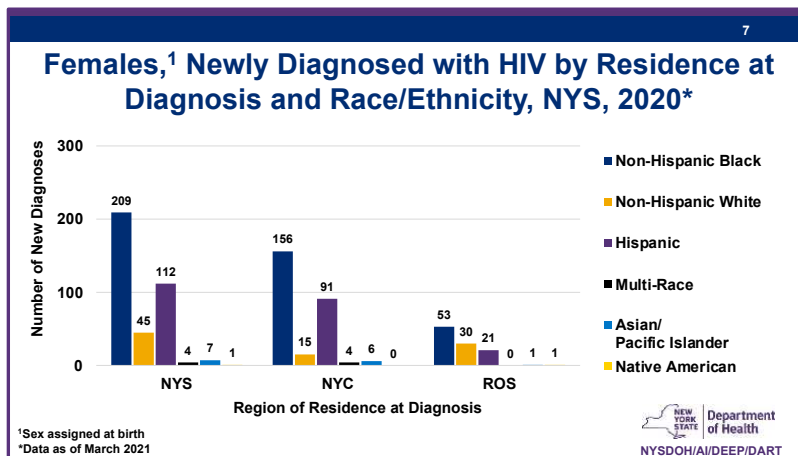
Black and Hispanic/Latino MSM

- Of the total 1,993 individuals newly diagnosed with HIV in 2020, 681 (35%) were Black and Hispanic/Latino MSM, 526 of whom resided in NYC. Black and Hispanic/Latino MSM made up more than two-thirds of all MSM diagnosed in 2020. While the number of MSM diagnosed with HIV has decreased in recent years, Black and Hispanic/Latino MSM continue to be disproportionately represented among new diagnoses.
- Many Black and Hispanic/Latino MSM with HIV, particularly young MSM, are unaware of their HIV infection. This may be due to recent infection, underestimation of personal risk, or fewer opportunities to get tested.
- Black and Hispanic/Latino men have lower rates of ART adherence and viral suppression.
- Providers are less likely to discuss PrEP with black and Hispanic/Latino MSM than White MSM.



Cisgender Women of Color

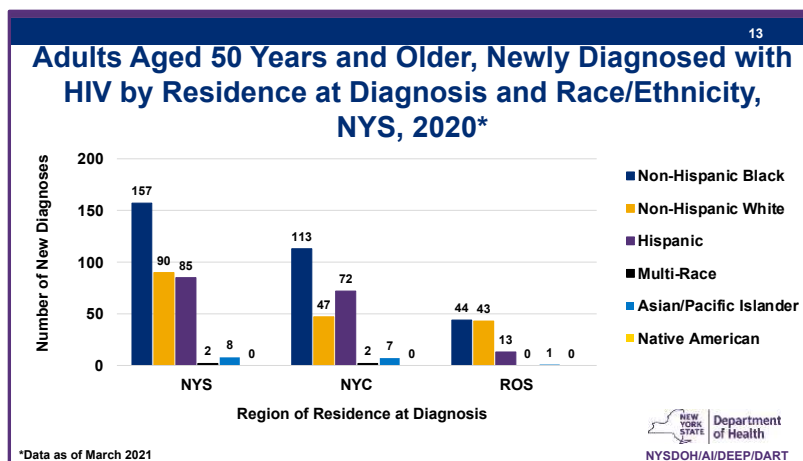
- Women made up 19.5% of new HIV diagnoses in 2020; 378 women were diagnosed that year. Of these, 88% were women of color. This represents a significantly disproportionate impact on women of color given that they make up just 45% of women living in NYS.
- Condomless sex continues to be a significant risk factor for cisgender women of color.
- Awareness of PrEP remains low among cisgender women of color. PrEP education has primarily focused on men.



People with HIV age 50 and over

- Fifty-six (56) percent of people with HIV in NYS are over age 50.
- Eighteen (18) percent of New Yorkers who were newly diagnosed with HIV in 2020 were over the age of 50 (342 out of 1,933).
- Of adults aged 50 and older who were newly diagnosed with HIV in 2020, 70% were from NYC and 46% were non-Hispanic Black. Those over 50 were more than twice as likely to be diagnosed late than those under 50 (34% vs. 16%).

- Aging is a time of transition, which can result in reduced income, less mobility, changes in support networks, and mental health issues.
- Loneliness, depression, and anxiety are significant issues for this population and more support services to address these issues are needed, especially as this population will continue to grow.



While these are the specific populations, all people placed at risk and those living with HIV will continue to be a focus of HIV prevention and treatment activities, with attention paid to geographic differences.

NYS will also continue to tailor services to meet the needs of populations disproportionately impacted by HIV. In particular, NYS will continue to work with partners to provide and improve tailored services for transgender individuals given the unique needs of this population.

How the Integrated Plans Goals Address the Needs of Specific Populations.

With two exceptions, the Integrated Plan goals are designed to respond the needs and improve services for all populations, including specific populations, and bring NYS closer to achieving the ETE goals. Likewise, almost all the strategies apply to all populations.

Because of the low viral suppression rates of Black and Hispanic/Latino people with diagnosed HIV, goals focused on improving this metric (and the health of these populations) are included. Establishing these goals will bring ongoing focus on supporting improvement in this area.

Goal: Increase the percentage of Black persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%.

Input from Advisory Groups

The ETE Advisory Groups that developed implementation strategies are listed below. Their suggestions were incorporated into ongoing planning processes.

[Black Men who Have Sex with Men](#)

[Latino Gay and Bisexual Men](#)

[Older Adults](#)

[Women](#)

[Young Adults](#)

Goal: Increase the percentage of Hispanic/Latino persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%.

NYC and Nassau-Suffolk Specific Populations

Specific populations identified by NYC and Nassau-Suffolk as service priorities are aligned with the three primary specific populations of the Integrated Plan, and include:

**New York and Nassau-Suffolk EMAs:
Specific Priority Populations**

- Black MSM, including Black cisgender MSM and Black transgender MSM
- Hispanic/Latino MSM, including Hispanic/Latino cisgender MSM and Hispanic/Latino transgender MSM
- Black women, including Black cisgender women and Black transgender women
- Hispanic/Latina women, including Hispanic/Latina cisgender women and Hispanic/Latina transgender women
- All people of trans experience and people who identify as gender nonconforming, gender non-binary, or genderqueer
- People with HIV ages 50 years and older
- Youth and young adults ages 13 to 29 years
- Those who can benefit from HIV prevention and care services



Section V: 2022-2026 Goals

The goals presented in this Integrated Plan reflect the CDC/HRSA guidance to align our work with the four pillars of the Ending the HIV Epidemic initiative. These four areas of focus are: diagnose, treat, prevent, and respond.

In addition, we present strategies for implementing and achieving the goals. Below we describe how these strategies were identified and prioritized.

The goals reflect the state's three-point ETE plan that aims to improve the health of all New Yorkers living with HIV. The three points highlighted in the ETE plan are:

- 1) Identify people with HIV who remain undiagnosed and get them linked to care;
- 2) Link and retain people diagnosed with HIV in healthcare to maximize viral suppression; and
- 3) Increase access to PrEP for people who are HIV negative.

2022-2026 Integrated Plan: Areas of Focus

Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.

Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs.

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

Goals in Support of Health Equity

In addition to standard goals that will be used to measure NYS's progress in the four focus areas, NYS has identified 14 goals to ensure that our work continues to address health equity and reduce health disparities. At their core, the goals are developed as SMART goals (**specific, measurable, achievable, relevant, and time-bound**). Several of the goals have an expanded definition and are SMARTIE goals, with the "IE" standing for "inclusive" and "equitable."

Inclusive. Invite and incorporate input from the specific populations, people with lived experience, partners, and other stakeholders.

Equitable. Address the unique needs and circumstances of different populations, increase quality services where needed, and seek to address disparities (e.g., access to PrEP).

By incorporating inclusion and equity components to SMART goals, this approach strengthens our commitment to racial equity and inclusion by identifying tangible and actionable steps that will be integrated throughout NYS's ETE work.

Prioritizing Strategies to Achieve Goals

To support achievement of the goals, NYS compiled strategies currently being used in NYS's ETE response and identified potential new strategies through our planning and community

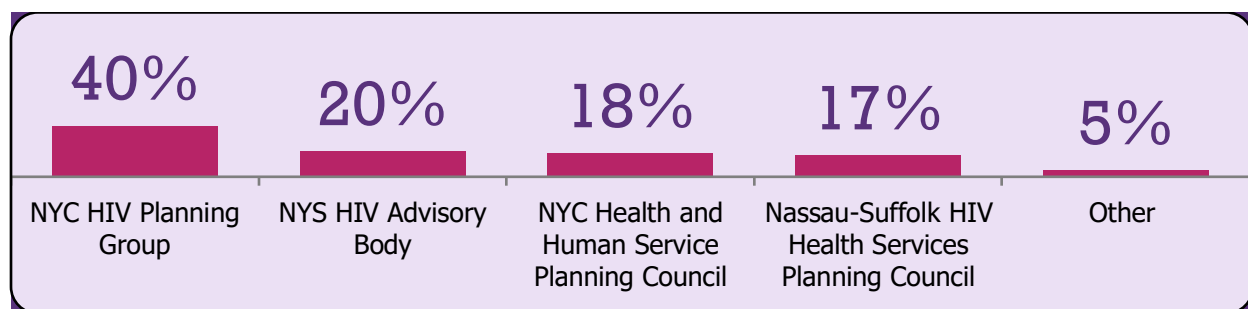
engagement activities. NYS engaged planning groups to prioritize the strategies based on four criteria: 1) magnitude of impact; 2) alignment with ETE plan; 3) sustainability; and 4) ease of implementation.

Prioritization Criteria

Magnitude of Impact	Alignment with ETE Plan	Sustainability	Ease of Implementation
Likely to have a significant impact on HIV prevention and care	Likely to directly address ETE three-point plan	Likely to be maintained over time	Likely to be implemented with ease

Survey Responses

Surveys were provided to planning group members in summer 2022. They were instructed to rank the strategies based on the criteria listed above. Sixty (60) responses were received.



For each focus area, strategies were ranked using a five-point Likert scale (five being most highly rated) for the four criteria. Weighted averages calculated across the responses were used to rank the strategies. An overall score was used to rank the strategies based on the four criteria.

NYS will focus on the top strategies related to goals. Over the next five years, strategies will be modified, and new strategies added as needs change, evidence-based interventions are identified, and advances occur in treatment and prevention. These modifications will be informed by NYS's planning and community engagement activities.

1. Description of 2022-2026 Goals

The following goals for the next five years reflect strategies that will help ensure a unified, coordinated approach for all HIV prevention and care funding and program priorities.

2022-2026 Goals and Strategies: Diagnose

Goal: Increase the percentage of persons living with HIV who know their serostatus to at least 98%.

Goal: Increase the percentage of New Yorkers who tested for HIV in the past 12 months.

Goal: Reduce the number of new HIV diagnoses by 55%.

Diagnosis Strategies Ranked Based on the Four Prioritization Criteria	
1.	Promote HIV, STD/STI low cost or free testing locations. Promote free HIV at home testing kits sponsored through the NYSDOH AI by utilizing social media platforms and existing program materials to help engage high-risk individuals to get tested and know their status.
2.	Improve access to regular repeat HIV testing among members of specific populations and other New Yorkers vulnerable to acquiring HIV through strategies such as co-location of services.
3.	Improve detection of acute HIV infection.
4.	Provide trainings for medical and other providers to assess barriers and increase, promote and expand access to routine HIV testing as per NYS guidelines in medical and nonmedical settings.
5.	Increase public awareness of the current recommendations for routine, ongoing testing using social media, and increase specificity in advertising with other technologies and methods. Engage planning bodies to review/recommend social media messages and updated NYS educational materials for distribution.
6.	Build stronger connections with urgent care networks such as CitiMD and specialty care centers for LGBTQ+ individuals to connect consumers to HIV-specific service providers.
7.	Educate communities on their sexual health rights and how to navigate testing.
8.	Expand opportunities (data collection/programmatic) to include specific populations that are not currently always reflected in existing data (e.g., transmasculine individuals, same gender loving women).

2022-2026 Goals and Strategies: Treat

Goal: Increase the percentage of persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%.

Goal: Increase the percentage of persons living with diagnosed HIV who receive HIV medical care to 90%.

Goal: Increase the percentage of Black persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%.

Goal: Increase the percentage of Hispanic/Latino persons living with diagnosed HIV who receive HIV medical care with suppressed viral load to 95%.

Goal: Reduce current disparities in median CD4 among persons living with diagnosed HIV.

Treatment Strategies Ranked Based on the Four Prioritization Criteria
1. Promote access to bias-free and culturally and linguistically appropriate HIV care, treatment, secondary prevention, healthcare, and supportive services.
2. Provide health literacy resources with emphasis on bilingual patient education specific to non-English speaking consumers to improve disease knowledge, adherence, and retention in care.
3. Improve access to services by expanding program hours, availability of appointments, locations, and staffing composition.
4. Improve linkage and retention in care through targeted support and follow-up of medical care to confirm that continuity of care is provided.
5. Employ peer workers (especially members of specific populations) to support sustained engagement in HIV prevention and care services.
6. Support peer employment and fair compensation while maintaining their benefits in peer transition to work.
7. Increase trainings to build the capacity of the HIV workforce to deliver high-quality care, treatment, and secondary prevention services and to ensure effective referrals, follow-up, and engagement for consumers.
8. Partner with local and state government agencies to leverage and promote workforce development opportunities for people with HIV and members of specific populations.
9. Promote strategies (e.g., patient-reported outcome measures, patient-reported experience measures) to improve patient encounters, experiences, and outcomes, which will support engagement and retention in care.
10. Increase access to healthcare and support services, including social support services, necessary to ensure optimal care to people (50+) as they age with HIV.

2022-2026 Goals and Strategies: Prevent

Goal: Increase the number of individuals filling prescriptions for PrEP to 65,000.

Goal: Reduce current disparities in PrEP utilization rates (defined as the number of individuals on PrEP/100,000) across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS.

Goal: Reduce current disparities in statewide SSP service utilization across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS.

Prevention Strategies Ranked Based on the Four Prioritization Criteria	
1.	Increase public awareness and uptake of PrEP, emergency PEP, and U=U through social media educational campaigns, print media, and engaging social media influencers to educate, and address stigma.
2.	Implement programming to empower specific populations to increase access to behavioral health and evidenced-based HIV prevention interventions, including those promoting PrEP and emergency PEP.
3.	Build provider capacity to take comprehensive sexual histories and offer PrEP and emergency PEP to consumers.
4.	Enhance existing care networks to improve and increase access to the referral system across the region focusing on cultural competency and stigma-free care.
5.	Strengthen relationships with CBOs that provide free or low-cost prevention methods such as condoms and other social & health services.
6.	Promote the availability of online and hotline resources (such as the NYS HIV/STI/HCV Hotline, United Way Long Island 2- 1-1, and the Long Island Crisis Center Hotline).
7.	Engage/partner with NYS Clinical Education Initiative (CEI) to establish curriculum, training requirements, Continuing Medical Education (CME) credits, and evaluation to increase training opportunities for non-HIV specialties.
8.	Develop status neutral toolkit for providers to increase their ability to communicate with consumers.
9.	Create forums to facilitate dialogue between cisgender men and cisgender women on heterosexual prevention measures.

2022-2026 Goals and Strategies: Respond

Goal: Analyze surveillance data monthly to identify HIV transmission clusters and outbreaks to facilitate prompt public health response.

Goal: Re-engage 75% of persons identified as out of care within six months.

Goal: Reduce current disparities in the reengagement rate of persons living with diagnosed HIV identified as out of care within six months across all racial and ethnic groups, age groups, and across all genders (identified by assigned sex at birth) across all regions in NYS.

Response Strategies Ranked Based on the Four Prioritization Criteria	
1.	Improve capacity for community/zip code level surveillance data to better identify clusters and high need areas.
2.	Use zip code level and unmet need data to refine targeted outreach strategies.
3.	Increase flexibility of funding applications and allocations to redirect funds to priorities and programs that meet the needs of the identified cluster groups.

Section VI: 2022-2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up

The NYSDOH AI, with input from jurisdictional partners, planning groups, and stakeholders, will be responsible for ensuring the success of the Integrated Plan goals by overseeing the five key phases identified in the CDC/HRSA guidance: implementation; monitoring; evaluation; improvement; and reporting and dissemination.

NYSDOH AI and its jurisdictional partners, NYCDOHMH and NCDOH, will provide to their respective planning partners and stakeholders, including the NYS HAB, the HIV Health and Human Services Planning Council of New York, New York City HIV Planning Group, and the Nassau-Suffolk HIV Health Services Planning Council, regular updates on the progress of the Integrated Plan implementation, solicit feedback, and use the feedback for plan improvements. Working with federal partners at CDC and HRSA, each jurisdiction will use established reporting mechanisms (i.e., grant applications, annual progress reports, and communications with project officers) to document progress on achieving the goals presented in the Integrated Plan. These reporting updates will include each jurisdiction's plans to monitor and evaluate implementation of the goals and strategies included in the Integrated Plan.

In This Section

- Implementation;
- Monitoring;
- Evaluation;
- Improvement;
- Reporting and Dissemination;
- Updates to Other Strategic Plans Used to Meet Requirements

1. Implementation Approach

The sections below describe the infrastructure, procedures, systems, and tools that will be used to support the five key phases of integrated planning and ensure goals are met.

a. Implementation

This section describes the process for coordinating partners, including new partners, people with HIV, people at risk for exposure to HIV, contractors, and administrators from different funding streams to meet the Integrated Plan goals, with a focus on how NYS will leverage and coordinate funding streams.

NYSDOH AI awards funds in every region of the state to ensure geographic parity to the fullest extent possible. In procuring and reprocurring funds and making allocation decisions on funding for services for people with HIV, coordination takes place with Part A EMAs to avoid duplication and gaps in services in geographic areas. The Uninsured Care Programs (UCP) serve residents of all regions. The following is taken into consideration when making funding/contract decisions.

- Information gained through reporting and quality management mechanisms, such as onsite monitoring, helps to assess the performance of funded organizations, for documenting performance successes, and for anticipating challenges in the provision of contract services and deliverables.
- NYSDOH AI carries out quality management activities that monitor performance through review of contractual standards and deliverables, onsite monitoring, and continued provision of technical assistance.
- NYSDOH AI employs a participatory process for identifying service needs that impact program development and utilizes participation from consumer groups to guide policy and program development/revision. NYSDOH AI community engagement and planning processes are ongoing, involving established planning bodies whose members include people with HIV. Community engagement activities include focus groups and listening sessions with key stakeholders, including contractors, at-risk individuals, and people with HIV. Additionally, focus groups are held on specific policy or program issues. Regular communication with HIV providers, consumers, and community leaders has resulted in services that have supported improved health outcomes for people with HIV in NYS.
- Agencies receiving NYSDOH AI funds are required to involve people with HIV in the planning and design of services or have a consumer advisory body. This includes federal Minority AIDS Initiative (MAI) funds NYS receives that prioritize people of color.
- NYSDOH AI coordinates all program activities when allocating all funds. The various funding sources, such as Medicaid, RWHAP, MAI, and CDC, are taken into consideration when NYSDOH AI makes funding decisions. Coordination across all programs/initiatives follows the same process. For example, in allocating MAI funds, NYSDOH AI examines other existing outreach programs in each region to avoid duplication and ensure that RWHAP funds are the payer of last resort. Another example is that, under MAI, geographic boundaries were negotiated as part of the contract award process to define target service areas to ensure that MAI-funded agencies serve distinct regions. Contract managers work with their MAI-funded agencies to develop an outreach/education action plan that prioritizes the specific populations at disproportionate risk for HIV infection in the service area and focuses on the geographic areas to be served by the agency.
- Technical assistance is provided to contractors by NYSDOH AI on an as-needed basis. This ensures the success of all contractors, especially those that have contacts focused on providing services to specific populations. This TA can link them to evidence-based practices and the support needed to implement them.

b. Monitoring

Two types of monitoring are necessary as the state works to achieve the goals of the Integrated Plan. This first is monitoring our progress in achieving the plan's goals using epidemiologic, Behavioral Risk Factor Surveillance System (BRFSS), and PrEP data. The NYS HAB HIV Planning Coordinating Group will be convened at least twice a year to review goals, strategies, progress, and receive updates from each planning body to seek areas of alignment.

Programmatic monitoring helps to ensure the accessibility and quality of services provided and identifies possible gaps in services. NYSDOH AI used multiple methods to monitor consumers served, services provided, and the performance of contracted organizations. Program

monitoring is conducted through the review of work plans and periodic reports, on-site monitoring, the review of data reports, and the analysis of quality review results.

Client-level Data. All NYSDOH AI funded contractors are required to use the NYSDOH AI Reporting System (AIRS) to track consumers and services provided. This allows the NYSDOH AI to track consumers and services for all RWHAP Part B, CDC, and state-funded contracts. Providers are allowed to utilize the system to track consumers and services from other funding sources as well, such as, RWHAP Part C, D, and directly funded CDC contracts. In order to ensure that consumers and services are tracked appropriately, each contract is assigned a unique “program” within AIRS. Individual consumers are then enrolled into the appropriate program within AIRS to allow for reporting under each contract. Once a consumer is enrolled, all subsequent services entered for that consumer into that program are reported under the specific contract. For contracts funded by the NYSDOH AI, a special file is sent electronically to each provider to load into their AIRS system. This file “locks” the set-up information for each AI-funded program, ensuring that information cannot be changed by the provider. This file also assigns individual services to the program, which ensures that only the services approved in the contract can be entered and reported for the program. All data are then de-identified and securely transmitted to the NYSDOH AI electronically on a monthly basis where it is compiled in a statewide SQL database. This database is used by contract managers and management staff to monitor individual contract performance against their approved set of deliverables.

Site Visits. NYSDOH AI’s *Resource Guide for Site Visit Monitoring* established policies and procedures for program and fiscal monitoring. The Guide is continuously being updated to include new procedures for implementing the National Monitoring Standards as well as updating best practices. The guide addresses both fiscal and program monitoring. On-site monitoring is conducted every 24 months at a minimum. More frequent monitoring, sometimes targeted, is conducted as needed. Contractors are required to submit work plans identifying goals, objectives, and projected activities. Program reports are generally required on a monthly or quarterly basis. The process for corrective action involves the submission of a written plan of action or correction by the contractor and NYSDOH AI monitoring of the implementation of the plan until all concerns are resolved.

c. Evaluation

The measurable goals identified in the Integrated Plan will be tracked on an ongoing basis. Most goals will be tracked using HIV epidemiologic data. BRFSS data will be used to track the testing-related goals (Prevent) and PrEP data (purchased from contractor) will be used to track PrEP-related goals (Prevent). As stated above under monitoring, the HIV Planning Coordinating Group will be convened at least twice a year to review progress in achieving the goals and determine if changes to priorities or strategies are required.

In August 2022, the White House Office of National AIDS Policy (ONAP) released the *NHAS Federal Implementation Plan*. The plan introduces five new NHAS indicators of progress focused on quality of life among people with HIV. These indicators reflect the multi-dimensional nature of quality of life among people with HIV. The indicators address self-rated health, unmet need for mental health services, hunger/food insecurity, unemployment, and unstable housing or homelessness. They expand focus beyond just clinical measures for people with HIV. The

indicators closely align with the state's focus on SDOH and health equity. Over the next five years as the Integrated Plan is implemented, the state will explore ways to integrate quality of life indicators into evaluation activities. In late 2022, NYSDOH AI's Center for Quality Improvement and Innovation (CQII) plans to convene a national consensus meeting of HIV providers and people with lived experience to develop strategies to use QI methodologies and tools to improve quality of life for people with HIV served in HIV ambulatory care settings.

CQII was funded by HRSA in 2022 to conduct a national pilot project to explore measurement systems to utilize patient-reported outcome measures and patient-reported experience measures to improve HIV outcomes and patient experiences using QI methodologies and tools. Participating RWHAP recipients carried out improvement projects addressing various domains (well-being, housing stability, food insecurity, communications with clinicians). Prior to the pilot project, CQII developed a step-by-step guide to assist HIV providers to implement those domains in HIV clinic settings. The guide was forwarded to HRSA for review and approval for public dissemination. NYSDOH AI will be exploring similar ways to address patient-reported outcomes and experiences with providers in NYS.

d. Improvement

NYSDOH AI has a robust program designed to ensure quality HIV care is delivered to every New Yorker with HIV. The NYS Quality of Care (QOC) Program is committed to ensuring equitable access to HIV care that promotes the health and well-being of all people with HIV in NYS. The QOC Program collects data on the performance of medical and non-medical HIV providers, uses these data to identify areas for improvement, and fosters improvement both by supporting improvement activities and by building capacity for quality management. QOC Program Standards outline the expectations for HIV providers in NYS, regardless of their caseload, funding, location, or service delivery model. All HIV ambulatory programs and Part B-funded non-medical providers are expected to establish a Quality Management program to assess the extent to which HIV health services provided to consumers are consistent with these QOC Program Standards. QOC staff and coaches conduct organizational assessments of each HIV ambulatory care program in NYS annually to evaluate, track, and support adherence to the QOC Program Standards.

The following quality improvement initiatives are integrated into the QOC Program and are being implemented or continued statewide in 2020.

- Organizational HIV Treatment Cascade: With the goal of increasing the proportion of people with HIV who achieve durable viral suppression, the QOC program has asked clinical HIV providers across NYS to submit organizational treatment cascade data, which identify the proportion of people with HIV at each clinic at each stage of the care continuum, from diagnosis through viral suppression.
- Topic-specific reviews are conducted annually in accordance with identified priority areas such as: HIV and aging; hepatitis C co-infection; and sexual health.
- QOC focuses upon stigma reduction and resiliency building. The program works with the Stigma and Resiliency (STAR) Coalition, which includes NYCDOHMH, in identifying effective stigma reduction activities through interviewing HIV care providers.

- Quality Improvement (QI) curriculum is being developed by the program.
- The QOC program collaborates with clinical and supportive service providers, particularly Part B recipients, to provide QI coaching and training and to monitor the quality of care.
- The QOC program provides QI training for staff of the NYSDOH AI.
- The QOC program collaborates with NYCDOHMH in providing capacity building opportunities to providers, particularly programs that have been identified as having special challenges such as low viral suppression rates.
- The program works with NYCDOHMH Clinical Operations and Technical Assistance program to develop TA material for HIV providers regarding evaluative frameworks for remote/telehealth HIV care.
- The program maintains quality learning networks and NYLinks regional groups aimed at improving the health and well-being of people with HIV and ending the epidemic.

NYSDOH AI also works with NYCDOHMH to support the Part A Quality Assurance Program. This close partnership ensures alignment of quality improvement activities in NYS and NYC. Beyond the HIV-related indicators, there has been increased interest in identifying and measuring other indicators. Earlier this year, ONAP charged a small working group of representatives from six federal agencies involved in developing and implementing the NHAS to carefully listen to community input and evaluate options for possible data sources, measures, and targets that could be adopted starting this year. As a result of this work and community input, ONAP ultimately adopted five indicators that reflect the multi-dimensional nature of quality of life among people with HIV. The ONAP indicators address self-rated health, unmet need for mental health services, hunger/food insecurity, unemployment, and unstable housing or homelessness.

NYSDOH AI receives support from HRSA's HIV/AIDS Bureau (HRSA HAB) for CQII to provide quality improvement-related TA to all RWHAP recipients, including recipients and subrecipients in NYS. Two of CQII's recent activities supported by HRSA HAB efforts align with the goals of the Integrated Plan and broader goals (e.g., NHAS). In 2022, CQII conducted a pilot project on integrating patient reported outcome and experience measures into evaluation activities. These included indicators related to quality of life, which align with the NHAS indicators focused on quality of life for people with HIV. CQII developed a guide for incorporating patient-reported outcomes and experiences and will build on this work.

In addition, CQII has received funding from HRSA HAB to conduct a national learning collaborative focused on older people (50+) with HIV. This aligns with the Integrated Plan's specific populations. The findings and evidenced-based practices identified through the learning collaborative will inform state efforts to serve older people with HIV.

e. Reporting and Dissemination

NYSDOH AI has multiple methods for communicating with stakeholders on a range of critical issues, including progress in achieving the goals of the Integrated Plan.

Regular NYSDOH AI Communications with Stakeholders. NYSDOH AI maintains an email listserv of contractors/consultants, planning/advisory group members, people with HIV, and

other stakeholders. Topics include funding opportunities; technical assistance resources; emerging issues; policy updates; and events (e.g., awareness days, World AIDS Day)

Bi-Directional Communications with Planning Groups. Information flows in multiple ways between NYSDOH AI, NYCDOHMH, and NCDOH and their jurisdictional planning groups. These entities regularly provide information (e.g., data sets, presentations) to planning groups about the Integrated Plan and other critical issues, which they in turn, disseminate to stakeholders within their jurisdiction. For needs assessment, planning, and other community engagement activities, planning groups obtain input from members and stakeholders and report it to NYSDOH AI, NYCDOHMH, and NCDOH.

Regional, Topic-Specific, and Population-Focused Listening Sessions. NYSDOH AI makes tailored presentations at and/or provides data sets for regional, topic-specific, and population-focused listening sessions, as requested. Among the information provided is updates on progress to ETE and Integrated Plan goals, in general and related to the topics/populations. These sessions also provide an opportunity to hear from stakeholders about gaps, areas for improvement, and emerging issues.

Call to Action Letters. For the past several years, the NYSDOH AI *Call to Action* letters written by the AI Director, have been widely shared. They emphasize key priority areas—identified through needs assessment activities—to move the state toward achieving ETE goals and charge all grant-funded programs, clinical programs, healthcare providers, stakeholders, and community partners to implement strategies that prioritize state *Blueprint* goals and objectives as well as the priority areas. Providers and stakeholders are encouraged to use data, program evaluation, and quality improvement methods to assess and monitor progress. Topics covered over the last few years include stigma; trauma-informed care; and health inequities and SDOH. The 2022 letter focused on: reducing racial disparities in healthcare; increasing access to harm reduction and mental health services; meeting the needs of older (50+) people with HIV; and efforts to eliminate hepatitis C, a co-morbidity of HIV.

Notices about Community Engagement Activities. Opportunities for community engagement (e.g., listening sessions, surveys) are announced via email to partners, stakeholders, and others using mailing lists compiled by NYSDOH AI. The email messages contain pertinent information (e.g., purpose, location, RSVP requirements). Depending on the opportunities, flyers are sometimes attached that can be posted to increase outreach.

ETE Dashboard. Planning groups, partners, and stakeholders have access to data related to achieving the goals of the ETE. The purpose of the Ending the Epidemic (ETE) Dashboard System is to **measure, track, and disseminate actionable information on progress towards achieving ETE goals to all interested stakeholders.** Multiple data sets are used including HIV epidemiology, Medicaid Data Warehouse, the Electronic System for HIV/AIDS Reporting and Evaluation (eSHARE), the AIDs Institute Reporting System (AIRS), the Behavioral Risk Factor Surveillance System (BRFSS), the NYC Community Health Survey (CHS), and NYS Vital Statistics.

Section VII: Letters of Concurrence

Signed letters of concurrence with the Integrated Plan are included from the co-chairs of the following planning councils/groups:

- HIV Health and Human Services Planning Council of New York
- Nassau-Suffolk HIV Health Services Planning Council
- New York City HIV Planning Group (NYC HPG)
- New York State HIV Advisory Body (NYS HAB)



October 28, 2022

Kerry Hill, MSW
Public Health Analyst
Division of State HIV/AIDS Programs
HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Melissa Thomas Proctor, MS., MSW
Public Health Adviser
Centers for Disease Control and Prevention
NCHSTP/DHP/PDB

Dear Kerry Hill and Melissa Thomas Proctor:

On November 27, 2022, the HIV Health and Human Services Planning Council of New York ("Planning Council") voted unanimously to concur with the joint submission by the New York State Department of Health, New York City Department of Health and Mental Hygiene, and the Nassau County Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan ("Integrated Plan"), including the Statewide Coordinated Statement of Need (SCSN) for calendar years (CY) 2022-2026.

The Planning Council has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV. The planning body **concurs** that the Integrated Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance. The Integrated Plan identifies service needs and barriers; presents goals and strategies for program development, implementation, and evaluation; depicts the continuum of care statewide and by region and population; and demonstrates the extensive involvement of stakeholders. The Integrated Plan is also consistent with the National HIV/AIDS Strategy, New York State's Plan to End AIDS, including New York State's Ending the Epidemic Beyond 2020 Addendum Report, and New York City 2020: Ending the HIV Epidemic.

Below is a description of the key steps taken by our coordinated statewide planning process.

- Coordination of Planning.** New York State Department of Health, New York City Department of Health and Mental Hygiene, and Nassau County Department of Health program teams are responsible for coordinating the plan development, including developing and providing tools for facilitating the work of planning bodies, updating the Epidemiologic Snapshot for the state, completing the Resource Inventory, gathering data/plan segments from all entities, and writing the plan. The New York State HIV Planning Coordinating Group is responsible for reporting back to their home planning body on progress and interim milestones and bringing information and concerns to bi-monthly meetings. The coordinating group identified goals, objectives, and strategies for inclusion in the Integrated Plan. Members include representatives from Nassau and Suffolk HIV Health and Human Services Planning Council, New York City Department of Health, New York City HIV Planning Group, New York HIV Health and Human Services Planning Council, New York State AIDS Institute, and New York State HIV Advisory Body. The members of the HIV Planning Coordinating Group will continue to convene at least twice annually to review progress and ensure that the jurisdictional planning processes are well-coordinated and responsive to statewide needs and priorities.
- Planning Bodies/Councils Input.** Statewide HIV Planning Bodies/Councils contributed information to develop the Integrated Plan narrative, identify goals, objectives, strategies, and activities, and support stakeholder involvement.
- Stakeholder Input.** Stakeholders participated in surveys, focus groups, listening sessions, and other forums throughout the process to identify service and resource gaps and barriers, and identify monitoring and evaluation efforts, and jurisdictional follow-up actions.
- Additional Methods of Providing Input.** Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, various HIV-related programs, community leaders, government representatives, advocates, researchers, and other stakeholders. Clients are represented in all groups.

We look forward to continuing collaboration with our colleagues statewide and with our community partners in implementing the Integrated Plan to provide quality HIV prevention and care services throughout our jurisdiction.

The signatures below confirm the **concurrence** of the Planning Council with the Integrated Plan.



Graham Harriman
Governmental Co-Chair
HIV Health and Human Services Planning Council of New York



Dorella Walters
Community Co-Chair



November 10, 2022

Chrissy Abrahms Woodland
 Director, Division of Metropolitan HIV/AIDS Programs
 HIV/AIDS Bureau, HRSA
 5600 Fishers Lane, Room 09W12
 Rockville, MD 20857

Dear Ms. Abrahms,

The Nassau-Suffolk HIV Health Services Planning Council] concurs with the following joint submission by the New York State Department of Health, New York City Department of Health and Mental Hygiene, and the Nassau County Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN) for calendar year (CY) 2022-2026.

The Nassau-Suffolk HIV Health Services Planning Council has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV. The planning body **concurs** that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance. The Integrated Plan identifies service needs and barriers, presents goals and strategies for program development, implementation, and evaluation, depicts the continuum of care statewide and by region and population, and demonstrates extensive involvement of stakeholders. The Integrated Plan is also consistent with the National HIV/AIDS Strategy, New York State's Plan to End AIDS, including New York State's Ending the Epidemic Beyond 2020 Addendum Report, and New York City 2020: Ending the HIV Epidemic.

Below is a description of the key steps taken by our coordinated statewide planning process.

- **Coordination of Planning.** New York State Department of Health, New York City Department of Health and Mental Hygiene, and Nassau County Department of Health program teams are responsible for coordinating the plan development, including developing and providing tools for facilitating the work of planning bodies, updating the Epidemiologic Snapshot for the state, completing the Resource Inventory, gathering data/plan segments from all entities, and writing the plan. The HIV Planning Coordinating Group is responsible for reporting back to their home planning body on progress and interim milestones and bringing information and concerns to bi-monthly meetings. The coordinating group identified goals, objectives, and strategies for inclusion

in the Integrated Plan. Members include representatives from Nassau and Suffolk HIV Health and Human Services Planning Council, New York City Department of Health, New York City HIV Planning Group, New York City HIV Health and Human Services Planning Council, New York State AIDS Institute, and New York State HIV Advisory Body. The members of the HIV Planning Coordinating Group will continue to convene at least twice annually to review progress and ensure that the jurisdictional planning processes are well-coordinated and responsive to statewide needs and priorities.

- **Planning Bodies/Councils Input.** Statewide HIV Planning Bodies/Councils contributed information to develop the Integrated Plan narrative, identify goals, objectives, strategies, and activities, and support stakeholder involvement.
- **Stakeholder Input.** Stakeholders participated in surveys, focus groups, listening sessions, and other forums throughout the process to identify service and resource gaps and barriers, and identify monitoring and evaluation efforts, and jurisdictional follow-up actions.
- **Additional Methods of Providing Input.** Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, various HIV-related programs, community leaders, government representatives, advocates, researchers, and other stakeholders. Clients are represented in all groups.

We look forward to continuing collaboration with our colleagues statewide and with our community partners in implementing the Integrated Plan to provide quality HIV prevention and care services throughout our jurisdiction.

The signature(s) below confirm the **concurrence** of the planning body with the Integrated HIV Prevention and Care Plan.



Traci Shelton, Chair



Kerri Thomas, Vice-Chair

cc.- Nina Sculco, Nassau County Department of Health
Georgette Beal, United Way of Long Island
JoAnn Henn, United Way of Long Island



New York City HIV Planning Group
42-09 28th Street, 22nd Fl., CN#A-1
Queens, NY 11101

Phone: 347-396-7700
Fax: 347-396-7791
E-mail: dohmhppg@health.nyc.gov

Jorge Soler, *Community Co-Chair*
Shirley Torho, *Governmental Co-Chair*

Luz Santiago, *Community Co-Chair Elect*
Deidre Miller, *Secretary*

November 7, 2022

Kerry Hill, MSW
Public Health Analyst
Division of State HIV/AIDS Program
HIV/AIDS Bureau
Health Resources and Services Administration

Melissa Thomas Proctor, MS., MSW
Public Health Adviser
Centers for Disease Control and Prevention
NCHSTP/DHP/PDB

Dear Kerry Hill and Melissa Thomas Proctor:

The New York City HIV Planning Group concurs with the following joint submission by the New York State Department of Health, New York City Department of Health and Mental Hygiene, and the Nassau County Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN) for calendar year (CY) 2022-2026.). Of the twenty-one (21) members who voted, nineteen (19) voted to concur with the Plan, one (1) voted to abstain, and one (1) casted a vote of non-concurrence.

As in previous years, the New York City HIV Planning Group has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV. The planning body **concurs** that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance. The Integrated Plan identifies service needs and barriers, presents goals and strategies for program development, implementation, and evaluation, depicts the continuum of care statewide and by region and population, and demonstrates extensive involvement of stakeholders. The Integrated Plan is also consistent with the National HIV/AIDS Strategy, New York State's Plan to End AIDS, including New York State's Ending the Epidemic Beyond 2020 Addendum Report, and New York City 2020: Ending the HIV Epidemic.

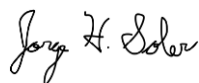
Below is a description of the key steps taken by our coordinated statewide planning process.

- **Coordination of Planning.** New York State Department of Health, New York City Department of Health and Mental Hygiene, and Nassau County Department of Health program teams are responsible for coordinating the plan development, including developing and providing tools for facilitating the work of planning bodies, updating the Epidemiologic Snapshot for the state, completing the Resource Inventory, gathering data/plan segments from all entities, and writing the plan. The HIV Planning Coordinating Group is responsible for reporting back to their home planning body on progress and interim milestones and bringing information and concerns to bi-monthly meetings. The coordinating group identified goals, objectives, and strategies for inclusion in the Integrated Plan. Members include representatives from Nassau and Suffolk HIV Health and Human Services Planning Council, New York City Department of Health, New York City HIV Planning Group, New York City HIV Health and Human Services Planning Council, New York State AIDS Institute, and New York State HIV Advisory Body. The members of the HIV Planning Coordinating Group will continue to convene at least twice annually to review progress and ensure that the jurisdictional planning processes are well-coordinated and responsive to statewide needs and priorities.
- **Planning Bodies/Councils Input.** The New York City HIV Planning Group engaged in a multi-year process to contribute information to develop the Integrated Plan narrative, identify goals, objectives, strategies, and activities, and review the Plan at various stages.
- **Stakeholder Input.** Stakeholders participated in surveys, focus groups, listening sessions, and other forums throughout the process to identify service and resource gaps and barriers, and identify monitoring and evaluation efforts, and jurisdictional follow-up actions.
- **Additional Methods of Providing Input.** Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, various HIV-related programs, community members and leaders, government representatives, advocates, researchers, and other stakeholders. Clients are represented in all groups.

The signatures below confirm the New York City HIV Planning Group's **concurrence** with the Integrated HIV Prevention and Care Plan.

We look forward to a continued collaborative and productively supportive relationship with our colleagues and community partners statewide as we implement the Integrated Plan to provide quality HIV prevention and care services throughout our jurisdiction.

Sincerely,



Jorge Soler
Community Co-Chair



Shirley Torho
Governmental Co-Chair



Luz Santiago
Community Co-Chair Elect



Deidre Miller
Secretary



KATHY HOCHUL
Governor

Department
of Health

HIV Advisory Body

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

October 26, 2022

Kerry Hill, MSW
Public Health Analyst
Division of State HIV/AIDS Program
HIV/AIDS Bureau
Health Resources and Services Administration

Melissa Thomas Proctor, MS., MSW
Public Health Adviser
Centers for Disease Control and Prevention
NCHSTP/DHP/PDB

Dear Kerry Hill and Melissa Thomas Proctor:

The New York State HIV Advisory Body concurs with the following joint submission by the New York State Department of Health, New York City Department of Health and Mental Hygiene, and the Nassau County Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN) for calendar year (CY) 2022-2026.

The New York State HIV Advisory Body has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV. The planning body **concurs** that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance. The Integrated Plan identifies service needs and barriers, presents goals and strategies for program development, implementation, and evaluation, depicts the continuum of care statewide and by region and population, and demonstrates extensive involvement of stakeholders. The Integrated Plan is also consistent with the National HIV/AIDS Strategy, New York State's Plan to End AIDS, including New York State's Ending the Epidemic Beyond 2020 Addendum Report, and New York City 2020: Ending the HIV Epidemic.

Below is a description of the key steps taken by our coordinated statewide planning process.

- **Coordination of Planning.** New York State Department of Health, New York City Department of Health and Mental Hygiene, and Nassau County Department of Health program teams are responsible for coordinating the plan development, including developing and providing tools for facilitating the work of planning bodies, updating the

Epidemiologic Snapshot for the state, completing the Resource Inventory, gathering data/plan segments from all entities, and writing the plan. The HIV Planning Coordinating Group is responsible for reporting back to their home planning body on progress and interim milestones and bringing information and concerns to bi-monthly meetings. The coordinating group identified goals, objectives, and strategies for inclusion in the Integrated Plan. Members include representatives from Nassau and Suffolk HIV Health and Human Services Planning Council, New York City Department of Health, New York City HIV Planning Group, New York City HIV Health and Human Services Planning Council, New York State AIDS Institute, and New York State HIV Advisory Body. The members of the HIV Planning Coordinating Group will continue to convene at least twice annually to review progress and ensure that the jurisdictional planning processes are well-coordinated and responsive to statewide needs and priorities.

- **Planning Bodies/Councils Input.** Statewide HIV Planning Bodies/Councils contributed information to develop the Integrated Plan narrative, identify goals, objectives, strategies, and activities, and support stakeholder involvement.
- **Stakeholder Input.** Stakeholders participated in surveys, focus groups, listening sessions, and other forums throughout the process to identify service and resource gaps and barriers, and identify monitoring and evaluation efforts, and jurisdictional follow-up actions.
- **Additional Methods of Providing Input.** Hundreds of people are involved in these committees and groups, including recipients of RWHAP funds, various HIV-related programs, community leaders, government representatives, advocates, researchers, and other stakeholders. Clients are represented in all groups.

We look forward to continued collaboration with our colleagues statewide and with our community partners in implementing the Integrated Plan to provide quality HIV prevention and care services throughout our jurisdiction.

The signature(s) below confirm the **concurrence** of the planning body with the Integrated HIV Prevention and Care Plan.



Melanie Dulfo, Community Co-Chair
NYS HIV Advisory Body



Yosman Rucker, Community Co-Chair
NYS HIV Advisory Body

Appendix A: Governmental Partner, Stakeholder and Public Comments

Overview of Comments and Process

After developing the complete first draft of the Integrated Plan, NYSDOH AI requested and encouraged review and comment from governmental partners, including the NYCDOHMH and NCDOH, and from planning council/group stakeholders, including the HIV Health and Human Services Planning Council of New York, the Nassau-Suffolk HIV Health Services Planning Council, the New York City HIV Planning Group, and the NYS HAB. In addition, NYSDOH AI posted the Integrated Plan draft for Public Comment in October 2022. All comments were reviewed and considered. Many comments suggested content already included in the Integrated Plan.

Several comments, both from stakeholders and during public comment, suggested changes to the wording or the metrics of the goals presented in the draft Integrated Plan. While these suggestions were considered, ultimately it was decided that since the goals were developed, vetted, and approved by stakeholders during the planning process, and the goals align with existing ETE goal and metrics, apart from some minor changes in wording, the goals presented in the draft Integrated Plan were retained.

Below is a summary of the comments received.

Governmental Partner and Stakeholder Comments

Comments were received from governmental partners and by planning council/group stakeholders and many of these comments were incorporated into the final Integrated Plan document. In addition to receiving written comments from partners and stakeholders, NYSDOH AI staff made presentations to the planning councils/groups and received feedback during the meetings and in breakout sessions. The following were comments that were incorporated into the Integrated Plan:

- Emphasize the importance of addressing stigma in improving HIV prevention and care services.
- Explain the role of people with HIV in developing the Integrated Plan and in other planning processes.
- Include information on the potential for disruptive changes to the 340B prescription drug discount program.
- Include strategies for co-location of HIV testing.
- Include routine testing for high-risk populations in specific settings.
- Address continuity of care for people with HIV.
- Expand HIV surveillance efforts (to address populations not currently captured).
- Address patient experience (and how it relates to engagement and retention).

- Address the needs of people over 50 living with HIV.
- Provide information on low HIV testing rates during COVID-19 pandemic.
- Ensure communities of color are captured in data related to HIV testing, care, and services.

Public Comments

Specific comments on recommended language and additions were received from two individuals that were incorporated into the Integrated Plan:

- Revise 2020 STI data to reflect access to services during COVID-19.
- Increase references to the Tri-County region of the New York EMA (Putnam, Rockland and Westchester Counties).

Comments were received from four individuals who recommended increased emphasis of issues in certain areas. It should be noted that the Integrated Plan is a framework for providing services and evaluating efforts for the next five years. Needs assessment, community engagement, and planning processes will be ongoing during this time and will focus on responding to ongoing and emerging needs. These public comments have been noted and can be revisited moving forward.

- Do not require social service providers to collect demographic information since disclosing this information may serve as a deterrent to people seeking services, such as HIV testing.
- Increase focus on addressing persistent disparities in new HIV diagnoses and HIV viral suppression rates for Black New Yorkers.
- Increase training opportunities for healthcare workers, including primary care providers.
- Balance focus on New York City vs. the rest of NYS.
- Focus on health equity related to specific populations (e.g., people with substance use disorder, people experiencing housing instability, people with serious and persistent mental illness).
- Include more information on the development of the Integrated Plan and the involvement of key stakeholders (e.g., people with HIV, managed care organizations, faith-based organizations, educational organizations).
- Include recommendation to allow condoms in prison.
- Include recommendation to expand scope of practice for pharmacists.



Appendix B: Abbreviations

AAC AIDS Advisory Council

ACA Affordable Care Act

ADAP AIDS Drug Assistance Program

AETC AIDS Education and Training Center

AI AIDS Institute

AIRS AIDS Institute Reporting System

ART Antiretroviral therapy

BHHS Bureau of Hepatitis, HIV, and STI (NYC)

BIPOC Black, Indigenous, People of Color

BRFSS Behavioral Risk Factor Surveillance System

CBO Community-Based Organization

CDC Centers for Disease Control and Prevention

CME Continuing Medical Education

CMS Centers for Medicare & Medicaid Services

CPW Certified Peer Worker

CQII Center for Quality Improvement and Innovation

CQM Clinical Quality Management

EC Emerging Community

EHE Ending the HIV Epidemic in the U.S. Initiative

EIIHA Early Identification of Individuals with HIV/AIDS

EIS Early Intervention Services

EMA Eligible Metropolitan Area

eSHARE Electronic System for HIV/AIDS Reporting and Evaluation

ETE Ending the Epidemic

FPL Federal Poverty Level

FQHC Federally Qualified Health Centers

FY Fiscal Year

HCV Hepatitis C Virus

HHS Department of Health and Human Services

HIV Human Immunodeficiency Virus

HOPWA Housing Opportunities for Persons with AIDS

HRSA Health Resources and Services Administration

HRSA HAB HRSA HIV/AIDS Bureau

iART Immediate antiretroviral treatment

LAI long-acting injectable ART

LGBTQ+ Lesbian, Gay, Bisexual, Transgender, and/or Questioning

MAI Minority AIDS Initiative
MPV Monkeypox virus
MSM Men Who Have Sex with Men
MTCT Mother to Child Transmission

NECA Northeast/Caribbean
NHAS National HIV/AIDS Strategy
NYC New York City
NYC HPG New York City HIV Planning Group
NYCDOHMH New York City Department of Health and Mental Hygiene
NYS New York State
NYS AAC New York State AIDS Advisory Council
NYS HAB New York State HIV Advisory Body
NYSDOH AI New York State Department of Health AIDS Institute

OPC Overdose Prevention Center
ONAP Office of National AIDS Policy

PEP Post-Exposure Prophylaxis
PHL Public Health Law
PLWDH Persons Living with Diagnosed HIV
PrEP Pre-Exposure Prophylaxis
PSA Public Service Announcement

QI Quality Improvement
QOC Quality of Care

RWHAP Ryan White HIV/AIDS Program

SAMHSA Substance Abuse and Mental Health Services Administration
SCSN Statewide Coordinated Statement of Need
SDOH Social Determinants of Health
SPNS Special Projects of National Significance
SSP Syringe Services Program
SNP Special Needs Plan (Medicaid)
STAR Stigma and Resilience
STD Sexually Transmitted Disease
STI Sexually Transmitted Infection

TA Technical Assistance
TB Tuberculosis

UCP Uninsured Care Program
US United States

VLS Viral Load Suppression

WICY Women, Infants, Children, and Youth

Appendix C: Integrated Plan Checklist

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 - A. Approach
 - B. Documents Submitted to Meet Requirements
- ☒ **II. Community Engagement (Pages 13-28)**
 - 1. Description of Jurisdictional Planning Processes
 - a. Entities Involved in Planning Process
 - b. Role of the RWHAP Part A Planning Councils
 - c. Role of Planning Bodies (CDC Planning, EHE)
 - d. Collaboration with RWHAP Parts
 - e. Engagement of People with HIV
 - f. Priorities
 - g. Updates to Other Strategic Plans
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 - 3. HIV Prevention, Care and Treatment Resource Inventory
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EXHIBIT C

Achieving Gender Affirming Care in the Ryan White Part A Portfolio

Recommendations from the
Needs Assessment Committee of the
NY HIV Health & Human Services Planning Council
July 2018

Approved by the Executive Committee on July 24, 2018



The Trans Community's Overlooked
Struggle For Basic Healthcare | Trans 102 | Refinery29
https://www.youtube.com/watch?v=UPJE4XTy_h4

Need:

TGNB experience significant
disparities in health outcomes
among PLWH

Goal:

To improve the health outcomes
of TGNB in the
NY Eligible Metropolitan Area

3

Timeline of NAC Findings Process

2/2018: Identification of Special Populations

- Transgender Women of Color identified for further study

3/2018: Presentations on TG Women of Color

- Viral Suppression Among Transgender Women Of Color Diagnosed With HIV/AIDS In NYC: 2016, Cristina Rodriguez-Hart, PhD
- Transgender Women of Color in Ryan White, Nadine Alexander
- Ryan White Housing Data, 2/18, Housing Services Unit, DOH

**5/2018: Needs Assessment Committee Special Outreach Meeting:
Voices of Transgender Women of Color**

- Presentation: Recommendations to End the Epidemic for TGNC People, Carrie Davis, MSW & NYS TGNC ETE Working Group

6/2018: Formulation of TGNB Recommendations

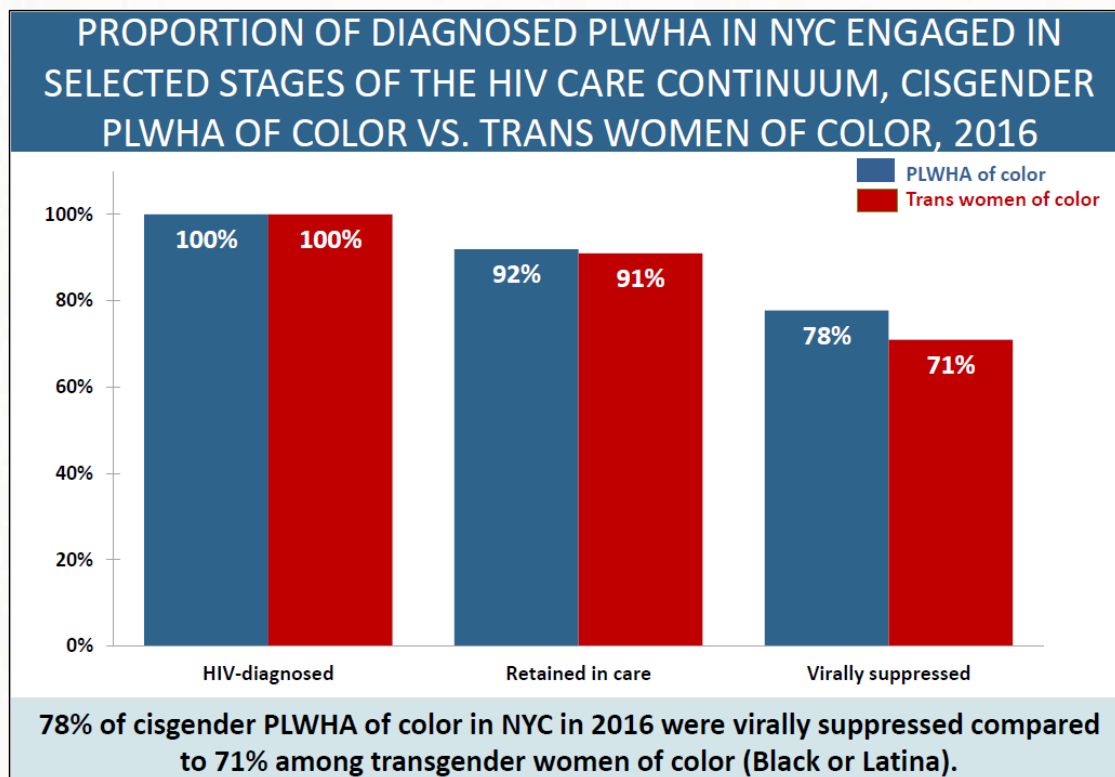
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NAC Findings Process Guiding Principles

- The input and participation of TGNB community members is central to the development and implementation of these recommendations.
- These recommendations are intersectional by necessity, and require collaboration across agencies and institutions to maximize their effectiveness in improving the health outcomes for TGNB individuals.
- The development and implementation of these recommendations assume support, guidance and collaboration with regard to program evaluation, research, and policy efforts.

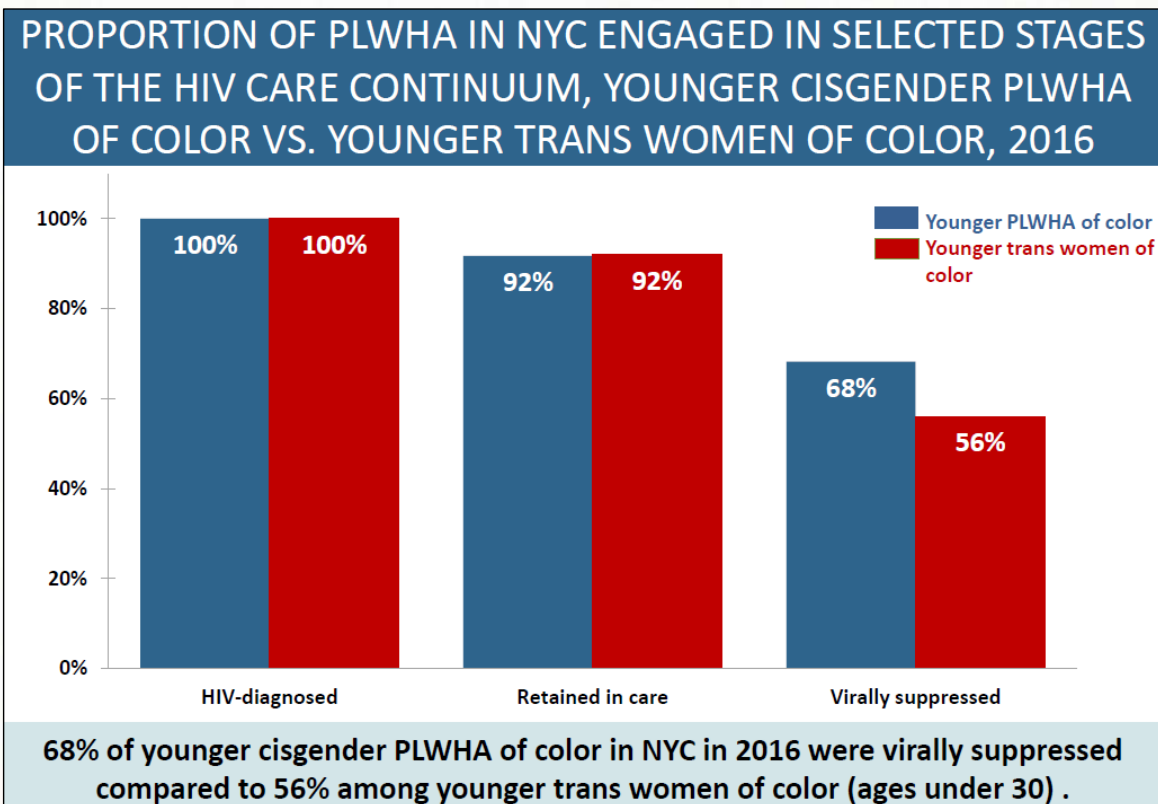
5

Assessing the Need*



Across NYC TG Women of Color have significantly lower levels of viral suppression

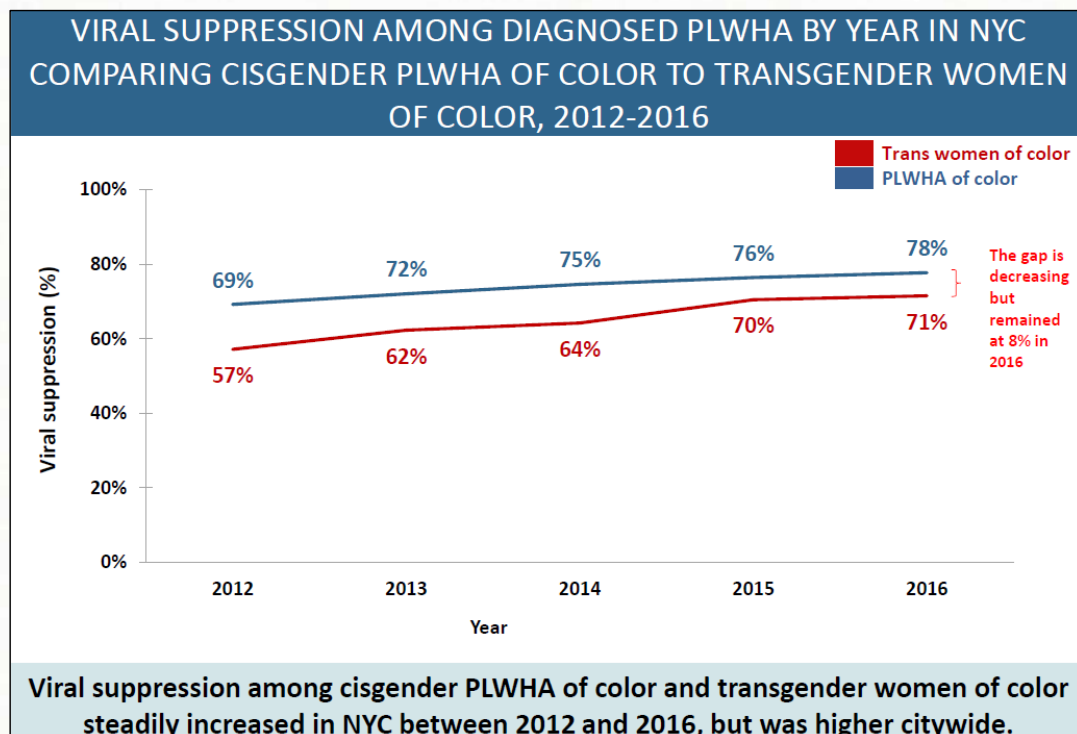
Assessing the Need (Cont'd)*



Younger TG Women of Color are even less likely to achieve viral suppression

7

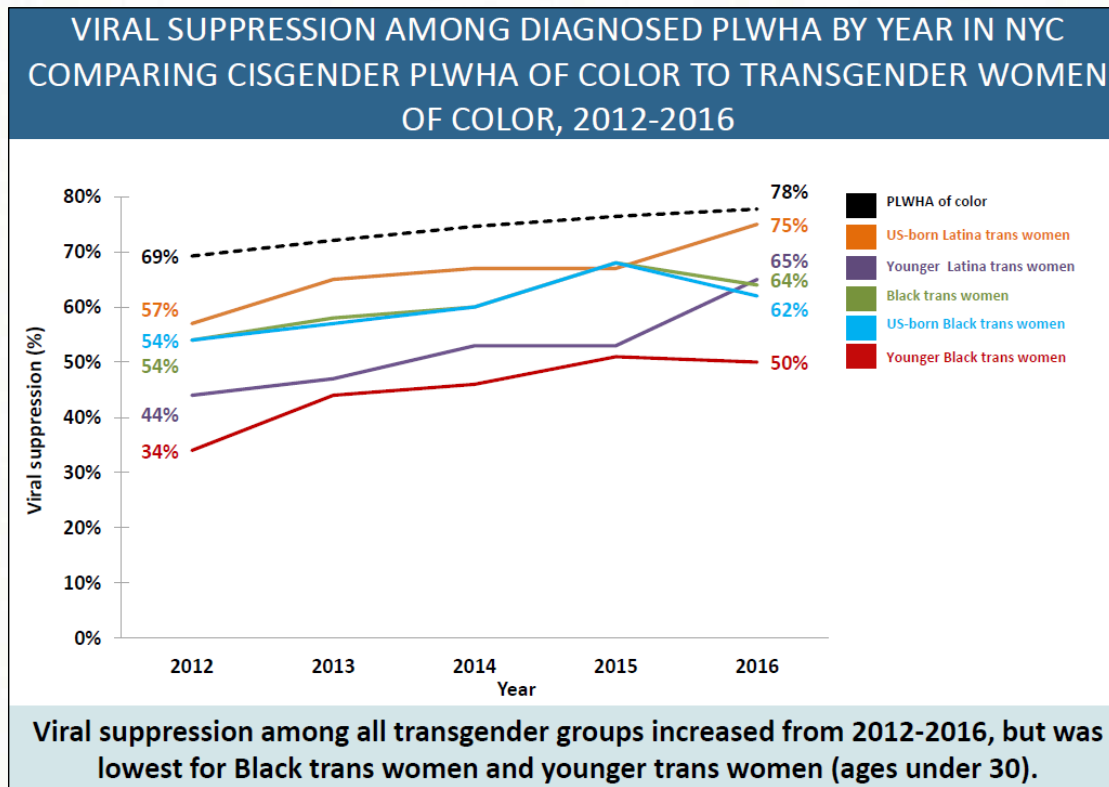
Assessing the Need (Cont'd.)



The gap in viral suppression for TG women of color compared to all PLWHA of color has narrowed, but persists. There is also a gap between PLWHA of color and white PLWHA.

8

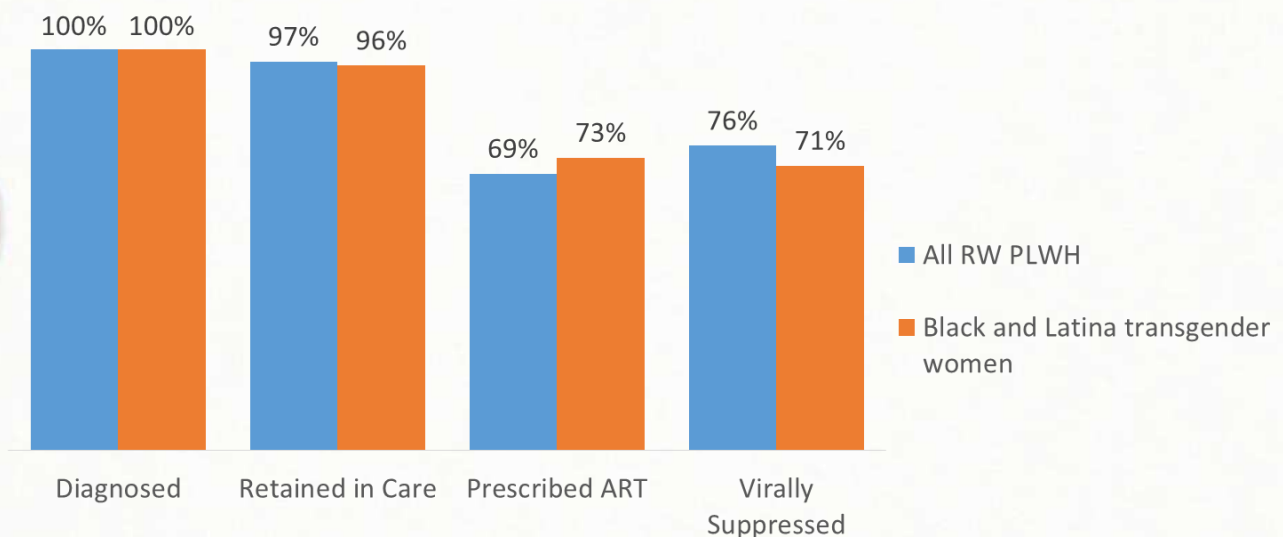
Assessing the Need (Cont'd.)



Younger, US born and all Black trans woman have some of the lowest rates of viral suppression, indicating that racism, among other barriers to care, is likely.

9

All Ryan White Part A PLWH vs. Black and Latina Transgender Women Clients Engaged in Selected Stages of the HIV Care Continuum, 2016*



Compared to all Ryan White Part A PLWH, a lower proportion of black and Latina transgender women clients were virally suppressed in 2016, despite a higher proportion of those transgender women clients being prescribed ART.

Needs Assessment Committee Findings

- TGNB do not feel welcome or comfortable accessing healthcare and support services. Gender affirming care is the exception and not the rule at most agencies, with a lack of representation seen in everything from the images on the walls to the staff make-up
- TGNB experience pervasive and widespread discrimination and violence, even in the offices of service providers, where a lack of expertise, sensitivity and awareness frequently characterizes service delivery
- Service barriers to engagement in and adherence to treatment among TGNB persons have not been adequately identified and bears out in inconsistent TGNB enrollment and service utilization throughout the Ryan White Part A portfolio
- The quality of gender affirming care available throughout the portfolio is not transparent and lacks accountability.

11

Purview of the Recommendations

1. **NY HIV PLANNING COUNCIL:** Increase the capacity of the NY HIV Planning Council to address the needs of TGNB individuals seeking services provided by Ryan White Part A programs.
2. **GRANTEE:** Increase and ensure the capacity of Ryan White Part A (RWPA) funded organizations to provide appropriate and relevant services to TGNB
3. **GRANTEE'S RESEARCH AND EVALUATION UNIT:** Evaluate current capacity of RWPA portfolio to improve health outcomes among TGNB clients
4. **NY HIV PLANNING COUNCIL & GRANTEE:** Develop strategies, best practices and interventions that address stigma and discrimination against TGNB clients in RWPA services
5. **NY HIV PLANNING COUNCIL:** Assess and address barriers to care unique to the TGNB experience

12

Recommendations

1. **Increase the capacity of the NY HIV Planning Council to address the needs of TGNB individuals seeking services provided by Ryan White Part A programs.**
 - Conduct a mandatory TGNB-specific trainings in a series format for NY HIV Planning Council and committee members
 - Develop a TGNB Advisory Board for the NY HIV Planning Council to guide best practices
 - Review service categories and models to ensure TGNB needs are addressed
 - Ensure TGNB representation reflective of the epidemic in the NY HIV Planning Council and the committees

13

Recommendations (Cont'd.)

2. **Increase and ensure the capacity of Ryan White Part A (RWPA) funded organizations to provide appropriate and relevant services to TGNB**
 - Mandate regular Gender Affirming Care Trainings for all RWPA staff and organizational leadership in a series format developed and led by TGNB
 - Facilitate development of a peer certification specialization for working with TGNB clients and peer leadership development through inter-institutional collaborations
 - Develop and enhance NY HIV Planning Council's standards of care, and policy guidance with best practices specific to TGNB clients, including issues of stigmatization and discrimination
 - Ensure the provision of technical assistance to organizations to integrate TGNB peers for service delivery and the implementation of Gender Affirming Care
 - Publish a public facing report card that assesses the quality of gender affirming care provided by funded RWPA organizations

14

Recommendations (Cont'd.)

3. Evaluate current capacity of RWPA portfolio to improve health outcomes among TGNB clients

- Conduct qualitative and quantitative analyses of service gaps within the RWPA portfolio
- Conduct an analysis on the quality of care and effectiveness of services, including experiences of stigma and discrimination, provided to TGNB within the RWPA portfolio
- Ensure participation of TGNB clients in the evaluation of services and programs

15

Recommendations (Cont'd.)

4. Develop strategies, best practices and interventions that address stigma and discrimination against TGNB clients in RWPA services

- Assemble research on best practices and standards of care to eliminate stigmatization and discrimination against TGNB clients during the delivery of RWPA services
- Conduct regular updates of policy requirements, trainings, guides to practices, standards of care and service models to reflect emerging research, practices and policies

16

Recommendations (Cont'd.)

5. Assess and address barriers to care unique to the TGNB experience

- Allocate funding for non-medical case management and/or psychosocial support services to support a service model that specifically targets barriers to care and treatment that TGNB individuals face to achieve viral suppression

EXHIBIT D



San Francisco's Integrated Ending the Epidemics Plan

**2024 – 2026 STRATEGIES AND
ACTIVITIES**

Serving as the HRSA/CDC-
required integrated plan
for the HIV Community
Planning Council; SF's
local strategy to align with
California's Integrated
Statewide Strategic Plan
for Addressing HIV, HCV,
and STIs from 2022-2026;
and SF's local Ending the
Epidemics plan.



San Francisco
Department of Public Health

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1. Introduction

BACKGROUND

In 2020, San Francisco (SF) received funding from the federal Ending the HIV Epidemic initiative, and in October of that year released its plan entitled ***Ending the Epidemics: Collective Strategies for Addressing HIV, Hepatitis C, and Sexually Transmitted Infections in San Francisco***. SF’s plan laid out an ambitious agenda for ending the syndemic of these three conditions, and this plan paved the way for a number of innovative strategies and activities that rolled out from 2020 through 2024, at which time the federal CDC EHE funding will be folded into cooperative agreements with states and directly funded cities. Concurrently, the California Department of Public Health (CDPH) published its ***Integrated Statewide Strategic Plan for Addressing HIV, HCV, and STIs from 2022 – 2026***, and invited CA counties to join their efforts by developing locally tailored versions of the State’s plan. While developing its strategic plan, CDPH collaborated with HRSA and CDC to allow their plan to fulfill the CDC and HRSA requirement that funded jurisdictions develop an integrated HIV care and prevention plan, and SF signed on to this agreement. In short, this plan serves multiple purposes, helping to streamline the many plans and planning processes that exist, in order to take a holistic, coordinated approach to the syndemic.

This plan:

- Meets CDC and HRSA (both EHE and Ryan White Part A) requirements for an HIV Integrated Plan
- Fulfills CDPH’s recommendation that each California county have a local plan that reflects CDPH’s strategic plan;
- Outlines SF’s strategies and activities to end the epidemics for 2024 – 2026; and
- Informs the priorities for HIV, HCV, and STI-related funding applications for 2024 – 2026.

Ultimately, the purpose of this plan is to provide a roadmap to overcoming inequities in health outcomes in HIV, HCV, and STIs in SF. This plan will be updated at least every 5 years, and more frequently if needed. Each year, SFDPH will provide an update to the HIV Community Planning Council (HCPC) on progress made on the blueprint activities.

HOW THIS PLAN IS ORGANIZED

This plan begins with an overview of the foundational services, programs, and other efforts that are the hallmark of SF’s approach to serving communities affected by HIV, HCV, and STIs – in other words, the service infrastructure and signature strategies that have been established over many decades, and what many have come to think of as the “San Francisco model.” A high-level overview is offered, because to describe the extensive network of services would take hundreds of pages.

The next section describes the efforts that SF is undertaking and will undertake in the next few years that go above and beyond the core work – bold strategies and activities that aim to make a significant contribution to ending the epidemics. In alignment with CDPH’s strategic plan, this section is organized by the social determinants of health (SDoH), because these are the factors that continue to drive new infections and poor health outcomes among

people living with and at risk for HIV, HCV, and STIs. SF cannot end the epidemics without lifting up these root causes and doing what is possible to lessen their impacts on health and wellness.

INPUT AND ENGAGEMENT

Drafts of this plan were shared with the following key stakeholders for input/feedback throughout plan development:

- ETE Steering Committee (October 17, 2023)
- SDFPH ETE Leadership Committee (October 24, 2023)
- SDFPH HIV Working Group (November 13, 2023)
- HCPC Council Affairs Committee (November 14, 2023; April 9, 2024)
- HIV Community Planning Council (HCPC) (November 27, 2023; April 22, 2024)
- Getting to Zero SF Steering Committee (February 12, 2024)
- HIV/AIDS Providers Network (March 1, 2024)
- HIV Housing Workgroup (March 26, 2024)
- End Hep C SF leadership (April 15, 2024)
- Frontline Organizing Group (April 16, 2024)

Input and feedback from these groups helped fill in gaps in the plan, including highlighting the Mayor's Office of Housing and Community Development's (MOHCD) efforts, ensuring that workforce development is inclusive of PLWH who are re-entering the workforce, recommending expansion of partnerships with local SAMHSA-funded programs, and much more.

2. Epidemiology and Priority Populations

EPIDEMIOLOGY OF HIV, HCV, AND STIS IN SAN FRANCISCO

The state of HIV, HCV, and STIs in SF

In the last decade, the landscape of HIV, HCV, and STIs has changed considerably in San Francisco (SF). Advances in treatment and prevention for HIV, HCV, and STIs have impacted the epidemiologic profiles, with some populations experiencing more benefit than others. This phenomenon—where the implementation of new interventions tends to disproportionately benefit people with privilege (e.g., white people, cis men, people with health insurance)—can be largely explained by the social determinants of health affecting those with less privilege. Factors such as lack of housing and income inequality are more pervasive and intense than ever before, resulting in disparities in health outcomes by race/ethnicity, housing status, transmission risk group, gender, and mental health and substance use, neighborhood, and other demographic and behavioral factors.

Declines in new HIV diagnoses and increases in HIV viral suppression rates, HCV cures for thousands of SF residents, and innovations in STI prevention are successes to be celebrated. In many ways, the most challenging work remains, because it requires going beyond the simple provision of services to addressing the deeply complex issues of poverty, racism, homophobia and transphobia, access to care, mental health and substance use, incarceration, and much more. An added challenge is that declines in the local and state economies and a large budget deficit are leading to reductions in funding for social services. These factors demand an increased focus on person-centered, integrated services, increased innovation, and a social determinants of health-informed approach.

The need for a syndemic approach

Syndemics are epidemics of diseases or health conditions that interact with each other, exacerbating their adverse effects on communities that face inequities,¹ and are often driven by the same upstream social determinants of health. Given the overlap in the populations experiencing disparities in HIV, HCV and STI outcomes, as well as the overlap in transmission routes of HIV, HCV, and STIs, strategies to address these epidemics must be coordinated and integrated. The interconnectedness of HIV, HCV, and STIs, and the shared social determinants of health affecting their health outcomes, including substance use, mental health,² homelessness, poverty, racism, and homophobia, among others, demand a syndemic framework and a fully integrated system of care.

The next several pages summarize the current status of HIV, HCV, and STIs, with an emphasis on persistent disparities that could be addressed through a syndemic approach.

¹ <https://www.cdc.gov/hiv/pdf/division-of-hiv-prevention/cdc-hiv-dhap-external-strategic-plan-2022.pdf> (p. 11)

² Substance use and mental health are medical disorders, which makes them different than the other SDoH. Like the other SDoH though, they are upstream factors (with social and environmental components as well as medical) that impact HIV/HCV/STI transmission and health outcomes.

HIV

Background

As a result of hard-fought accomplishments in prevention, care, and treatment services informed by a robust HIV surveillance system, SF is on track to achieve its goal to ‘Get to Zero’: zero new HIV infections; zero HIV deaths; and zero HIV stigma. Over the last decade, SF has implemented a data-driven, high impact prevention (HIP) strategy, with resulting significant, steady reductions in new HIV diagnoses and increasing linkages to care and viral suppression among people living with HIV (PLWH) (Exhibit 1).

As shown in Exhibit 2, in 2019, new HIV diagnoses dropped below 200 to 179, a 67% decrease since 2006.³ However, in 2021, for the first time in more than a decade, new HIV diagnoses increased (147 to 166), likely due to delayed diagnoses during the COVID-19 pandemic. In 2022, new diagnoses remained essentially level at 157.¹

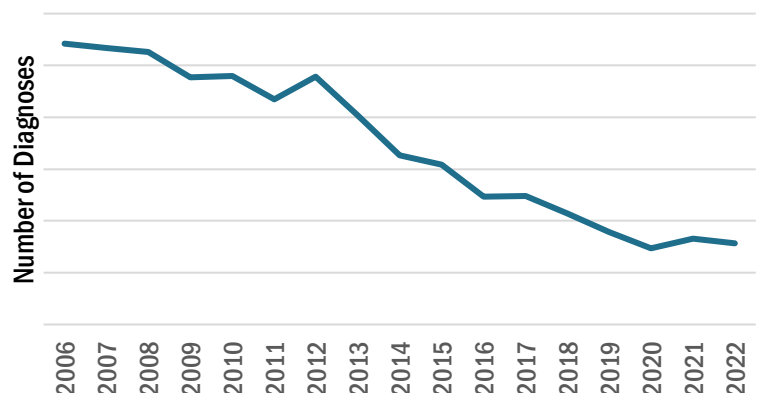
HIV Disparities and Health Inequities

Despite promising trends, HIV-related disparities persist in SF with respect to diagnosis and viral suppression rates. Populations experiencing HIV-related disparities include people who are Black/African American, people who are Latina/o/e/x, gay men and other men who have sex with men (MSM), trans women, people who inject drugs (PWID), and people experiencing homelessness (PEH). Select examples are shown in Exhibit 3, next page.

Exhibit 1: Key milestones in SF’s ‘Getting to Zero’ Efforts

- New HIV diagnoses have decreased 71% since 2006; no children <13 years have been diagnosed since 2005.
- Three-year survival rates for people with stage 3 HIV have nearly quadrupled—88% from 2012-21, vs. 23% from 1980-89.
- HIV-related deaths are making up smaller proportions of all deaths; 26% of deaths in SF were HIV-related from 2018-2021, versus 41% of deaths from 2010-2013.
- Most HIV-related deaths are occurring among people ages 60 and older.
- PLWH are aging, with 2/3 of PLWH in SF 50 years and older and 30% 60 years and older.
- 97% of PLWH are aware of their HIV status.
- 90% of people newly diagnosed with HIV in 2022 were linked to care within 1 month of diagnosis; 80% of those newly diagnosed were virally suppressed within 1 year.
- Linkage to care is typically fast; from 2018-2021 the median time between diagnosis and first care visit was 1 day, and the median time to ART initiation was 0 days.

Exhibit 2. New HIV diagnoses in SF have decreased 70% (2006-22)



³SFDPH HIV Epidemiology Annual Report 2022: <https://www.sfdph.org/dph/comupg/oprograms/hivepisecc/hivepiseccreports.asp>SFDPH

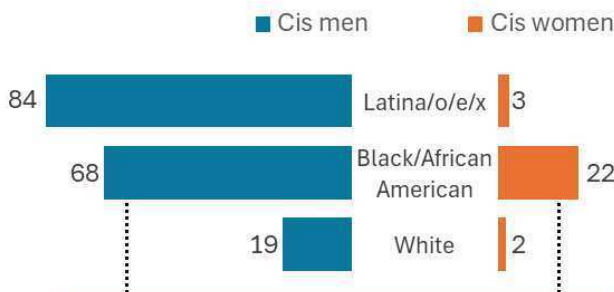
Summary of HIV Epidemiology

The overall decline in new HIV diagnoses and improvements in HIV care outcomes are encouraging. However, persistent disparities by race/ethnicity, housing status, transmission risk group, gender, and mental health and substance use factors highlight the critical need to address the social determinants of health.

Exhibit 3. Select examples of persistent HIV-related disparities in SF*

Among the SF populations with the highest numbers of HIV diagnosis, Latina/o/e/x and Black/African American **cis men** and Black/African American **cis women** experience higher rates of new HIV diagnosis, compared to white cis men and women.

HIV diagnosis rates per 100,000 shown below (2022)



Black/African American San Franciscans experience high HIV mortality :

- Mortality among Black cis men was double the rate of white cis men and nearly triple that of Latino/e/x cis men in 2021.
- Mortality among Black cis women was 4.1x that of Latina/e/x cis women and 5.9x that of white cis women in 2021.

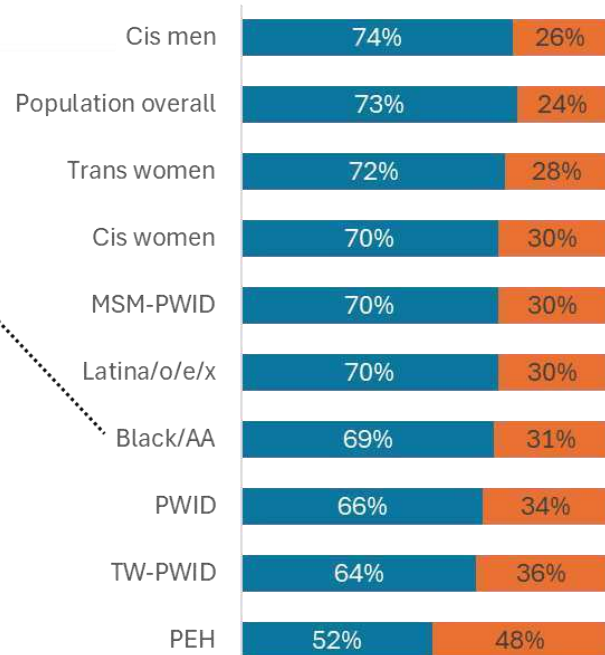
- 19% of new HIV diagnoses were among **PWID** in 2022, despite PWID making up ~3% of SF residents.
- Similarly, 17% of new diagnoses were among **PEH** in 2022, despite PEH making up <1% of SF residents.



- **MSM (including PWID)** made up 72% of new HIV diagnoses in 2022, despite making up 7.8% of the SF population.
- **Trans women** made up 3% of new HIV diagnoses in 2022, despite making up 0.1% of the SF population.

Viral suppression rates vary by race/ethnicity, gender identity, and injection drug use.

Percent virally suppressed shown below, 2022 (some groups overlap)



***PWID** = people who inject drugs; **PEH** = people experiencing homelessness; **MSM** = men who have sex with men; **AA** = African Americans; **TW** = trans women

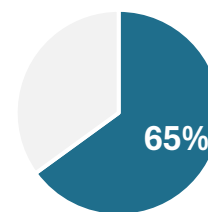
HEPATITIS C (HCV)

Background

In 2019, researchers from *End Hep C SF*—SF’s collective impact HCV elimination initiative—estimated that 22,585 residents of SF (2.6% of all SF residents) had antibodies to HCV. This is higher than the U.S. seroprevalence estimate of 1.7%. *End Hep C SF* also estimated that 11,582 SF residents (1.3%) still have untreated, active HCV infection, which can transmit to others and progress towards liver disease.

Before 2014, HCV treatment was highly toxic, required almost a year to complete, and had a very low success rate. As a result, many people who knew they were living with HCV chose to forgo treatment options, risking severe liver damage from chronic HCV infection. Today, curative treatment for HCV is now widely available in SF, easy to take with short treatment regimens, and has exceptionally high cure rates. Thousands have been cured since the advent of the new treatments, but those with the greatest barriers to care continue to experience disparities in access to these treatments and are also disproportionately represented among HCV cases. Therefore, identifying and addressing remaining disparities is critical to equitable HCV elimination in SF.

Key to improving HCV treatment rates is ensuring that people living with HCV are aware of their status and linked to care. In 2022, 62.4% of chronic HCV cases newly reported to the health department had positive HCV antibody tests *without* confirmation of a positive HCV RNA test that would indicate current HCV infection. Reporting of both negative and positive HCV RNA tests by labs (currently being integrated into laboratory reporting processes) is a critical step towards better understanding the epidemiology of HCV in SF, and in guiding programmatic efforts to support linkage to care and curative treatment to those with confirmed, chronic HCV.



In 2022, the majority of SF’s reported HCV antibody positive cases were **not confirmed** with an HCV RNA test.

Notably, people with HIV are disproportionately impacted by HCV. In SF, it is estimated that 11.5% of PLWH are co-infected with HCV, with co-infection particularly high among MSM and PWID. Despite successful citywide efforts to increase HCV treatment uptake, there are still an estimated 500 to 1,000 San Franciscans who are co-infected with HIV/HCV who need HCV treatment. This includes approximately 130 people who are SF Health Network (SFHN) patients.

HCV Disparities and Health Inequities

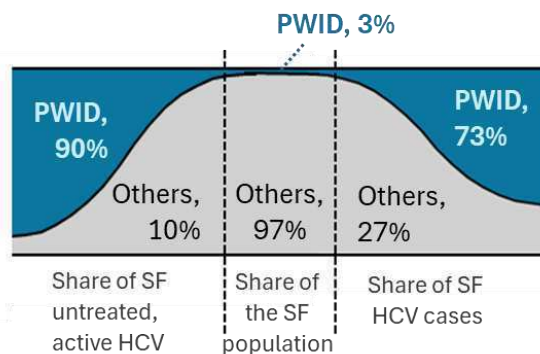
Groups of people less likely to be engaged in medical care account for most people living with HCV in SF. Similar to HIV, the SF populations most disproportionately impacted by HCV include PWID, trans women, MSM, and people who are Black/African American (Exhibit 4, next page).

Summary of HCV Epidemiology

HCV elimination in SF is a reachable goal, given curative treatments, but barriers to treatment access must be addressed. SF’s HCV efforts prioritize reaching and effectively serving populations with the greatest disparities and highest barriers to treatment and cure. People co-infected with HCV and HIV are a priority, as people who are co-infected are more likely to experience adverse health consequences of HCV compared to those who are not also living with HIV.

Exhibit 4. Select examples of HCV-related disparities in SF***Many SF populations experience a disproportionate burden of HCV.**

- An estimated **63% of PWID** (10,468 people) have untreated active HCV infection in SF.
- Shown below, PWID make up a disproportionate percent of untreated, active HCV infections (left) and HCV cases overall (right), compared to their population size (middle).

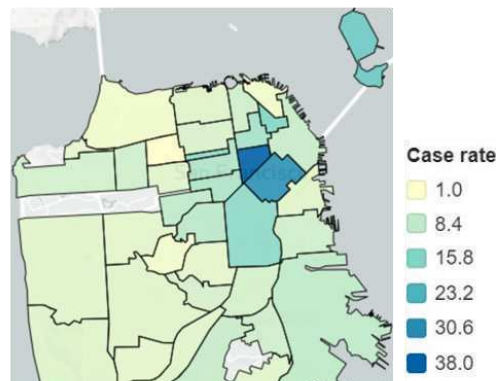


- **An estimated 57% of low SES trans women** have untreated active HCV infections; these women account for 1.6% of untreated active infections despite making up 0.1% of the total SF population.
- 70% of SF chronic HCV cases reported to SFDPH in 2022 were among **men**. Among men, **MSM** are estimated to account for 11.7% of HCV cases and only 7.8% of the population; 1% of cases are estimated to still have untreated active infections.
- **People who are Black/African American** comprise 22.5% of all SF chronic HCV cases reported to SFDPH in 2022 but only 4.9% of the SF population.

Age trends in HCV

Most HCV cases in SF are older; however, younger people (<45 years old) are increasingly represented:

- Among all cases reported to SFDPH in 2022, 46.4% of all cases were born between 1945 and 1965 (“baby boomers”), compared to 32.8% of newly reported cases in 2022.
- Newly reported cases in 2022 were more likely to be born after 1984 when compared to all cases reported in 2022 (38 years or younger). The proportion of newly reported cases born after 1984 was 30.9%, compared to only 20.4% of all cases reported in 2022.

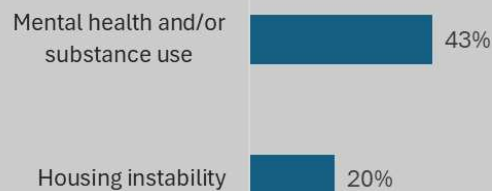
Neighborhoods with lowest median income have higher HCV rates.

The rate of newly reported cases in 2022 was highest for the Tenderloin, South of Market, and Treasure Island neighborhoods. The Tenderloin and Treasure Island neighborhoods have the second and third highest poverty rates in SF, respectively.

Top barriers to HCV care among people coinfecting with HIV and HCV

Among people coinfecting with HIV and HCV, those who experience the highest barriers to HCV care and cure often have **co-occurring medical and mental health diagnoses, and are often experiencing housing instability and other socioeconomic challenges.**

Percent of people coinfecting with HIV/HCV reporting the barrier at Zuckerberg San Francisco General Hospital HIV/AIDS clinic



*PWID = people who inject drugs; SES = socioeconomic status; MSM = men who have sex with men; PLWH = people living with HIV

SEXUALLY TRANSMITTED INFECTIONS

Background

SF has higher chlamydia, gonorrhea, and early syphilis rates compared to all of California and the U.S., as well as Los Angeles and New York City. From 2008 to 2018, while the number of new HIV diagnoses declined by over 60%, the rate of chlamydia increased 244%, the rate of gonorrhea increased 195%, and the rate of early syphilis increased 157%. However, in recent years (2017-2022), SF has seen decreased annual incidence rates for chlamydia, gonorrhea, and early syphilis. Between 2019-2022, citywide chlamydia rates declined by 32%, gonorrhea by 7%, and early syphilis by 26%, likely related to changes in sexual behaviors and disruptions in access to health services during the COVID-19 pandemic.

In San Francisco, cis men make up 95% of new early syphilis cases,¹ and about two-thirds of new early syphilis cases occur among gay, bi, and other men who have sex with men (MSM).⁵ However, **syphilis rates have been increasing rapidly among cis women in San Francisco**, mirroring a marked increase in reported cases of syphilis among women and congenital syphilis both nationally and in California. From 2017–2021, syphilis diagnoses among cis women in San Francisco increased by 200% (1582 to 1642) and **CS cases increased 333%** (13 cases) compared to the prior five-year period (3 cases). SFDPH focused efforts on identifying and prioritizing pregnant women with syphilis, and on better understanding the populations most impacted by female syphilis.

Since the national mpox outbreak in 2022, SF has recorded 940 total cases as of 4/12/24⁴ and the highest cumulative mpox case rate in the state. Cases have declined overall since 2022 (842 cases), with 91 cases reported in 2023; 96% of cases have been among men and the majority reported sex with other men. Cases have also disproportionately impacted people who are Hispanic/Latina/o/e/x and white.

The effects of doxycycline post-exposure prophylaxis (doxy-PEP) for STI prevention on rates of STIs are being monitored. Among MSM, chlamydia and syphilis cases have declined from 2022 to the end of 2023 - since the introduction of doxy-PEP in the last quarter of 2022. However, the number of chlamydia cases among cis women (for whom doxy-PEP is not recommended) have been increasing over the same time period.

Given the relatively high incidence of STIs in SF, SFDPH is prioritizing populations disproportionately impacted (Exhibit 7, next page), including: 1) gay, bisexual, and other MSM; 2) adolescents and young adults, particularly those who are BIPOC; 3) trans persons; and 4) cis women of reproductive age who are at risk for syphilis infection

Exhibit 5: Explaining STI rises (2008-18)

Paradoxically, increased STIs may have been driven by gains in HIV prevention. Decreases in HIV in SF are the result of scaled-up HIV testing, promotion of early and widespread HIV treatment, a strong linkage to care program, and access to pre-exposure prophylaxis (PrEP). As taking PrEP if HIV-negative or maintaining an undetectable HIV viral load if living with HIV can prevent sexual transmission of HIV, condom use has declined, facilitating transmission of gonorrhea, chlamydia, and syphilis.

Exhibit 6: Increases in syphilis in cis women and congenital syphilis

Female syphilis cases rose from 114 to 184 between 2018-21 and then plateaued from 2021-24. Among 186 female syphilis cases in 2022, 18 were known to be pregnant, including 6 who were experiencing homelessness, 4 who reported methamphetamine use, and 1 who reported heroin use. Of the 16 pregnancy outcomes known, 9 averted congenital syphilis, 4 resulted in spontaneous or therapeutic abortion, and 3 resulted in congenital syphilis.

⁴ <https://www.sf.gov/data/mpox-case-counts#cumulative-cases>

(and therefore newborns with congenital syphilis). Across all four of these populations, people who are Black/African American experience higher rates of STIs than any other racial/ethnic group and are therefore included as a prioritized population.

Summary of STI Epidemiology

- Syphilis rates are still high among cis women. Congenital syphilis is of concern and complex to address, given its overlap with substance use and homelessness among pregnant people.
- Declines in chlamydia, gonorrhea, and syphilis among MSM since the emergence of mpox and doxy-PEP are being evaluated.
- An uptick in mpox cases since July 2023 reflects the need for ongoing vaccine promotion and education.
- Persistent STI disparities among adolescents and young adults requires continued efforts to promote screening and education, particularly among BIPOC youth.

Exhibit 7. Select examples of STI-related disparities in SF

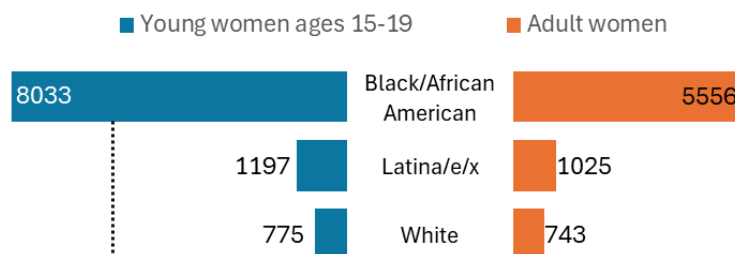
Among populations with at least 200 reported cases of chlamydia or gonorrhea and 100 cases of early syphilis in 2022, **Black/African American and Latina/o/e/x people experienced the highest rates of all three of these STIs.**



- **Gay men and other men who have sex with men** have the highest prevalence rates of gonorrhea, chlamydia, and early syphilis compared to other transmission groups.
- **Trans women** also have very high rates of STIs compared to other San Francisco residents; at SF City Clinic, STI positivity among trans women is similar to positivity among men who have sex men.

Chlamydia rates among women are extremely high among those who are Black/African American, followed by those who are Latina/e/x, compared to those who are white.

Chlamydia rates per 100,000 shown below (2022)



Among youth of all genders, Black/African American and Pacific Islander youth, followed by Latina/o/e/x youth, experience the highest chlamydia rates.

PRIORITY POPULATIONS

A key rationale for an integrated approach to HIV, HCV, and STIs is the strong (but not perfect) overlap in affected populations (Exhibit 8), because it creates numerous opportunities for programs to offer a comprehensive suite of prevention, testing, care, and treatment services that promote sexual health, harm reduction, and overdose prevention. Populations with **two or more** disparities in key epidemiologic indicators are deemed priority populations for ending the epidemics. Three common epidemiologic indicators of disparities are:

1. **High prevalence**, meaning that the percentage of people in the given population who are affected by HIV, HCV, or STIs is higher than for others. This indicator represents the disproportionate burden of disease carried by a population.
2. **Account for a disproportionate number of new infections**, meaning that the number of people newly acquiring HIV, HCV, or STIs is higher in a given population than would be expected given their representation in the overall SF population. For example, if there were 150 people in all of SF, and two-thirds of the population (n=100) was from population X and one-third (n=50) from population Y, you would expect that, all things being equal, population X would experience two-thirds of new infections and population Y one-third. If population X experienced more than two-thirds of new infections (or population Y experienced more than one-third of new infections), this would be considered a disparity.
3. **Less likely to be virally suppressed or experience other positive health-related outcomes**.

It is important to note that the highlighted priority populations are not the only ones in need of services. Limited data and/or small numbers for some populations, such as Native Americans, make it difficult to assess disparities that might exist. In addition, services are still needed for populations with low HIV/HCV/STI incidence and prevalence, to ensure that the low rates are sustained and to ensure equitable access to services for all. For example, while HCV and HIV prevalence and incidence are relatively low among youth, there are high rates of STIs among youth of color, and programs for youth are key opportunities for health education and support services. People who are incarcerated are also a critical population, although not separately highlighted as a priority population in this plan because PEH, PWU/ID, and Blacks/African Americans are disproportionately represented among this group. Lastly, Exhibit 8 does not represent the multiple intersectionalities of identity and experience, nor does it reflect the complexities of differences in health outcomes among population subgroups or the fact that a population can have positive outcomes with respect to some indicators and poorer outcomes with respect to others. All of these factors underscore the importance of tailored interventions that are data-informed, but also informed by community needs and experience.

Exhibit 8: Priority Populations for Ending the Epidemics

Population	HIV	HCV	STI
Blacks/African Americans	- Account for a disproportionate number of new infections - Less likely to be on PrEP or achieve viral suppression	Account for a disproportionate number of new infections	- Account for a disproportionate number of new infections - B/AA youth: High prevalence (GC, CT)
Latina/o/e/x	- Account for a disproportionate number of new infections - Less likely to achieve viral suppression		Latina/o/e/x youth: High prevalence (GC, CT)
Trans women	- High prevalence - Account for a disproportionate number of new infections	- High prevalence - Account for a disproportionate number of new infections	High prevalence
PWU/ID	- High prevalence - Account for a disproportionate number of new infections	- High prevalence - Account for a disproportionate number of new infections	Account for a disproportionate number of female syphilis cases
PEH	- Account for a disproportionate number of new infections - Less likely to be on PrEP or achieve viral suppression		Account for a disproportionate number of female syphilis cases
MSM	High prevalence	Account for a disproportionate number of new infections	- High prevalence (GC, CT, syphilis, mpox) - Account for a disproportionate number of new infections
Cis women	Less likely to be on PrEP or achieve viral suppression		Vertical transmission risk among cis women of reproductive age (syphilis)

3. Foundational Efforts Addressing HIV, HCV, and STIs

SF'S APPROACH

Integrated services and whole-person care approach

Given the overlap in the populations experiencing persistent disparities in SF, whenever appropriate, all three epidemics are approached jointly to ensure a whole-person care approach to HIV, HCV, and STI prevention, care, and treatment. This aligns with key values and principles in the SF EtE Plan.

- 1) **Integration of HIV, HCV, and STI prevention, care and treatment services, and harm reduction and overdose prevention.** Given the interconnectedness of these diseases and the broader drivers of the disparities such as substance use, mental health disorders, homelessness, poverty, racism, homophobia, sexism, and transphobia, to succeed at ending the epidemics, SF has committed to fully integrated systems and programs whenever appropriate that are person-, not disease-centered.
- 2) **Whole person care.** In the broadest sense, whole person care is predicated on the understanding that the best way to care for people with complex needs is to consider the full range of those needs – including physical, mental, social, and economic needs. SF's whole person care approach builds on an “ecosystem of care” model that emphasizes care coordination across medical, mental health, substance use, housing, and social needs.

An ideal integrated service model allows a person to get support for all their health and social service needs, whether it's HIV/HCV/STI testing or care, or, for example, other support for quitting smoking, benefits navigation, or substance use counseling. With this approach, the clients' experience and health outcomes are improved. SF's approach to integrated services and coordinated strategies is exemplified by Health Access Points and the Centers of Excellence.

SF's Foundational HIV/HCV/STI Efforts: Setting the Stage for Ending the Epidemics

The EtE initiative focuses on scaling up and implementing innovations in four science-based strategies—diagnosis, treat, prevent and respond—that together can end the HIV/HCV/STI epidemics. Starting on p. 18, SF's plans for scaling and innovating services are described. However, it is critically important to note that these efforts are layered on top of a strong foundation of strategically developed HIV, HCV, and STI services built over decades (in the case of HIV and STIs) and more recently (HCV). This section describes this foundation, its evolution, and how that groundwork is acting as a springboard to end the epidemics. The diagnose, treat, prevent, and respond pillars are a useful framework, but many of the existing foundational efforts cut across the pillars because many programs in SF already offer integrated testing, treatment, and prevention services. For the purposes of this plan, the services are described in the most relevant pillar.

Pillar 1: Diagnose

Over the last decade, SF's HIV testing providers—in both community and clinical settings—helped normalize HIV testing as part of regular health maintenance, especially among the most impacted communities, contributing

significantly to 97% status awareness among PLWH in SF. Chlamydia, gonorrhea, and syphilis testing has been available at SF City Clinic, in public and private primary care settings, and some community-based sites, but not all HIV testing locations offer STI testing. Community-based HCV testing, particularly for PWID and people experiencing homelessness, has scaled up dramatically since the advent of direct-active antivirals for HCV treatment, but requires the capacity for wide and deep reach into communities at risk, many of which do not access health care in traditional settings, or at all. Given the overlapping epidemics and risk factors, siloed testing represents lost opportunities for diagnosis, treatment, and education. SF aims to expand integrated HIV/HCV/STI testing in 2024-2026.

The infrastructure built to support CLIA-waived rapid HIV community-based testing and to routinize HIV screening in primary care and other clinical settings serving priority populations represents a solid foundation to achieve this aim. Successful integrated testing already exists at SF City Clinic and some other locations. This plan describes a number of activities to scale up HIV/HCV/STI integrated testing in the context of a broader effort to address the social determinants of health. For example, the new Health Access Points, which are tailored to specific populations experiencing disparities (described under Pillar 3 and throughout this plan) are required to offer integrated testing, and SFDPH's public health detailing program will be working to integrate HCV and STI testing in clinical settings where it makes sense given the population served.

Other innovative efforts identified for scale-up include pharmacy-based integrated testing, mobile testing, self-testing, and integrated testing in non-traditional settings where syndemic-affected populations can be reached, such as supportive housing, jails, and substance use treatment programs.

Pillar 2: Treat

HIV

SF is home to one of the first outpatient HIV clinics in the nation (ZSFG Ward 86). It was also the first city to establish a policy that ART should be universally offered to people upon HIV diagnosis, and is widely known for its rapid adoption of new advances in treatment. PHAST (Positive Health Access to Services and Treatment) is an interdisciplinary team at Ward 86 staffed by a registered nurse, clinician, and social worker who offer low-barrier access to RAPID ART and linkage to care support to patients coming into Ward 86 after a new HIV diagnosis or those re-engaging in care after being out of care. The PHAST team supports over 500 patients a year, primarily priority populations described above, by providing expedited clinic intake, nursing care coordination, and psychosocial stabilization to patients vulnerable to being lost to follow-up due to high rates of homelessness, mental illness, and active substance use. The PHAST model addresses the social determinants of patient health along with addressing the barriers to care.

SF has exceptional capacity for providing state-of-the-art HIV treatment, including through the Ryan White-funded HIV Centers of Excellence (CoEs). CoEs were created to serve severe-need clients and special target populations. The CoE model establishes primary medical care at the center of an integrated service delivery model offering integrated access to both primary medical care and critical services. At a minimum CoE must provide: 1) primary medical care, 2) medical case management, 3) psychiatric assessment and psychiatric medication monitoring, 4) treatment adherence and medication assistance, 5) outpatient mental health treatment, and 6) substance use assessment, counseling, and referral. Each multidisciplinary CoE, while open to all, is customized to serve a particular population that has unique or disproportionate barriers to care, needs additional or unique services, or requires a special level of expertise to maintain them in care:

- **Homeless Aging and Long-term Survivors (HALT) Center of Excellence**

Focuses on services for people experiencing housing instability and homelessness; men who have sex with men; Latina, African American and trans women; and immigrants, with a focus on undocumented Spanish-speaking persons.

- **HIV Integrated Services (HIV-IS)**

Focuses on the coordination of care for HIV-positive incarcerated and post-release people and serves the SF County jails.

- **Mission Center of Excellence**

Focuses on services for Latino/Latina populations, including monolingual Spanish speakers and immigrants, regardless of legal status.

- **Black Health Center of Excellence**

Focuses on services for underserved and uninsured Black/African Americans, including cis women and trans women.

- **Tenderloin Area Center of Excellence**

Focuses on homeless and marginally housed persons, active substance users; transgender persons, Asian/Pacific Islander groups, and prison populations.

- **Women's Center of Excellence**

Focuses on underserved and severe-need cis and transgender women.

There is also a vast network of services beyond the CoEs for people living with HIV, including job training, housing, benefits counseling, and much more.

SFDPH's LINC'S (Linkage, Integration, Navigation and Comprehensive Services) program is also a core part of SF's foundation for HIV treatment. LINC'S serves people newly diagnosed with HIV and prioritized individuals who are not-in-care, including those who access care intermittently, and supports them to engage in care. All people who newly test positive for HIV in SF are offered linkage to care and partner services through LINC'S. LINC'S, which is housed at SF City Clinic, maintains strong partnerships with HIV care sites throughout SF. One of LINC'S' closest partnerships is with the PHAST team, which as mentioned above supports PLWH in accessing expedited care and RAPID ART. The partnerships with PHAST and other clinical care sites allow for successful linkage and engagement by lowering barriers to care and offering care coordination, system and insurance navigation, and appointment tracking.

In summary, PLWH experience many barriers to HIV care engagement in SF, especially barriers related to the social determinants of health, but due in part to numerous high-quality, culturally tailored treatment options, SF has linkage to care and viral suppression rates that are higher than for CA and the U.S.

HCV

With the advent of direct-acting antiretrovirals in 2015, HCV became treatable in the primary care setting, whereas before it could only be treated in specialty settings (such as in liver clinics or by hepatologists). Shortly thereafter, SFDPH's primary care providers were offered training to treat HCV, and a clinical consultation line was established. HCV curative treatment is covered by Medi-Cal. This extraordinary medical advance made it possible to envision an end to HCV in SF, and in 2016, the End Hep C SF collective impact initiative was born. This group has engaged in advocacy, fundraising, provider training, research, and service provision to take advantage of this historic opportunity to eliminate HCV in SF. End Hep C SF began an HCV navigator program to link people to treatment, which is still in place today. LINC'S provides navigation to HIV/HCV-coinfected patients. A major gap is the provision of HCV treatment in the jail setting, because incarcerated people do not retain Medi-Cal while in jail, and the City currently only covers the cost of HCV treatment during incarceration for a limited number of people

each year; thus, there has been a dedicated jail health navigator for many years who works to link people to treatment upon release.

STIs

With SF's high rates of chlamydia, gonorrhea, and syphilis, easy access to diagnosis and treatment is a critical prevention strategy. SF City Clinic, SF's only municipal STI clinic, is a nationally recognized center of excellence in the provision of quality STI clinical services and serves as a critical access point for low-barrier, confidential, and culturally sensitive clinical STI diagnostics, prevention, and treatment, in addition to offering family planning, HIV care, PEP, and PrEP. STI diagnosis and treatment is also available in primary care settings in SF and at many CBOs. STIs have increased among MSM, making easy access to diagnosis and treatment critical. SF's collaboration with TakeMeHome, a national HIV/STI self-testing program, and doxycycline PEP (doxy-PEP), which can be taken after sex to prevent bacterial STIs, are two key efforts that have already begun and will scale up over the next several years.

Pillar 3: Prevent

In the decades prior to U=U⁵ and PrEP, SF's primary approach to HIV prevention involved providing health education and risk reduction to people at risk for HIV as well as people already living with HIV. In the early 2010s, we learned that HIV is virtually untransmissible if a person with HIV is virally suppressed or a person without HIV is on PrEP, and this was a game changer for HIV prevention. Since then, SF has invested heavily in universal and rapid HIV ART, PrEP, and HIV testing so people can learn their HIV status early on to improve outcomes. The results can be clearly seen with the significant decline in new diagnoses between 2012 and 2022. Similar treatment and testing strategies are also being heavily deployed throughout SF for HCV and STIs.

Syringe access and disposal and condom access continue to play a significant role in the HIV prevention landscape, with syringe access also a key HCV prevention strategy and condoms also protective for STIs. SF services aim to be non-stigmatizing, sex-positive, and harm reduction-focused.

In 2023, SFDPH implemented a new service model as part of the shift to a syndemic approach using an SDoH lens: Health Access Points (HAPs). The HAPs, funded and overseen by the CHEP Branch, are integrated low-barrier HIV/HCV/STI service models, where each HAP delivers services for a specific priority population—similar to the CoE model for care services. Each HAP is required to provide integrated testing, linkage to PrEP, HIV/HCV/STI treatment, harm reduction and overdose prevention services, health education, and referrals to services to meet basic needs (e.g., food, housing). The goal is to grow the HAPs into fully functioning “one-stop shops.” The HAPs are:

- LOTUS, serving Asians & Pacific Islanders
- Umoja, serving Blacks/African Americans
- Latina/o/e/x HAP
- MSM HAP
- The Lobby, serving PWUD
- Transitional age youth HAP
- STAHR, serving trans women

⁵ U=U means undetectable=untransmissible, a phrase that is used to denote the fact that studies have demonstrated that the risk of sexual HIV transmission is nearly 0 when the partner with HIV is virally suppressed.

Pillar 4: Respond

SFDPH is well-prepared to identify and respond to HIV transmission clusters and outbreaks. SFDPH offers partner services to all individuals newly diagnosed with HIV. This service includes assistance with notifying partners and linking them to testing, prevention and treatment if needed. Partner services can aid in the identification of epidemiologically linked or location-based clusters. SFDPH uses molecular HIV surveillance (MHS) to identify clusters of patients who have similar HIV genotypes. Large and closely connected clusters are reviewed to ensure that all individuals in the cluster are linked to care. SFDPH proactively meets with communities and organizations to keep them informed on MHS activities. This is especially important, given past and present harms committed by our medical, legal, and immigration systems, to address perceptions and respond to concerns that such activities could pose risks. In addition, SFDPH has processes in place to identify and reach out to people diagnosed with HIV who do not have recent evidence of medical care, such as a viral load test, in order to offer them linkage to care. Partner services are also important as a component of STI prevention and response. SFDPH offers partner services to prioritized patients with syphilis, as well as to patients with antibiotic-resistant gonorrhea.

4. Ending the Epidemics Plan

The SDoH have a disproportionate impact on BIPOC, economically fragile, and other vulnerable populations and drive the inequities in new infections and health outcomes for HIV, HCV, and STIs. For this reason, the SDoH are central to SF's ending the epidemics strategy, and therefore this plan is organized around that framework.

The six SDoH addressed in this plan are pictured below. Each SDoH has a section. The first page of the section is an introduction, describing the SF context, with SF's strategies listed on the bottom half of the page. The subsequent pages are a single table listing SF's activities related to that SDoH. The first column of the table lists the strategies related to each activity – including strategies that are part of other SDoH sections. This was necessary because the SDoH and therefore the activities are strongly interrelated. The *Related Strategies* column uses the SDoH abbreviations shown underneath the image below.



Lastly, the activities listed are either implemented or funded by SFDPH, unless another organization is listed at the end of the activity in [blue highlight](#).

Introduction

Inextricably linked to the stark racial disparities in HIV, HCV, and STIs in SF is the structural racism embedded in our systems and services, which exclude communities of color from economic opportunities, increasing their vulnerability and preventing them from experiencing optimal health. Structural racism persists because our systems were fundamentally, and in many cases intentionally, designed to benefit white people and to harm people of color. For example, the practice of redlining, in which neighborhoods where Blacks/African Americans (B/AA) lived were systematically denied financial lending opportunities. The effects of this practice were pervasive and severe; cutting off these neighborhoods resulted in reduced economic mobility for residents, spawning a cycle of intergenerational poverty, that today manifests as a stark wealth and income gap between B/AA San Franciscans and other groups. Systems designed to penalize immigrants, particularly Latina/o/e/x immigrants and other immigrants of color, represent barriers to accessing care, for fear that they may get deported and permanently separated from their family. The increase in hate crimes perpetrated against SF's A&PI residents in the wake of COVID-19 is yet another example of an unacceptable status quo. These realities represent chronic stressors that people of color must deal with, not to mention the stress and trauma resulting from the multitude of microaggressions they face in daily interactions, and an unimaginable host of other unjust circumstances from police brutality to inferior educational opportunities. It is no surprise that health outcomes across nearly all diseases are poorer among people of color.

The HIV, HCV, and STI sector, through thoughtful planning and implementation of services, is well-poised to break down barriers to access that cut across racial lines. Key strategies include transforming the composition of the workforce by increasing BIPOC representation, ensuring that funding and resources are allocated based on data and with an equity focus, and community engagement in planning and services delivery.

San Francisco Racial Equity Strategies

(see also *Economic Justice*)

- ✓ **Strategy 1: Leadership and Workforce Development**

Expand pathways and workforce development initiatives to increase the proportion of BIPOC public health staff, leadership, and administrators within SFDPH and funded HIV/HCV/STI community-based organizations.

- ✓ **Strategy 2: Racial and Ethnic Data Collection and Stratification**

Identify, collect, analyze, and publicly share data that reflects the specific trends, needs, and outcomes of HIV, HCV, and STIs for BIPOC communities, to inform resource allocation and identify community-based strategies and solutions.

- ✓ **Strategy 3: Equitable Distribution of Funding and Resources**

Review SFDPH HIV/HCV/STI policies, practices, and program decisions, such as processes related to contracts and budgets, with a racial justice lens, to advance equitable delivery of resources and opportunities to BIPOC.

- ✓ **Strategy 4: Community Engagement**

Forge strategic partnerships to ensure more diverse public outreach, involvement, and engagement processes to reframe the structure, funding, and policies of HIV, HCV, and/or STI services and messaging to all Californians.

- ✓ **Strategy 5: Racial and Social Justice Training**

Implement capacity building and training opportunities and requirements for SFDPH and its funded HIV, HCV, and STI service providers, to strengthen out movement towards achieving cultural humility, equity, and racial justice in our prevention, testing, treatment, and care services.

Social Determinant of Health				
RACIAL EQUITY				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
RE1 EJ1 EJ3	New Deputy Director of Workforce Development. Strengthen SFDPH's workforce planning, systems, processes, and policies to improve hiring, retention, and training, under the leadership of a new permanent Deputy Director of Workforce Development for the SFDPH Population Health Division (initially funded through the CDC Project INVEST grant). This position will lead and collaborate with a Population Health Division-wide workforce development working group to promote creative options for pathways to new positions within SFDPH (e.g., short-term "residencies" in other branches/divisions), strengthen existing staff well-being programs, launch and maintain a leadership development fund for community health and public health leaders, and start a community of practice for Community Health Workers.	X	X	X
RE1	Coaching and leadership development at SF City Clinic. Develop a coaching and leadership development initiative focused on building leadership capacity among mid-level BIPOC managers.	X		
RE1 EJ1 EJ2 EJ4	Annual conference/training for frontline HIV/HCV/STI workers. Implement an annual conference to support workers, especially newly hired direct service workers, to keep up to date on the vast landscape of HIV/HCV/STI prevention and care services. Include training on the system of care, referral/linkage protocols, and networking opportunities.		X	X
RE1 EJ1 EJ2	Community Health Leadership Initiative (CHLI). Continue to implement CHLI, which provides training on sexual and drug user health and mentorship to people interested in entry-level roles in the field. CHLI also offers internships, funding for micro-grants for community members to launch innovative ideas (e.g., podcasts), workforce appreciation and networking events, and spaces for peer connection.	X	X	X
RE1	The Academy. Continue to implement the Academy, with a focus on developing trainings and curricula for supporting the onboarding of new staff, especially those from affected communities (e.g., BIPOC, people with lived experience of HIV/HCV/STIs) working in the HIV/HCV/STI programs and services.	X	X	X
RE1	Workforce Development Collective. Convene a multisector Workforce Development Collective that meets monthly, facilitated by the CHLI Program's Workforce Development Director to foster relationship building, organic collaborations, resource sharing, thought partnership, sharing and creating best practices, strategies for burnout prevention and workforce sustainability.	X	X	X
RE1 EJ2	SFDPH's HIV/HCV/STI counselor training. Leverage the counselor training to create pathways for meaningful employment by recruiting and supporting people with lived experience of HIV, HCV,	X	X	X

Social Determinant of Health				
RACIAL EQUITY				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
	and STIs to participate in the training and pursue employment in the field.			
RE1 EJ1	End Hep C SF Leadership Development. Offer ongoing opportunities for professional and leadership development within the End Hep C SF initiative through supporting community leadership of workgroups, supporting community members to attend conferences and participate in trainings, and providing professional development mentorship to people with lived experience of HCV. <i>(End Hep C SF)</i>	X	X	X
RE1 EJ1 EJ2	SF HIV Frontline Workers Mentor Program (FMP). Continue to implement the FMP, which provides mentorship to people in entry-level roles who are new to the SF HIV Systems of Care. The FMP builds the capacity of new workers to effectively support their clients, stimulates collaborative cross-agency service delivery, and invests in the professional development of new and veteran workers alike.	X	X	X
RE1	Leverage current programs to increase workforce racial diversity. Work with existing workforce development programs, such as the HIV work re-entry program, to ensure that opportunities to support the next generation of HIV/HCV/STI providers better reflect the priority populations in terms of race/ethnicity.	X	X	X
RE2 RE3 RE4	Racial data stratification to inform resources and programs. Continue to stratify HIV, HCV, and STI data by race in monthly and annual surveillance reports and present this data to HCPC, Getting to Zero SF, End Hep C SF, and other community stakeholders to inform data-driven resource allocation and program planning.	X	X	X
RE3	Expand TakeMeHome, a mail order HIV and STI self-testing program. Expand partnership with TakeMeHome to promote self-testing for ETE priority populations via a variety of placements (websites, social media, through printed materials, via SMS).	X	X	X
RE4	SFDPH City Clinic Community Perspectives Assessment. Conduct a Community Perspectives Assessment with SFDPH City Clinic patients and community members to better understand why those who are most vulnerable to HIV infection, including MSM of color, trans women, people experiencing homelessness, and people who use/inject drugs do and do not seek services at City Clinic, to inform how to adapt and market SFCC services to ensure these communities feel well served.	X (conduct assmt.)	X (imple- ment recs.)	X (imple- ment recs.)
RE5	Participate in available cultural humility and racial justice trainings. Participate in CDPH's free cultural humility, equity, and racial justice training opportunities (when they become available), the SFDPH HIV Health Services Training Program's racial/culturally specific trainings, and the SFDPH's Black/African American Health Initiative (BAAHI) trainings. Encourage or require community-based providers to participate as training capacity allows.	X	X	X

Introduction

One of the most profound effects of San Francisco's economic shifts has been a surge in the number of San Francisco residents who are unhoused or unstably housed. It is important to note that this is not a monolithic group; it includes people who are temporarily sheltered, people who live outdoors, both individuals and families, and people with and without serious mental health diagnoses. This diversity means that tailored interventions are needed. In particular, the extremely high cost of housing has produced a wave of displacement that has pushed many middle- and working-class individuals and families from San Francisco, especially people of color, to outer areas of the region and has contributed to rapidly accelerating homelessness and housing instability. In San Francisco, people experiencing homelessness represent a large percentage of those diagnosed with HIV and HCV, and PEH are disproportionately represented among cis women with syphilis. Being homeless or marginally housed is strongly and unequivocally linked to poor health outcomes among people living with HIV (PLWH). Homelessness, mental health diagnoses, and substance use disorders frequently co-exist, compounding the challenges in serving this population effectively.

In SF, there are no easy solutions. While SF's HIV/HCV/STI programs cannot solve the housing crisis, SF can **greatly strengthen the connections between HIV/HCV/STI testing and treatment and housing-related services**. As the strategies below demonstrate, we envision this connection working in both directions—expanding HIV, HCV, and STI services in settings that serve people who are homeless or marginally housed while also strengthening access to housing supports such as coordinated entry, housing case management, housing subsidies and service linkages for individuals receiving HIV, HCV, or STI services.

San Francisco Housing First Strategies

(see also *Healthcare Access for All* and *Mental Health and Substance Use*)

- ✓ **Strategy 1: Data Collection and Use**

Improve the ability of local data systems to collect information on housing status so that we can better monitor differences in HIV, HCV, and STI rates and health outcomes by housing status and use this information to inform public health action.

- ✓ **Strategy 2: Strengthening Infrastructure**

Develop the collaborations necessary for integrated, multidisciplinary, whole-person services in order to effectively address the multiple and complex needs among people experiencing homelessness, including HIV/HCV/STI prevention, screening, and treatment; housing; harm reduction and substance use treatment; and mental health, medical, and social services.

- ✓ **Strategy 3: Street Medicine Strategies**

Expand and improve coordination of street-based and mobile programs (e.g., walking teams, medical vans, outdoor clinics) that provide medical and support services to people who are unhoused.

Social Determinant of Health HOUSING FIRST				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
HF1	Move towards a collective definition of homelessness across local data systems. Bring into alignment the multiple definitions of homelessness across EPIC (the SFDPH electronic health record), ARIES, HIV prevention data systems, HIV/HCV/STI surveillance, and Department of Homelessness and Supportive Housing (HSH), and other data systems.	X	X	
HF1	Aim to eliminate disparities in viral load suppression among PEH. SFDPH Health Services is implementing a CQI project aimed at eliminating the health outcome disparities (viral suppression) in people experiencing housing instability/homelessness for all clients receiving HIV medical care through SFDPH or an HHS funded agency. Data is reviewed on a quarterly basis to inform CQI strategies.	X	X	
HF2	HIV Homeless Outreach Mobile Engagement (HHOME). Ensure this program's continued capacity to provide intensive, community-based medical care and case management to PLWH experiencing homelessness who are not comfortable accessing four-walls clinics and to move them along the homelessness-to-housing continuum.	X	X	X
HF2	Tighten City systems to support smooth access to housing services. Work with the HIV Housing Workgroup to identify and address weak points in City systems that work together to support housing access, such as partnering with HSH to ensure people with HIV are prioritized during coordinated entry and expanding the impact of Transitional Residential Care Facilities to support housing readiness/independent living skills. <i>(Mayor's Office of Housing and Community Development)</i>	X	X	X
HF2 MHSU2	SF City Clinic staff training on SDoH referrals. Conduct ongoing training for the LINC team (DIS and navigators), clinicians, and nurses to strengthen skills in benefits navigation and referrals to housing, mental health, and substance use treatment services.	X	X	X
HF2 MHSU4	ZSFG pop-up clinic. Expand the new POP-UP clinic at the Positive Health Program on Ward 86 at Zuckerberg San Francisco General Hospital (ZSFGH). The clinic provides open-access, incentivized, comprehensive, relationship-centered care and enhanced outreach for PLWH not engaged in HIV medical care who are unhoused and not virologically suppressed. Other services include directly-observed therapy and medication pick-ups; behavioral health services, food, clothing, and hygiene kits; and referrals to social services, including vocational training, financial management, legal services, and transportation.	X	X	X
HF2 HAF2 MHSU4	Collaborate with HSH to ensure improved access to HIV, HCV, STI, and overdose prevention services. Work with HSH, supportive housing site managers, and tenant leaders to ensure that syringe services, overdose prevention and education, behavioral health, and sexual health services are available at shelters, navigation centers, supportive-housing sites, and single-room occupancy (SRO) hotels.	X	X	X

Social Determinant of Health HOUSING FIRST				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
HF2	Linkage and navigation systems. For PLWH, people with HCV, and people who are or can become pregnant experiencing homelessness, continue to improve linkage and navigation processes in hospitals, emergency departments, and jails to appropriate HIV primary care, biomedical HIV/STI prevention, and prenatal care destinations.	X	X	X
HF2	Programs for underrepresented minority (URM) patients. Support development of novel programs to target needs for URM patients and other special populations. Despite dropping rates of new HIV infections in San Francisco, the incidence of people newly diagnosed with HIV is rising in the Latine community. Getting to Zero SF is working to identify ways to improve the HIV prevention and care cascade for the Latine community. As described above, additional efforts are in place for the HAPs to focus on reaching specific populations (e.g., Black, Latino/a/x/e, PWU/ID, trans women, MSM, youth, etc.) in low-barrier settings. <i>(Getting to Zero SF)</i>	X		
HF2	Advocate for resources for pilot program for PLWH experiencing homelessness. Advocate for expanding successful evidence-based services like case management for PLWH experiencing homelessness. Identify and apply for funding from external sources to support pilot programs. <i>(Getting to Zero SF)</i>	X		
HF2	Further strengthen housing-related collaborations. SFDPH already has strong collaborations with the Mayor's Office of Housing and Community Development (MOHCD) and will continue to work with MOHCD to improve efficiencies in HOPWA-supported housing services.	X	X	X
HF2	Support housing navigation services. Fund an HIV Housing Navigator to collaborate with HSH and MOHCD to move Coordinated Entry Housing Referral Status clients with HIV through the placement process and ensure that HSH has a way to identify PLWH in the Coordinated Entry system.	X	X	X
HF3	Improve access to low-barrier programs. Streamline eligibility criteria for low-barrier and mobile-based HIV programs, and support movement between programs. Create a warm handoff referral guide for programs that focus on low-barrier care and access for PEH, including a small palm card with provider contacts. <i>(Getting to Zero SF)</i>	X		
HF3	Expand availability of long-acting injectable (LAI) ART and PrEP. Continue to work to expand access to LAI ART and PrEP in and outside of clinic environments, including through Health at Home, partnerships with behavioral health programs, and permanent supportive housing sites with nursing on site, and in collaboration with the Whole Person Integrated Care Initiative (WPIC) in shelters and navigation centers. <i>Getting to Zero SF</i> will also support development of pilot studies and research to assess acceptability, feasibility, and efficacy of LAI PrEP and ART, especially for people experiencing homelessness.	X	X	X

Social Determinant of Health HOUSING FIRST				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
HF3	Best practices for mobile care. Develop and disseminate toolkits for best practices regarding implementation in low-barrier, mobile care models. <i>(Getting to Zero SF)</i>	X		
HF3	Expand SFDPH capacity for mobile HIV/HCV/STI services. Develop a locally tailored, integrated, harm reduction-based mobile services model (“mobile HAP”) for HIV/HCV/STI testing and other prevention services, including overdose prevention and low-threshold access to medication-assisted treatments (MATs) such as naltrexone and buprenorphine. Priority neighborhoods include the Bayview and Mission, where a substantial percentage of the population is Black and Latina/o/e/x, respectively.	X	X	X

Introduction

San Francisco is known throughout the country and the world for its innovative models of HIV, HCV, and STI service delivery, including, but not limited to:

- Integrated, person-centered service models, such as the SFPD-funded Centers of Excellence and Health Access Points designed for specific populations
- Mobile and street-based health care and support services, provided by Whole Person Integrated Care (WPIC), which includes the Street Medicine Team, and other homeless outreach teams
- Extensive services delivered by peers with lived experience in HIV, HCV, and STI, such as End Hep C SF's HCV Community Health Navigator program
- Comprehensive sexual health services available to all at SF City Clinic

With these successes in mind, SF continues to innovate to break down the barriers to prevention and care access for communities affected by HIV, HCV, and STIs. SF is largely focused on expanding population-specific strategies, as opposed to “one-size-fits-all” models of care. This means making services quick, easy, and readily accessible, as well as redesigning service delivery to be more responsive to the needs of specific populations. Because the population-specific services SF offers are too numerous to name, the activities in this section focus on new and emerging population-specific models of care. In addition, we have highlighted programs that facilitate language access.

San Francisco Health Access for All Strategies

(see also *Housing First* and *Mental Health and Substance Use*)

- ✓ **Strategy 1: Redesigned Care Delivery**
Work with health care providers, local health departments, public and private insurers, and private industry to increase access to care statewide through mobile healthcare, pharmacy-based care, and at-home testing programs.
- ✓ **Strategy 2: Trauma-Informed and Responsive Services**
Train medical and public health service providers in trauma-informed approaches to create trauma-responsive care to minimize retraumatization of patients, clients, and providers.
- ✓ **Strategy 3: Fewer Hurdles to Healthcare Coverage**
Train more community-based organizations to support benefits enrollment in communities with high numbers of uninsured people.
- ✓ **Strategy 4: Culturally and Linguistically Relevant Services**
Improve capacity of public health and health care providers to offer HIV, HCV, and STI services that are responsive to diverse cultural health beliefs and practices, preferred languages, health literacy, and other communication needs.
- ✓ **Strategy 5: Collaboration and Streamlining**
Develop secure ways for clinical providers, local health jurisdictions, homeless services programs, and other community-based organizations to share information and resources to coordinate people's care while protecting their right to privacy.

Social Determinant of Health HEALTH ACCESS FOR ALL				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
HAF1A1	Implement point of care (POC) syphilis testing for people who are or could become pregnant. Conduct public health detailing for POC syphilis testing in clinical settings, and issue written guidance for community settings (e.g., HAPs) regarding HIV/HCV/STI testing for this population.	X	X	X
HAF1A1 SF4	Provider education. City Clinic staff will educate San Francisco Health Network providers to improve knowledge and comfort around sexual health care, including guidance and technical assistance on identifying risk factors and conducting appropriate screening and treatment for syphilis, as well as pregnancy and STI counseling.	X	X	X
HAF1A1 HAF1A5	Syphilis screening workflows. Develop workflows in the emergency department and urgent care that facilitate syphilis screening before discharge for all pregnant people, PEH, people with a history of meth use, and those receiving a HIV test.	X (develop)	X (imple- ment)	X (imple- ment)
HAF1A1 HAF1A5 SF4	Increase HIV, HCV, and STI screening, and PrEP prescribing at ZSFG. Through clinical education, consultation, and continuous QI efforts, clinical champions will work to implement the following improved protocols: 1) asking all hospitalized patients about HIV transmission risk factors to see if they qualify for PrEP counseling; 2) ordering HIV/HCV/STI testing; and 3) initiating or referring to PrEP if indicated.	X	X	X
HAF1A4	Advertising of sexual health services. City Clinic will create and disseminate public services video ads, in multiple languages, on social media and social networking sites aimed at increasing access to City Clinic testing, treatment, and vaccination services for HIV, STI, HCV, and Mpox.	X	X	X
HAF1A1	Accelerate efforts to increase PrEP use. We will implement a multi-layered strategy to address barriers to PrEP uptake, including regionally with Alameda County, with a focus on improving PrEP provision to people of color, trans women, PWUD, and people who are unhoused. Strategies will include expanding PrEP 2-1-1; mobile PrEP; making PrEP available at Mission Wellness pharmacy; and same-day PrEP models.	X	X	X
HAF1A1	Self-collection/home testing. SF is partnering with the TakeMeHome program to provide free mail order kits with the following: HIV dried blood spot test and STI self-test kits (oral, vaginal, and anal swabs, and urine for CT/GC and dried blood spot for syphilis). Users of networking apps, like Grindr, can access ordering links embedded within HIV-related app content and they will also be able to access their lab-based results through a secure portal. SFDPH will promote this program on websites and social media, through printed materials, and via mobile texts.	X	X	X
HAF1A1 HAF1A2	Improve low-threshold, trauma-informed, substance use harm reduction services in community settings. Integrate HIV/HCV/STI	X	X	X

Social Determinant of Health HEALTH ACCESS FOR ALL				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
MHSU2 MHSU4	prevention and care services, contingency management services to address methamphetamine use, and street-based/mobile behavioral health and harm reduction education, referrals and linkages.			
HAF3	Increase training and access to information on benefits enrollment. Train providers on current issues related to benefits enrollment, including complexities of navigating the AIDS Drug Assistance Program (ADAP), Office of AIDS-Health Insurance Premium Payment (HIPP) Assistance (OA-HIPP), Employer-Based HIPP (EB-HIPP), and Medicare Part D Premium Payment Assistance (MPPP). Develop client-facing materials to educate clients on these and other benefits options.	X	X	X
HAF4	Continue to improve language access to comprehensive services. SFDPH funds several programs where services can be accessed in Spanish and A&PI languages. Spanish services include outpatient mental health for PLWH. The following services are available through the COEs and HAPs in both Spanish and A&PI languages: HIV/HCV/STI testing, linkage and navigation, harm reduction and syringe access services, HIV/HCV/STI health education and prevention, services to meet basic needs (such as food security), HIV primary care, HIV PrEP, ART, HCV treatment, STI treatment, mental health services, and a host of wraparound services. SFDPH will continue to assess demand for services in other languages (such as Portuguese) and implement improvements as needed.	X	X	X
HAF5	Expand care coordination (CC). Continue to build on current CC efforts, such as weekly, cross-agency, multi-disciplinary care coordination calls (with follow-up via EPIC charting, chat, emails, and calls), including calls focused on pregnant people experiencing homelessness and HIV not-in-care.	X	X	X
HAF5	Make data systems that support making CC more accessible to community-based organizations and medical providers. In 2021, City Clinic transitioned to the SFDPH-wide enterprise electronic health record, EPIC, which has improved STI/HIV care coordination across SFDPH providers. SFDPH will continue to identify areas where data access would improve care, such as ensuring that all HIV/HCV/STI community-based providers have access to the One System—the Coordinated Entry System for housing services—as well as other key systems.	X	X	
HAF5	Develop a sustainable inventory of services, including eligibility criteria, location and hours, and referral procedures. Explore possible solutions to fragmented and duplicative resource lists and client referral procedures, such as collaborating with https://sfserviceguide.org/ to expand its resource inventory, leveraging the Frontline Organizing Group's listserv to provide	X	X	X

Social Determinant of Health				
HEALTH ACCESS FOR ALL				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
	regular updates to changes in services, and/or issuing a monthly newsletter to HIV/HCV/STI CBOs.			
HAF5	Streamline linkages for people released from jail. Expand HIV/HCV/STI treatment, care, and prevention navigation services to three HAP sites to establish a comprehensive, streamlined service model for people who are newly released from SF County Jail.		X	X

Introduction

The trifecta of homelessness, mental health, and substance use is one of the key drivers of new HIV, HCV, and STI infections, and has contributed to an alarming uptick of fatal overdoses in SF in recent years. In San Francisco, access to culturally appropriate mental health and substance use services is an essential component of HIV, HCV, and STI prevention and care. But that access is still limited for many of the people who most need it, despite Medi-Cal expansion, Mental Health SF and other attempts to increase access.

SF's success at addressing mental health and substance use will rely on the following overarching approaches:

- Improving and expanding options for harm reduction and substance use treatment, including low-barrier medication assisted treatment (MAT) and comprehensive syringe services programs, regardless of HIV, HCV, or STI status;
- Ensuring equitable access to naloxone and overdose prevention and response trainings; and
- Partnering with SFPD Behavioral Health Services (BHS) and the San Francisco Behavioral Access Center (BHAC) to work towards expanding availability of systemwide access to mental health services.

SAN FRANCISCO MENTAL HEALTH AND SUBSTANCE USE STRATEGIES

(see also **Housing First** and **Healthcare Access for All**)

✓ **Strategy 1: Overdose prevention in correctional settings**

Promote medication for opioid use disorder during incarceration in prison and jails and naloxone distribution and continuity of substance use disorder and medical care upon release.

✓ **Strategy 2: Mental health and substance use disorder treatment access through telehealth**

Leverage telehealth to increase access to mental health and SUD services, especially for people newly linked to stable housing and people who are monolingual in a language other than English.

✓ **Strategy 3: Build harm reduction infrastructure**

Expand syringe services in federally qualified health centers, hospitals, and SUD treatment facilities; build up staffing, brick and mortar locations, and comprehensive support services (health, legal, housing, benefits, employment) in existing syringe services programs.

✓ **Strategy 4: Expand low-threshold SUD treatment options**

Expand options for harm reduction-based treatment, including contingency management programs and easier access to buprenorphine and methadone, including in street medicine programs.

✓ **Strategy 5: Cross-Sector Collaboration**

Encourage collaboration between local and statewide mental health programs, substance use programs, and harm reduction and HIV/HCV/STI programs.

Social Determinant of Health MENTAL HEALTH AND SUBSTANCE USE				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
MHSU1	Comprehensive status-neutral sexual and drug user health services in jails, including naloxone. SFDPH's Jail Health Services provides HIV, HCV, and STI testing, naloxone, HIV primary care, and a wide range of other services to people experiencing incarceration. A goal for 2024-2026 is to move towards status-neutral services, where HIV care is not siloed from prevention so that all can benefit from the whole suite of services, including overdose prevention and HCV and STI services.	X	X	X
MHSU1	Comprehensive support for PLWH upon discharge from jail. Support comprehensive medical care and support services to people exiting SF jails, including case management, referral, and linkage to vital medical, behavioral health, and support services to people exiting jail. A navigator coordinates care and plans post-release services, meeting clients directly upon their release from jail (especially for those released at night, when regular services and support systems are unavailable) or as soon as possible. The navigator stays engaged with clients for at least 90 days following release.	X	X	X
MHSU3 MHSU4	Continue to provide comprehensive community-based drug user health services. The Health Access Point for people who use drugs provides comprehensive sexual and drug user health services, as do many other programs. In addition to the full suite of sexual health services, the following are also available: medication storage, safer injection and drug use supplies, harm reduction support, naloxone, drug sample testing, and substance use treatment.	X	X	X
MHSU5	Implement the most feasible recommendations from the HIV Mental Health Landscape Analysis. These recommendations will improve service access, delivery, and cross-referral for PLWH.	X	X	X
MHSU5	Collaborate with SAMHSA-funded programs. Increase collaboration and coordination with and among SAMHSA-funded programs in place at local CBOs.	X	X	X

 Social Determinant of Health
ECONOMIC JUSTICE

Introduction

In the last decade, SF has undergone dramatic economic transformation, resulting in rapidly growing economic inequality in the city and in the Greater Bay Area. The impact of this change on the lives of the city's most vulnerable communities cannot be overstated. This shift mirrors a trend toward income inequality throughout the entire state of California, whereby millions are consumed with the daily struggle of managing on extremely low incomes, while at the same time the incomes of higher income households continue to grow.

The sustainability of SF's rich network of high-quality HIV, HCV, and STI services relies on being able to hire and retain a highly qualified, diverse workforce. Anecdotally, sexual and drug user health nonprofits are having unprecedented challenges in filling positions, given the high cost of living in SF and the surrounding Bay Area. The San Francisco Living Wage Coalition estimates that in 2023, the minimum livable wage would be \$29.92/hour for a single adult with no children; yet, SF's legal minimum wage is \$18.07, with a modest increase to \$18.67 slated to go into place 7/1/2024.

At the same time, as of April 2024, SF City and County is facing a several billion dollar budget deficit, necessitating funding cuts across all city departments. In addition, in 2024, SFDPH received funding cuts from formula-based CDC awards due to a decline in the number of PLWH in SF. These economic realities make it even more challenging to successfully implement economic justice strategies such as wage equity initiatives.

SAN FRANCISCO ECONOMIC JUSTICE STRATEGIES

(see also *Racial Equity*)

- ✓ **Strategy 1: Workforce Development**
Create pathways to employment in public health for people from communities most affected by HIV, HCV, and STIs, including, but not limited to, offering paid internships and entry-level positions with clear opportunities for professional advancement.
- ✓ **Strategy 2: Employment for People with Lived Experience**
Encourage programs that employ people with lived experience in the communities the program serves, programs that can demonstrate frontline staff are paid a living wage, and/or programs that have BIPOC people serving in meaningful leadership positions.
- ✓ **Strategy 3: Equitable Hiring Practices and Fair Pay**
Examine state and local health jurisdiction hiring practices to promote equity and inclusion; look to remove barriers such as college and advanced degree requirements; offer extra pay to people who speak languages other than English or who have lived experience with HIV, HCV, STIs, substance use, mental health challenges, or homelessness.
- ✓ **Strategy 4: Leadership Development**
Fund and support pilot training programs for development of leadership and management skills among frontline and mid-level workers in HIV, HCV, and STI programs.
- ✓ **Strategy 5: Universal Hiring and Housing Policies**
Work with community partners and other State agencies to move toward universal "ban the box" hiring and housing policies in California, which remove questions about criminal history from the job application process until after a candidate has been given a chance to show whether they qualify for the position.

Social Determinant of Health ECONOMIC JUSTICE				
Related Strategy(ies)	Activities	2024	2025	2026 & beyond
EJ1 EJ2	Develop employment pathways for people with lived experience. Through CHLI, FOG, and other workforce initiatives, create pathways for people with lived experience to receive training, earn certificates, and be linked to potential job opportunities, with a special focus on PLWH who are looking to re-enter the workforce	X	X	X
EJ3 EJ5 RE1	Promote “Strengthening the HIV/HCV/STI Workforce.” This workforce equity resource guide for employers in the HIV, HCV, and STI sectors offers resources, examples, and best practices for recruitment, hiring, and retention of BIPOC and people with lived experience. There is a strong emphasis on wage equity, as well as information about hiring formerly incarcerated people. <i>(Workforce Development Collective)</i>	X	X	X
EJ3	Encourage CBO wage equity initiatives. Some community-based organizations are conducting compensation studies that lead to organizational changes toward wage equity.	X	X	X
EJ3	Explore innovative approaches to removing barriers to employment and retention. For both SFDPH and its funded CBOs, look for opportunities to remove barriers, such as not requiring advanced degrees for positions that do not need them, incorporating retention pay into benefits packages, or offering premium pay to workers who speak any of the non-English languages commonly spoken in SF.	X	X	X

Introduction

During the community engagement process that informed SF's 2020 Ending the Epidemics Plan, a recurring theme among participants was their experience of stigma. Stigma was a topic in every community engagement session, and in some cases was cited by participants as the largest barrier to accessing healthcare. Participants experience stigma from both providers and other community members related to HIV, race, gender, sexuality, immigration status, drug use, and homelessness. These stigmatizing actions take different forms: trans women described having to articulate that they are not "men who have sex with men" when being questioned around HIV risk; people experiencing homelessness feel unwelcome in healthcare facilities due to lack of access to spaces where they can clean themselves; PWUD describe having their complaints of pain ignored by providers. Particularly within communities of color, anti-gay stigma was felt to be a barrier to testing or treatment.

Participants named several approaches to help combat stigma in health care systems, and these are reflected in SF's strategies and activities:

- Provider education on delivering culturally appropriate sexual and drug user health services;
- Acknowledgment of and taking responsibility for past harms, and working toward ending current mistreatment; and
- Normalization of HIV/HCV/STI testing, as part of a larger health screening package that also includes screening for other conditions such as diabetes.

SAN FRANCISCO STIGMA FREE STRATEGIES

- ✓ **Strategy 1: Nothing About Us Without Us**
Meaningfully and consistently involve people living with HIV, HCV, and STIs in state and local planning, decision making, and service delivery.
- ✓ **Strategy 2: Reframe Policies and Messaging**
Work with communities to reframe the structure and policies of HIV, HCV, and STI services and associated messaging so they do not stigmatize people or behaviors.
- ✓ **Strategy 3: Positive, Accurate Information**
Ensure images and language used in communications show accurate and diverse depictions of communities, and do not reinforce stereotypes; speak out against and correct negative language.
- ✓ **Strategy 4: Acknowledge Medical Mistrust**
Recognize medical mistrust as a rational response to stigmatizing treatment, rather than a failure of individuals or communities; work to build trust and correct misperceptions by example.
- ✓ **Strategy 5: Ongoing Partnerships**
Use 'promotores' and other models of paid peer engagement by people from the communities being served to educate, support, advocate for, and link to care people who have historically been mistreated by public health services and the health care system.

Social Determinant of Health STIGMA FREE				
Related Strategy(ies)	Activities	2024	2025	2026
SF1	SF Ending the Epidemics community engagement. Continue innovative community engagement activities to obtain community guidance on all SF Ending the Epidemics activities by issuing community mini-grants to engage with key subpopulations.	X	X	X
SF1	Participation of people with lived experience in HCV planning. Define and publicize different roles that individuals can play in End Hep C SF, taking into account barriers related to experience, confidence, time of day, physical accessibility, technological know-how, and available time to participate. (End Hep C SF)	X	X	X
SF1	End Hep C Community meetings. Relaunch End Hep C SF community meetings, which before COVID-19 were a vital opportunity twice a year to break bread, learn together, and have fun meeting new people who are also committed to eliminating HCV. (End Hep C SF)	X	X	X
SF1	Partnership with SF HIV Community Planning Council (HCPC). Strengthen the partnership with HCPC and engage them in ending the epidemics discussions. Provide annual updates to the HCPC regarding cluster response. Include a representative from the SFCC leadership team on the HCPC and present an SF City Clinic update to the HCPC at least once per year and obtain input on gaps in HIV/STI services and prioritization, both at SFCC and citywide.	X	X	X
SF1 SF3	Develop an approach to community engagement with youth. Work with youth organizations to engage youth in conversations about sexual and drug user health and include them in policy and program development.	X	X	X
SF1 SF2 SF3	Develop and implement a prevention social marketing campaign for the Latina/o/e/x community. Bring together the Latina/o/e/x HAP agencies and other key partners to develop a media campaign to increase awareness and uptake of prevention services, especially HIV/HCV/STI testing and PrEP. The campaign will be inclusive of monolingual Spanish speakers, including new immigrants from Latin America.	X (develop)	X (imple- ment)	X (imple- ment)
SF2	STI Community Conversations. Host a series of “Community Conversations” to better understand the community’s perspective on sexual health and sexual health services in SF and at SFCC, and to determine how to adapt SFCC services to ensure these communities are well-served. We plan to collaborate with CBOs (e.g., the CAPs, CBO HAP providers) to recruit community members from priority populations to participate in the conversations.	X		
SF3 HAF4	Update City Clinic website to improve inclusivity. Update website images and language to reflect diversity of SF, including in threshold languages: English, Spanish, Russian, Vietnamese, Tagalog, and Chinese.	X		
SF4	Public health detailing. Conduct public health detailing to routinize HIV/HCV/STI risk assessment and screening and PrEP and doxy-PEP	X		

Social Determinant of Health				
STIGMA FREE				
Related Strategy(ies)	Activities	2024	2025	2026
	assessment and referral in medical settings so that provider bias does not factor into who is offered these services.			
SF5	Peer programs. Continue to encourage and support SFDPH-funded HIV/HCV/STI community-based organizations to incorporate peer programs.	X	X	X

For more information, visit:

<https://sf.gov/departments/departments-public-health>

Please direct questions and comments to:

dph-chepadmin@sfdph.org



with support from



EXHIBIT E



Los Angeles County Integrated HIV Prevention and Care Plan, 2022-2026

December 2022



LOS ANGELES COUNTY
COMMISSION ON HIV



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Section I: Executive Summary of Integrated Plan

The *Los Angeles County Integrated HIV Prevention and Care Plan, 2022-2026* is Los Angeles County's third integrated HIV services plan. Led by the Los Angeles County Commission on HIV's Priorities, Planning and Allocations (PP&A) Committee, this plan was developed in partnership with the Los Angeles County Department of Public Health Division of HIV and STD Programs (DHSP) and a vast array of community and organizational partners. The plan is developed in response to the *Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022-2026* disseminated by the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC), and as such presents a blueprint for HIV service coordination along the entire spectrum of HIV prevention and care.

The Integrated Plan is designed to reflect local vision, values, needs and strengths. It is also designed to align with *California's Integrated Statewide Strategic Plan for Addressing HIV, HCV, and STIs from 2022-2026*, and *The National HIV/AIDS Strategy (2022-2025)*. In 2020, the *Ending the HIV Epidemic Plan for Los Angeles County, 2020-2025*¹ (EHE Plan) was developed and disseminated. As described in more detail below, this document served as the core of the Integrated Plan.

The Integrated Plan's seven priority populations are:

1. Latinx men who have sex with men (MSM)
2. Black/African American MSM
3. Transgender persons
4. Cisgender women of color
5. People who inject drugs (PWID)
6. People under the age of 30, and
7. People living with HIV who are 50 years of age or older

These populations were prioritized given the disproportionate impact of HIV and other STDs that they endure, as substantiated by the most current data, and as described in more detail throughout this document. With the exception of people living with HIV who are 50 years of age or older, these priority populations mirror the priority populations found in the EHE Plan. The latter category was included given the aging of the HIV-positive population and concerns related to the long-term impact of living with HIV and co-morbidities.

a. Approach

The EHE Plan formed the foundation for the Integrated Plan and provided Los Angeles County (LAC) an opportunity to add goals, objectives and strategies in response to newer data and more recent developments in the field since the EHE was originally crafted. The EHE Plan was also written and structured in accordance with the CDC's requirements and guidelines for *Notice of Funding Opportunity (NOFO) PS19-1906: Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States Component B: Accelerating State and Local HIV Planning to End the HIV Epidemic* and does not include descriptions of the entire existing LAC HIV portfolio. The Integrated Plan herein contains sections of the EHE Plan, including the situational analysis and the goals and objectives, that have been updated and expanded since 2020.

¹<https://www.lacounty.hiv/wp-content/uploads/2021/04/EHE-Plan-Final-2021.pdf>

2. COMMUNITY ENGAGEMENT & PLANNING PROCESS

b. Documents submitted to meet requirements

The Integrated Plan fully meets submission requirements for each section (see Appendix 1 Checklist) through the use of existing materials, updated materials and newly developed materials, including the following:²

- Section I: Executive Summary of Integrated Plan: New material is submitted for this section.
- Section II: Community Engagement and Planning Process: A combination of new material and narrative from the EHE Plan are used in this section. The description of the Jurisdictional Planning Process includes material from the EHE Plan and a description of planning process steps that were taken since the EHE Plan was released.
- Section III: Contributing Data Sets and Assessments: The Data Sharing and Use subsection contains new material. The Epidemiological Snapshot is material largely based on the most recent HIV surveillance report, the *HIV Surveillance Annual Report 2021*,³ as well as STD data provided by DHSP. The Resource Inventory and Needs Assessment consists largely of new material, including new HIV testing data.
- Section IV: Situational Analysis: The Situational Analysis is updated material based on the EHE Plan with new narrative in some sections.
- Section V: 2022-2026 Goals and Objectives: Goals and Objectives are updated based on the EHE Plan.
- Section VI: 2022-2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up: The Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up is new material.
- Section VII: Letters of Concurrence: The Letter of Concurrence is new material.

Section II: Community Engagement and Planning Process

Jurisdictional Planning Process: Because the EHE Plan forms the core of the Integrated Plan, the narrative below first describes the EHE community engagement process followed by the Integrated Plan community engagement process.

EHE Community Engagement Process: Prior to the launch of *Ending the HIV Epidemic: A Plan for America* (EHE), LAC developed and released its own jurisdictional plan in November 2017, the *Los Angeles County HIV/AIDS Strategy for 2020 and Beyond* (LACHAS), which offered a framework of policies, recommended strategies, and numerical targets that collectively we sought to achieve.

In February 2019, fifteen months after the release of LACHAS, the federal administration announced its plan to launch EHE, providing LAC with the opportunity to adapt and expand the goals and activities described in LACHAS and requiring LAC to align its current efforts with the national EHE initiative. LAC DHSP secured input and guidance on services and activities critical to LACHAS and necessary for EHE implementation through a series of listening sessions and planning meetings with community stakeholders. Stakeholders included the LAC Commission on HIV (local Ryan White Program (RWP) planning body), LAC Substance Abuse Prevention and Control (SAPC), LAC Acute Communicable Disease Control (ACDC), the California Department of Public Health Office of AIDS (California OA), the University

² See Appendix 1: *Integrated Prevention and Care Plan Guidance Checklist* for more information

³ Division of HIV and STD Programs, Department of Public Health, County of Los Angeles. *HIV Surveillance Annual Report, 2021*. Published June 29, 2022.

<http://publichealth.lacounty.gov/dhsp/Reports/HIV/2021AnnualHIVSurveillanceReport.pdf>. Accessed 7/3/22.

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of California at Los Angeles (UCLA) Center for HIV Identification, Prevention, and Treatment Services (CHIPTS), the local EHE Steering Committee,⁴ people living with HIV/AIDS (PLWH) and a broad network of community-based service providers. Planning meetings also took place in Oakland and San Diego. In addition, LAC DHSP engaged in meetings and site visits with multiple federal partners to inform local EHE efforts.

Local Prevention and Care Integrated Planning Body: The LAC Commission on HIV (Commission) is the local, federally mandated Ryan White Program community planning body that sets program priorities and funding allocations for HIV prevention, care, and treatment services throughout the County. The Commission is comprised of 36 members (all appointed by the Board of Supervisors) who represent the diversity of LAC and communities impacted by HIV. Currently, 42% of the commissioners identify as PLWH, 25% identify as Latinx MSM; 14% identify as women of color; and 6% identify as transgender. Other EHE and Integrated Plan priority populations are well represented on the various caucuses, including the Black/African American Caucus, the Transgender Caucus, the Aging Caucus, the Women's Caucus, and the Consumer Caucus.

After the release of the LAC HIV/AIDS Strategy (LACHAS), DHSP continued to collaborate with the Commission to disseminate, promote, and engage a broader set of community stakeholders to build knowledge and awareness of LACHAS strategies and goals, and to recruit new partners and voices into this effort. The Commission helped spearhead over a dozen call-to-action meetings, held in various communities and jurisdictions across the County, to inform, engage, and empower community stakeholders and residents to participate in LACHAS implementation. Through extensive outreach and promotion to the existing network of HIV planning, program and service partners as well as special invites to key stakeholders and elected officials not traditionally engaged in HIV efforts, over 750 community stakeholders were reached in the call-to-action meetings. Summary reports from these meetings included health district demographics, key takeaways, and top insights from the group discussions were developed and distributed to the community. The Commission was integral in promoting LACHAS, encouraging community involvement, and identifying non-traditional partners to join the movement to end the HIV epidemic. The ongoing community engagement and input conducted for LACHAS provided valuable perspectives on needed services and activities and helped drive the development of the EHE Plan.

In response to the announcement of EHE Plan, the Commission held an all-day community meeting in November 2019 with over 190 participants to: 1) Directly hear from community partners on an EHE Plan for LAC, 2) Determine the best way to engage the community moving forward while transitioning from LACHAS to the EHE Plan, and 3) Garner input on the leadership necessary to achieve EHE goals. Attendees included community stakeholders, PLWH, service providers, elected officials and/or their representatives, community clinics, County partners (Department of Mental Health, Department of Public Health, Department of Health Services and Substance Abuse and Prevention Control), universities, neighborhood associations, and faith-based organizations.

The meeting included a panel of representatives from the California OA; DHSP leadership; the Office of Assistant Secretary of Health's Region IX Prevention through Active Community Engagement (PACE) Team; UCLA CHIPTS, among other important HIV stakeholders. Key takeaways included the importance

⁴ http://publichealth.lacounty.gov/dhsp/EHE/Biosketches_EHE_SteeringCommittee_040521.pdf

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of multi-sector commitment to achieve EHE goals, a commitment to being disruptively innovative with new and expanded interventions and policies, ensuring transparency and accountability from all partners, and lifting voices of communities most impacted by HIV.

In January 2020, the Commission reinforced its commitment to EHE efforts by providing dedicated space for Commissioners and members of the public to participate in discussions focused on innovative community engagement and mobilization efforts that include bringing new voices to the table to end the epidemic. Participants broke out into small groups to discuss and address several key questions, including: 1) How can community members take individual action in EHE efforts, 2) Which sectors should partners prioritize for new or increased mobilization around EHE, and 3) How can the development of a new EHE Steering Committee be used to support efforts to recruit new perspectives, enlist change agents and spur more action. As a follow up to these community-driven discussions, the Commission is also working to increase membership on its planning body with persons representing pharmaceutical companies, commercial health plans, and California's Medicaid program.

In September 2020, LAC DHSP released the draft EHE plan to community stakeholders as part of a 30-day public comment period and partnered with the Commission to ensure individuals and communities were aware of the input opportunity. In addition, Commissioners were provided an opportunity to submit written feedback as a complement to the listening sessions facilitated by Commission staff. The Commission submitted 13 pages of public comments to be considered for inclusion in the EHE Plan including recommendations from the Black/African American Community Taskforce.

Local Service Provider Partners: Local service providers, including those who represent federally qualified health centers (FQHCs), medical providers in private practices and community clinics, and a variety of community-based organizations (CBOs) are represented and engaged through various committees, coalitions, working groups, and networks across LAC. There is a strong network of LAC DHSP funded CBOs that serve people living with and affected by HIV in diverse communities across the County. In addition, there are several public facing listservs that disseminate information for trainings, webinars, and events related to HIV and the social determinants of health that impact HIV outcomes. Service providers are also represented on the Commission, the EHE Steering Committee, and Service Provider Networks (SPNs) in specific jurisdictions across the County. There are strong coalitions and groups in LAC such as the LAC PrEP/PEP Working Group and the Ending the Epidemic's Statewide Coalition that address policy and advocacy on the intersection between HIV, sexually transmitted diseases (STDs), and viral hepatitis. By actively working with these groups and coalitions, LAC DHSP gained input and guidance on HIV prevention, care, and treatment efforts. Service providers were actively engaged in the various community listening sessions and health district discussions that were facilitated as part of the development and release of LACHAS; and most were active in the development and refinement of the EHE Plan. LAC DHSP continues to partner and collaborate with two city health departments that exist within the County (Long Beach Department of Health and Human Services and the Pasadena Public Health Department) to advance EHE strategies. We collectively work to ensure that existing HIV plans, programs and related goals in these jurisdictions are aligned with the LAC EHE Plan.

In addition to the existing service provider network, LAC DHSP has been working to enlist its five Regional Health Offices that oversee all public health issues in specific geographic service planning areas throughout the county as well as the LAC Community Prevention and Population Health Task Force which focuses on the social determinants of health but has not yet identified HIV as a priority public health issue. New potential EHE partners were also identified through the UCLA CHIPTS Regional EHE

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Coordination meeting held January 2020. In addition, LAC DHSP will continue to work with the LAC Departments of Mental Health and Health Services to develop systems and processes that more effectively align goals, strategies, and programming to optimize HIV-related services for clients and communities. The PACE Program has been an important resource to help advance local EHE community engagement efforts. Separately, the LAC DHSP HIV Medical Advisory Committee (which includes medical leadership from Ryan White Program-funded HIV Clinics across the County) and the Medical Care Coordination (MCC) Learning Collaborative (which provides feedback on all HIV prevention and treatment activities for high acuity clients in the MCC program) also provided valuable feedback and perspectives tied to the EHE Plan.

Integrated Plan Community Engagement Process: The development of the Integrated Plan was a collaborative process between the Commission on HIV (the local HIV planning council), LAC DHSP, and community stakeholders. As part of its existing structure, the Commission's Planning, Priorities and Allocations (PP&A) Committee leads needs assessment activities, planning, and resource allocations. As such, the PP&A Committee spearheaded the Integrated Plan planning process with the assistance of a contracted consultant. It was decided early on that, rather than have a dedicated task force to develop the plan, planning steps would be integrated into the overall work of the Commission.

The development of the Integrated Plan began in July of 2021 with a presentation at the Commission on HIV monthly meeting. During this meeting, the purpose and requirements of the Integrated Plan were presented to all attendees including Commission members and the public. The history of planning and the blueprint for plan development were also discussed, particularly given that many members had not previously been a part of any planning process. Following this initial meeting, the consultant leading the planning process met with numerous groups and individuals to develop each section of the plan, as described below.

To develop the needs assessment section, DHSP and Commissioners were hesitant to engage in any new assessment activities, given that much assessment had recently taken place to develop the EHE Plan and other local HIV/STD reports. However, as planning progressed, issues related to system and workforce capacity began to emerge as key barriers to achieving HIV-related goals. Thus, it was decided to take steps to assess this particular issue by developing and distributing an online survey in English and Spanish. The survey was developed with a team of stakeholders including PLWH, academic partners, and staff representing CBOs, FQHCs, and DHSP. To ensure that the voices and perspectives of priority population members and PLWH were reflected in the Integrated Plan, listening sessions were conducted with members of priority population groups (Black MSM, women of color, trans persons, people who inject drugs (PWID), people younger than 30 and PLWH 50 and older). The consultant worked with various community stakeholders to organize and facilitate these groups. For example, to convene a group of Black MSM, the consultant worked with staff at a community-based organization that primarily serves Black gay and bisexual men to recruit 16 participants. This listening session was co-facilitated by a staff member and the consultant. The other listening sessions were convened in a similar manner. These listening sessions attracted 86 community members, many of whom identified as PLWH. Survey and listening session findings, largely qualitative in nature, complimented the use of secondary data sources.

The EHE goals and objectives served as a foundational starting point to develop the Goals and Objectives section. A series of five workgroup meetings designed to capture ideas for additional goals, objectives, and strategies were convened. Workgroup participants included co-chairs of the Commission, the PP&A Committee, the Public Policy Committee, and community members, including PLWH.

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- a. **Entities involved in process:** Representatives from the following entities and population groups met to develop the Integrated Plan:
- The Los Angeles County Department of Public Health, Division of HIV and STD Programs
 - The City of Long Beach Health Department
 - The City of West Hollywood Health Department
 - The California State Office of AIDS
 - The AIDS Coordinator for the City of Los Angeles
 - Service providers and Commission members that represented at least 20 different community-based organizations, hospitals or universities serving PLWH or at risk for HIV
 - People with HIV including members of a Federally recognized Indian tribe as represented in the population, and individuals co-infected with hepatitis C
 - Ryan White Program Part C and D HIV clinical providers
 - Ryan White Program Part F – AETC providers
 - Faith-based CBOs
 - Community health clinics and Federally Qualified Health Centers (FQHCs)
 - Substance use treatment providers
 - Hospital planning agencies and health care planning agencies
 - Mental health providers
 - Formerly incarcerated PLWH
 - Social services providers including housing and homeless services representatives
- b. **Role of the RWHAP Part A Planning Council/Planning Body:** The Los Angeles County Commission on HIV serves as the local Ryan White HIV/AIDS Program (RWHAP) Part A Planning Council. The Commission's Priorities, Planning and Allocations (PP&A) Committee spear-headed the development of the Integrated Plan. Commission staff and PP&A leadership met regularly with the consultant to oversee the development of the Integrated Plan. The consultant provided updates at the monthly Commission meeting and PP&A meeting.
- c. **Role of Planning Bodies and Other Entities:** Throughout the development of the Integrated Plan, the consultant and/or Commission leadership met with members of the EHE Steering Committee and DHSP staff that are tasked with implementation of the EHE Plan. EHE Steering Committee members expressed an interest in making sure that the Integrated Plan was aligned with the EHE Plan, that community stakeholders were engaged in the planning process and that the Integrated Plan reflected new developments in the field (e.g. the use of long acting injectables for PrEP and HIV treatment). The consultant and other planning team members also convened and/or participated in over 35 meetings to engage with a variety of groups, caucuses and task forces throughout the County including:
- The Commission on HIV's:
 - Aging Caucus
 - Women's Caucus
 - Transgender Caucus
 - Black/African American Community Task Force (Later renamed the Black Caucus)
 - Consumer Caucus

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- Prevention Planning Work Group
 - Standards and Best Practices Committee
 - Public Policy Committee

 - Long Beach Community Planning Group
 - Service Planning Area (SPA) 2 HIV/AIDS Consortium Meeting
 - SPA 4 Provider Meeting
 - Los Angeles County Department of Public Health, DHSP
 - Los Angeles County Department of Public Health, Acute Communicable Disease Control (ACDC)
 - Community groups consisting of priority population members (outlined in more detail in the Needs Assessment section)
- d. **Collaboration with RWHAP Parts:** Providers from Ryan White HIV/AIDS Program Parts B, C, D and F were engaged in the planning process in a variety of ways. In early 2022, a meeting was convened with 12 representatives from seven different RWP Part C, D and F recipient organizations. Participants identified several key topics to be included in the Integrated Plan including a need to focus on social determinants of health and co-occurring disorders (especially syphilis, methamphetamine use and mental health issues); workforce development and capacity issues; culturally congruent services; and an aging population of PLWH.

Planning team members also met with stakeholders that were involved in the development of other Integrated HIV Plans within or inclusive of LAC in order to ensure alignment and avoid duplication of efforts. These plans included *California's Integrated Statewide Strategic Plan for Addressing HIV, HCV, and STIs from 2022-2026*; *the Long Beach HIV/STD Strategy, 2019-2021* and *the West Hollywood HIV Zero Strategic Plan, 2016-2021*. Although the time frame for the latter two plans had ended, it was important to meet with the planners to learn from their experiences and identify any priority areas to highlight in the LAC Integrated Plan. Key issues identified included a need to focus on stigma, social determinants of health and co-occurring disorders (including housing, mental health and meth use), and broadening harm reduction efforts.

- e. **Engagement of People with HIV:** PLWH were engaged in all stages of the planning process, including needs assessment, priority setting, development of goals and objectives, and development of the implementation plan. As noted above, 42% (or 15) of the 36 Commissioners are PLWH. Each of the six community listening sessions included PLWH and 57% of the community survey participants identified as PLWH. Priority setting took place at PP&A Committee meetings which are chaired by two PLWH. Goals and objectives and an accompanying implementation plan were developed over the course of several meetings, all of which included PLWH as active participants. In addition, the Integrated Plan was a key agenda item at the Commission's Annual Planning meeting with many people with HIV in attendance. There was also a public comment period of 30 days whereby PLWH and other key stakeholders were invited to review the Plan and provide feedback. All feedback obtained was used to help shape the final version of the Plan. The monitoring, evaluation and improvement of the Plan will be spearheaded by the PP&A Committee, with PLWH serving as active participants.
- f. **Priorities:** Key priorities that arose out of the planning and community engagement process included the need to:
- Embrace a status neutral approach to planning and implementation – equally respecting PLWH

3. CONTRIBUTING DATA SETS & ASSESSMENTS: DATA SHARING & USE

- and people at risk for HIV, their strengths, and their needs
- Address social determinants of health, especially housing
- Address co-occurring disorders including other STDs, mental health issues and meth use disorder
- Expand harm reduction services
- Address HIV-related disparities, particularly the disparities experienced by Black/African Americans
- Increase health literacy among PLWH and people at risk for HIV
- Increase workforce capacity
- Meet the needs of PLWH age 50 years old and older and/or long-term survivors
- Create more holistic services, especially for cisgender and transgender women
- Align funding streams and resources to ensure that PLWH and people at risk for HIV are able to seamlessly access high quality services

- g. **Updates to Other Strategic Plans Used to Meet Requirements:** As noted, portions of the LA County EHE Plan were utilized to develop the Integrated Plan. LA County uses surveillance data, assessment data, and the ongoing feedback of key stakeholders, including PLWH to update plans on a regular basis, typically annually.

Section III: Contributing Data Sets and Assessments

The *Contributing Data Sets and Assessments* section is comprised of four major sub-sections: (1) Data Sharing and Use; (2) Epidemiologic Snapshot; (3) HIV Prevention, Care and Treatment Resource Inventory; and (4) Needs Assessment.

DATA SHARING AND USE

Multiple data sources are utilized in LAC to monitor the HIV and STD epidemics, track service utilization, better understand service needs and assess progress in achieving county-wide and national HIV-related goals. The County uses the Electronic HIV Reporting System (eHARS), a CDC-developed information system for collecting, storing, and retrieving HIV surveillance data. In addition to eHARS, the main data sources include HIV incidence surveillance and molecular surveillance. Collectively, these data sources give LAC the ability to track the extent of the County's HIV epidemic including persons who are diagnosed and receiving care as well as those who are diagnosed and not in care. They also provide the data needed to develop the HIV Care Continuum measures, including the number of PLWH who are linked to care, in receipt of care, retained in care, and virally suppressed.

Data from population-based surveys conducted among key populations at increased risk for HIV and people living with HIV (PLWH) were also used to inform the Integrated Plan. This includes LAC data collected for the CDC-funded National HIV Behavioral Surveillance System from 2004 to 2019 and Medical Monitoring Project from 2015 to 2019.

National HIV Behavioral Surveillance (NHBS): LAC is one of 20 sites participating in this national CDC-funded HIV biobehavioral surveillance effort that allows state and local health departments to monitor HIV prevalence and risk behaviors among select populations at risk for HIV infection. These populations include men who have sex with men (MSM), persons who inject drugs (PWID), heterosexuals at increased risk for HIV infection (HET), and transgender (TG) women. NHBS participants were residents of

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

LAC and at least 18 years of age. Participants who provided informed consent completed an interviewer-administered anonymous standardized questionnaire about HIV-related behaviors and underwent confidential rapid HIV and standard Hepatitis B and C testing. In this document, key findings from NHBS available to date in LAC are reported. Results may not be generalizable to the broader population groups represented.

Medical Monitoring Project (MMP): The MMP is a national HIV surveillance system funded by the CDC and implemented by local health departments. The aim of MMP is to provide locally and nationally representative data on behavioral and clinical outcomes in a sample of persons receiving HIV medical care. MMP uses a two-stage probability-based sampling strategy that draws from the National HIV Surveillance System (NHSS) to select survey participants: the first stage is selecting the geographic areas to participate, and the second stage is selecting adults diagnosed with HIV and reported to NHSS within those participating areas. Sampled persons were recruited to participate in person, by telephone, or by mail. To be eligible for MMP, the person had to be living with diagnosed HIV infection, aged ≥ 18 years, and residing in an MMP project area. Participants were recruited via telephone, by mail, or in person. Interview questions include demographic information, health care use, met and unmet needs for ancillary services, sexual behavior, depression and anxiety, gynecologic and reproductive history (females only), drug and alcohol use, and use of prevention services.

Other datasets that LAC uses that contribute to the assessment of need and HIV-related health outcomes among people at risk for or living with HIV within the County include:

- (1) Ryan White Program (RWP) client and service utilization data through Casewatch (LAC's RWP client data system);
- (2) HIV testing data for testing conducted through DHSP's contracted providers;
- (3) STD Casewatch data; and
- (4) U.S. Census Bureau data, including data from the annual American Community Survey

LAC utilizes an evidence-based approach to planning that relies on an understanding of HIV surveillance and other sources of data. To ensure that planning participants, including Commission members and members of the community were well-versed in the most recent data, an HIV epidemiology training was conducted during the Planning, Priorities and Allocation Committee meeting in July 2022. This training presented key epidemiology terms as well as their application in examining the current LAC HIV epidemiology profile of PLWH, people at risk for HIV, and trends in the epidemic.

EPIDEMIOLOGIC SNAPSHOT

The Gabrielino Tongva, Fernandeño Tataviam, and Ventureño Chumash are the First People and original stewards of the land that today we call Los Angeles County, California. As the most populous county in the United States, LAC is home to an estimated 9,861,224 residents as of 2022. The County's urban, suburban and rural communities span over 4,000 square miles and comprise 88 incorporated cities and approximately 140 unincorporated areas. LAC is among the most ethnically and economically diverse regions in the nation with immigrants making up over a third of the County's population.⁵ An estimated 69,144 Angelenos are homeless on any given night⁶ and over 14,000 inmates are housed in county jails - the largest jail system in the U.S.⁷

⁵ <https://www.census.gov/quickfacts/fact/table/losangelescountycalifornia/POP645220>

⁶ <https://www.lahsa.org/documents?id=6515-lacounty-hc22-data-summary>

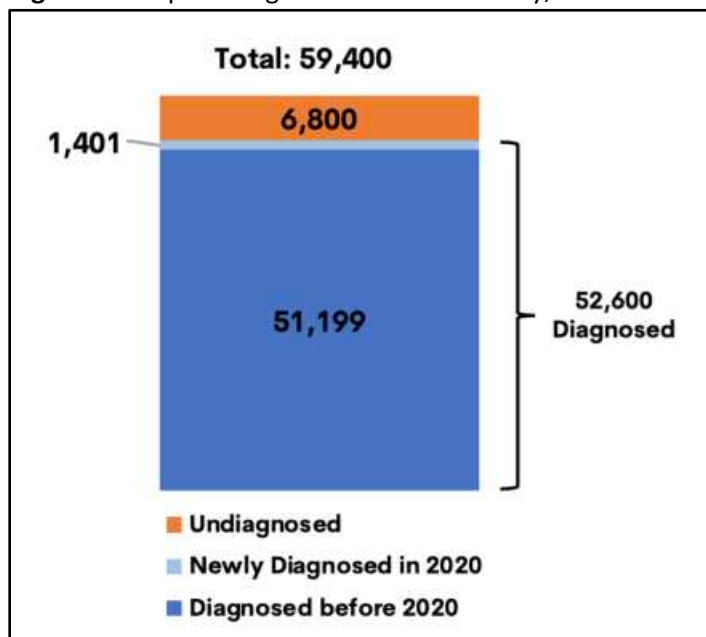
⁷ <https://www.prisonpolicy.org/origin/ca/2020/report.html>

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

I. People Living with HIV in LA County

At the end of 2020, there was an estimated 59,400⁸ PLWH,⁹ aged 13 years and older in LAC, including 1,401 who had been newly diagnosed (in 2020) and an estimated 6,800¹⁰ persons who were unaware of their infection (Figure 1). As described in more detail below, HIV continues to be driven by social determinants of health and co-occurring disorders and disproportionately impacts some population groups more than others.

Figure 1: People Living with HIV in LA County, 2020



a) Geographic Distribution of People Living with Diagnosed HIV (PLWDH): The County is made up of 26 different health districts which overlay eight distinct Service Planning Areas (SPAs).¹¹ As depicted in Figure 2, HIV diagnoses and prevalence are unevenly distributed geographically across the County with the highest density of both those newly diagnosed with HIV (between 2016-2020) and all PLWDH found in the central and southern regions. Among all 26 Health Districts, Hollywood-Wilshire, Central, and Long Beach are considered the three epicenters for HIV, reporting the largest numbers of new HIV diagnoses (170, 126 and 92, respectively) and PLWDH at year-end 2021 (9,352, 6,708 and 4,237 respectively).

⁸ 95% Confidence Interval: 57,500 – 61,300

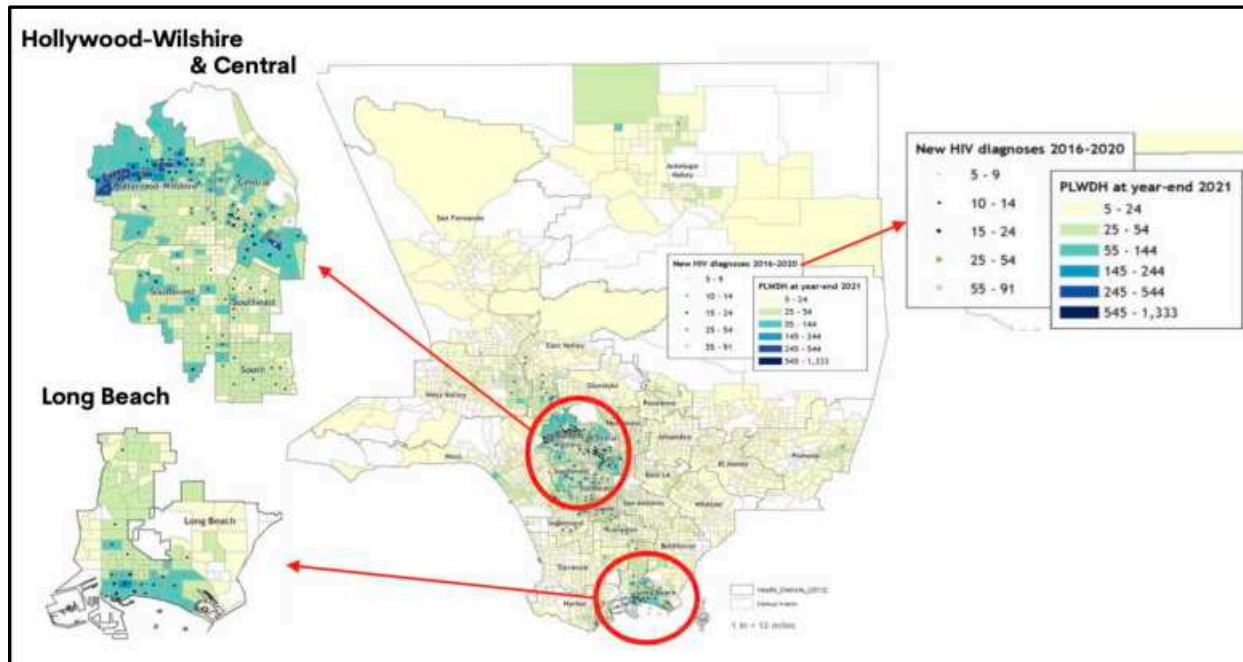
⁹ Throughout this document, "People Living with HIV," or "PLWH," is meant to denote *all* people living with HIV, whether or not they are diagnosed. This figure is always an estimation given that we are unsure of the exact number of people with HIV who are undiagnosed. By contrast, "People Living with Diagnosed HIV," or "PLWDH," is meant to denote all people who have been diagnosed with HIV and are living in LAC. This number does not include those who are undiagnosed.

¹⁰ 95% Confidence Interval: 4,800 – 8,700

¹¹ (1) SPA 1: Antelope Valley, (2) SPA 2: San Fernando Valley, (3) SPA 3: San Gabriel Valley, (4) SPA 4: Metro, (5) SPA 5: West, (6) SPA 6: South, (7) SPA 7: East, and (8) SPA 8: South Bay

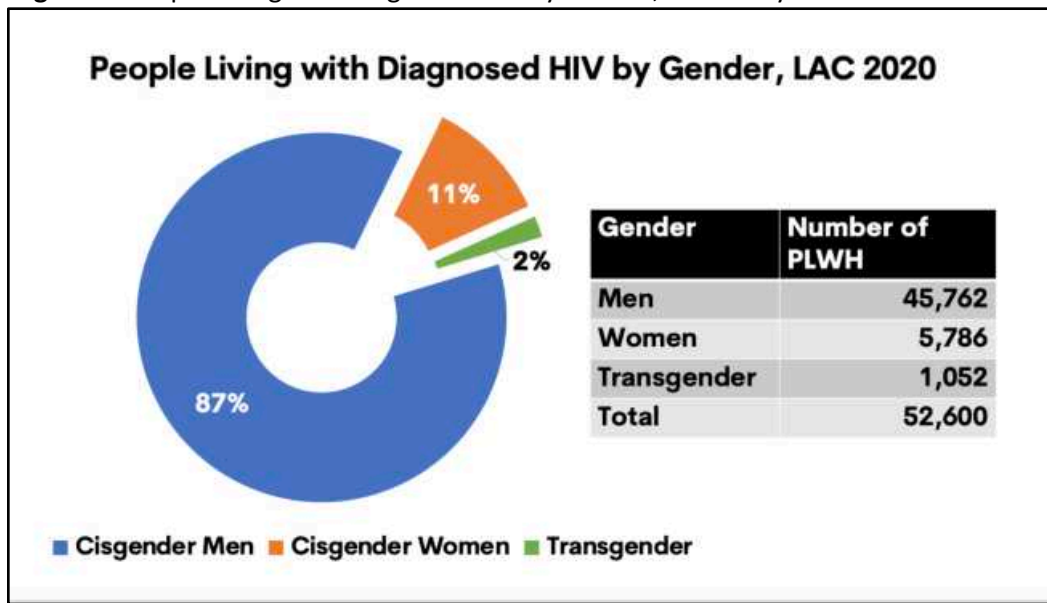
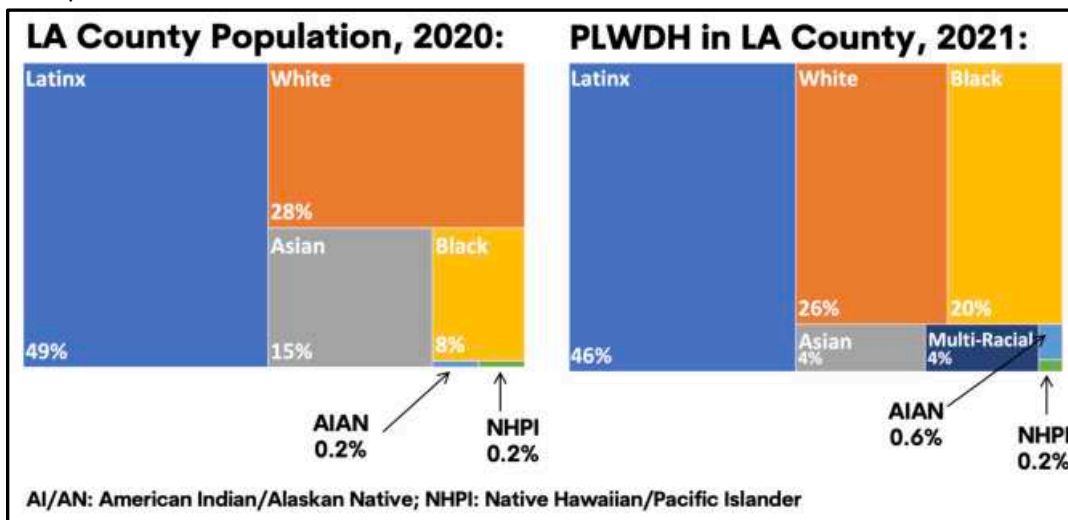
3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 2: Geographic Distribution of PLWDH at year-end 2021 & Persons Newly Diagnosed with HIV, 2016-2020, LA County



b) People Living with Diagnosed HIV in LA County, 2020: Of the 52,600 PLWDH in 2020, 87% were cisgender men, 11% were cisgender women and 2% were transgender persons (Figure 3). With respect to race/ethnicity, Latinx people make up the greatest proportion of PLWDH (46%), followed by the White population (26%), the Black/African American population (20%), the Asian population (4%), and those who identify as multi-racial (4%). The American Indian/Alaskan Native (AI/AN) and Native Hawaiian/ Pacific Islander (NH/PI) populations collectively make-up less than 1% of PLWDH. The Black/African American population is significantly over-represented among PLWDH, given that Black/African Americans make up 8% of the County's overall population, but 20% of the population of PLWDH. AI/AN people are also over-represented among PLWDH, given that they make up 0.2% of the overall population, but 0.6% of PLWDH (Figure 4).

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 3: People Living with Diagnosed HIV by Gender, LA County 2020**Figure 4:** Racial/Ethnic Composition of LA County,¹² 2020 Compared to Racial/Ethnic Composition of PLWDH in 2021

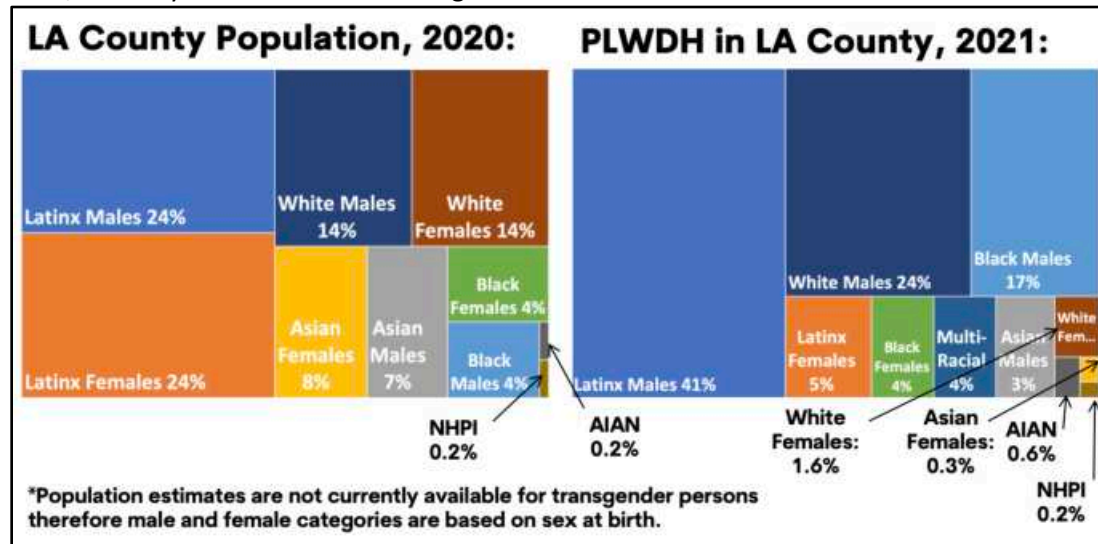
With respect to sex at birth and race/ethnicity (Fig. 5), the populations most impacted by HIV are Latinx males who represented 41% of all PLWDH followed by White males (24%) and Black males (17%). Combined, these groups represent 82% of all PLWDH in LAC. HIV disparities are even more pronounced when the population of PLWDH is compared to the overall population. For example, Latinx males represent 24% of the LAC population and 41% of PLWDH; Black males represent 4% of the population, and 17% of PLWDH; and White males represent 14% of the population and 24% of PLWDH. Altogether, AI/AN, NH/PI and multi-racial men and women represented less than 5% of PLWDH.¹³

¹² Based on the 2020 population estimates provided by LAC ISD & contracted through Hedderson Demographic Services.

¹³ PLWDH with unknown race/ethnicity were not presented in the graph (n=69). NH/PI and AI/AN represented less than 1% and were presented for males and females combined due to limited visibility on the graph. Population estimates for multi-racial persons are not available.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 5: Race/Ethnicity and Sex at Birth among LA County Residents, 2020, Compared to Race/Ethnicity and Sex at Birth among PLWDH in 2021



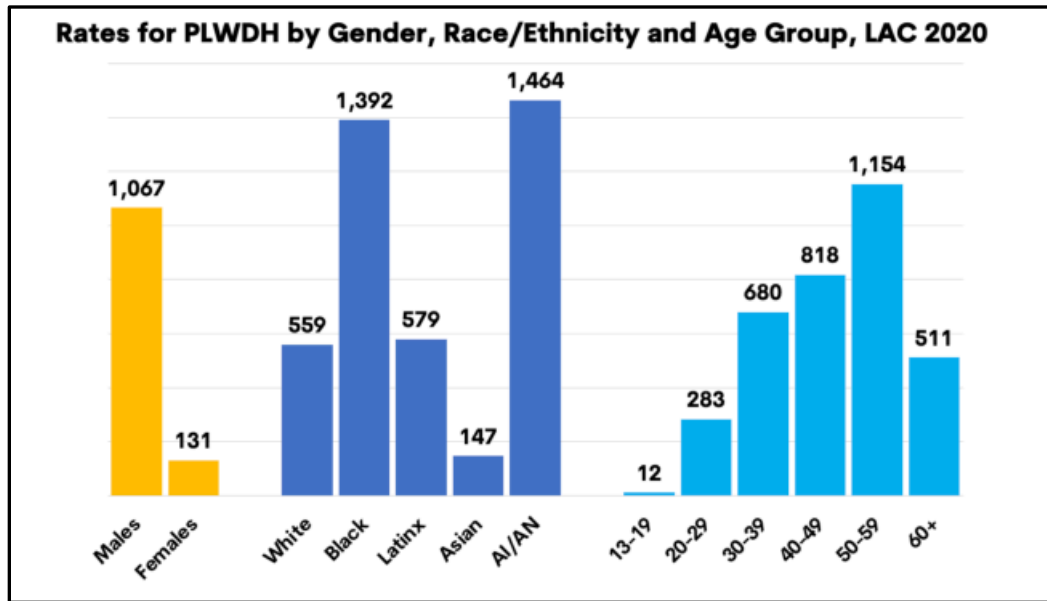
While Latinx people make up the largest *proportion* of PLWDH, AI/AN people have the highest *rates* of HIV.¹⁴ The Black/African American population also has extremely high rates of HIV per 100,000 population (1,392) compared to Latinx (579), White (559) and Asian (147) populations. Rates are also significantly higher among males (1,067) versus females (131); and among those aged 50-59 (1,154) and 40-49 (818) compared to other age groups (Fig. 6).

Rates for transgender people are not typically calculated, given the lack of reliable population estimates and the relatively small population size compared to cisgender men and women. However, the UCLA School of Law Williams Institute has recently published transgender population estimates based on data from the CDC's Behavior Risk Factor Surveillance System and Youth Risk Behavior Survey.¹⁵ They estimate that in California, among adults, 0.49% (150,100) identify as transgender and among youth ages 13 to 17 in the U.S., 1.93% (49,100) identify as transgender. They also report that of those that identify as transgender in the U.S., 38.5% are transgender women, 35.9% are transgender men, and 25.6% reported they are gender nonconforming. If we were to apply these percentages to LAC, we would find that there are approximately 38,050 people 18 or older in LAC that identify as transgender (7,765,339 people 18 or older in LAC x 0.49%); and that approximately 14,649 (38,050 x 38.5%) of them identify as transwomen, that 13,660 (38,050 x 35.9%) of them identify as transmen, and that 9,741 (38,050 x 25.6%) of them identify as gender nonconforming. Given that there are approximately 1,052 transgender PLWDH in LAC, the rate of HIV infection among trans persons would be 2,764 per 100,000 population. Assuming that approximately 90% of all transgender PLWDH are transwomen (1,052 x 90% = 947), the HIV rate among transwomen would be 6,464.

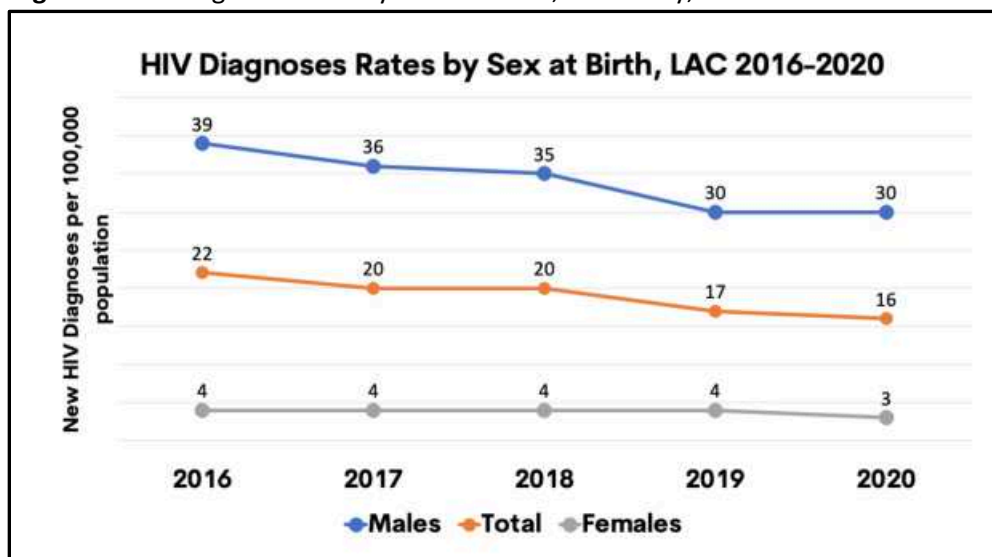
¹⁴ Given the relatively small population size of AI/AN people, rates may not be fully accurate.

¹⁵ Herman, J., Flores, A. & O'Neill, K. (2022). *How Many Adults and Youth Identify as Transgender in the United States?* The Williams Institute, UCLA, Los Angeles, CA.

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Figure 6: Rates for PLWDH by Gender, Race/Ethnicity and Age Group, LA County, 2020

c) People Newly Diagnosed with HIV: In 2020, 1,401 persons aged 13 years and older were newly diagnosed with HIV, down from 1,560 persons in 2019. Since 2016, the overall diagnosis rate has decreased from 22 (per 100,000 population) to 16. The gap between male and female new diagnoses rates has also decreased slightly although the rate among males is still ten times that of females (Figure 7). Rates have also decreased across all race/ethnicities although Black/African Americans continue to have the highest rates compared to other groups (Figure 8). Those aged 20-29 and 30-39 also continue to have the highest rates compared to other age groups (Figure 9).

Figure 7: HIV Diagnoses Rate by Sex at Birth¹⁶, LA County, 2016-2020**Figure 8: HIV Diagnoses Rate by Race/Ethnicity¹⁷, LA County, 2016-2020**

¹⁶ Rates are not available for trans persons given their small population size

¹⁷ Rate is unknown for AI/AN in 2019

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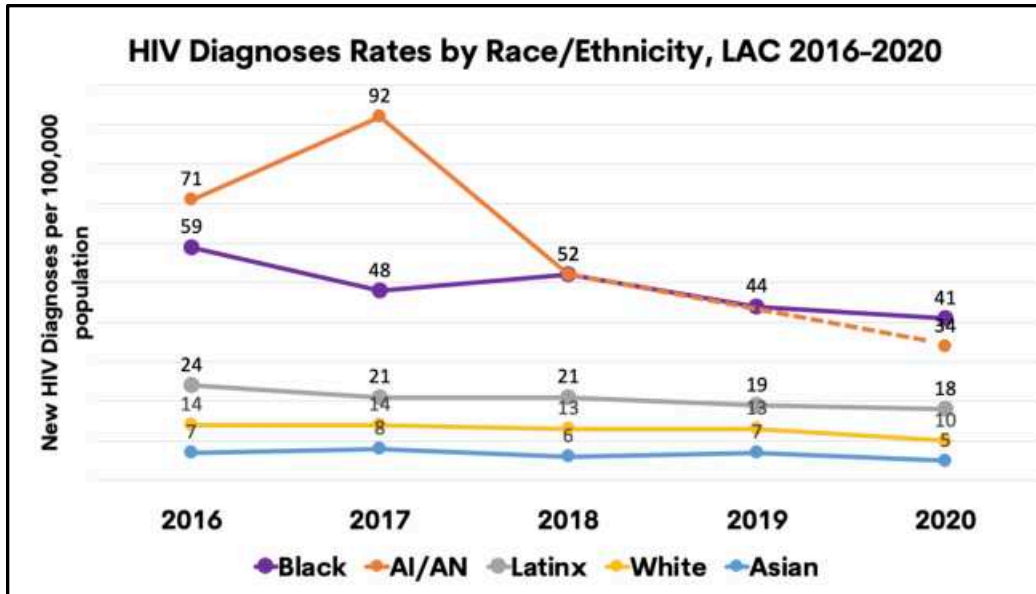
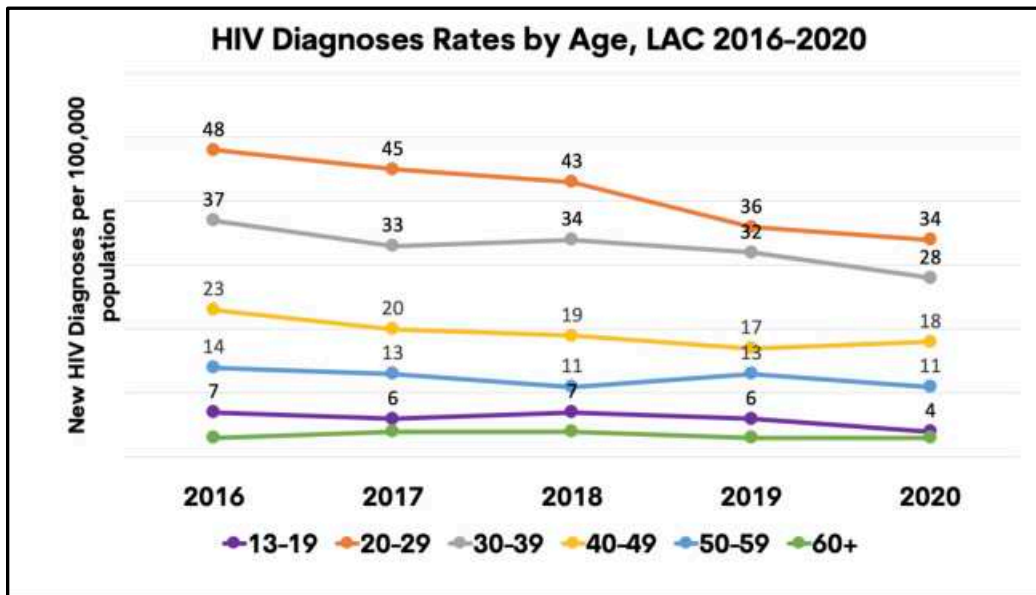
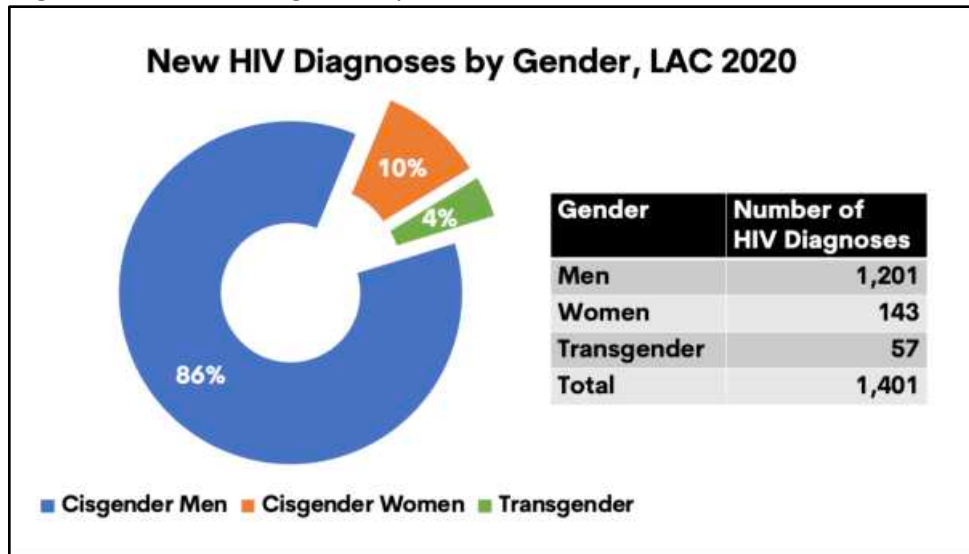


Figure 9: HIV Diagnoses Rate by Age Group, LA County, 2016-2020

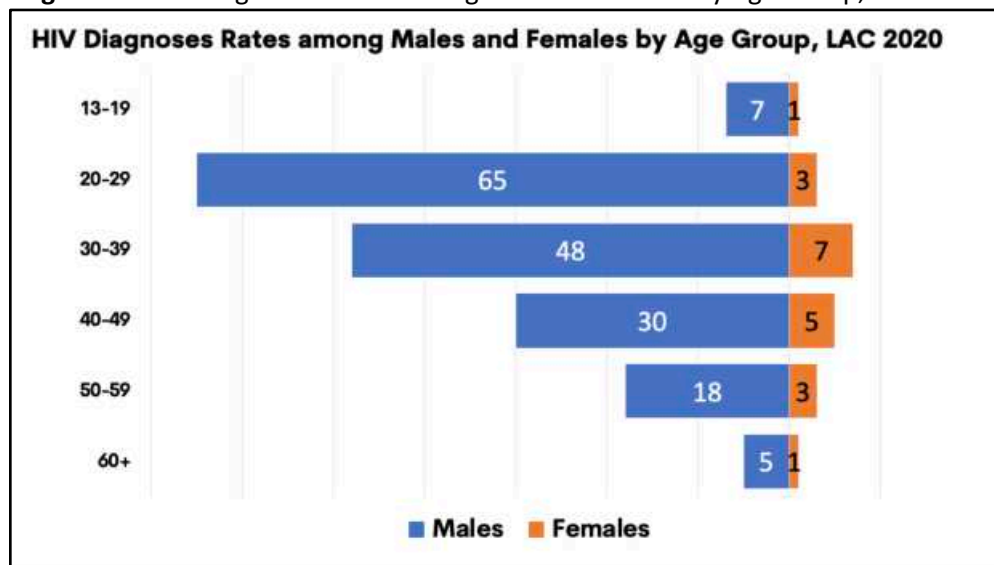


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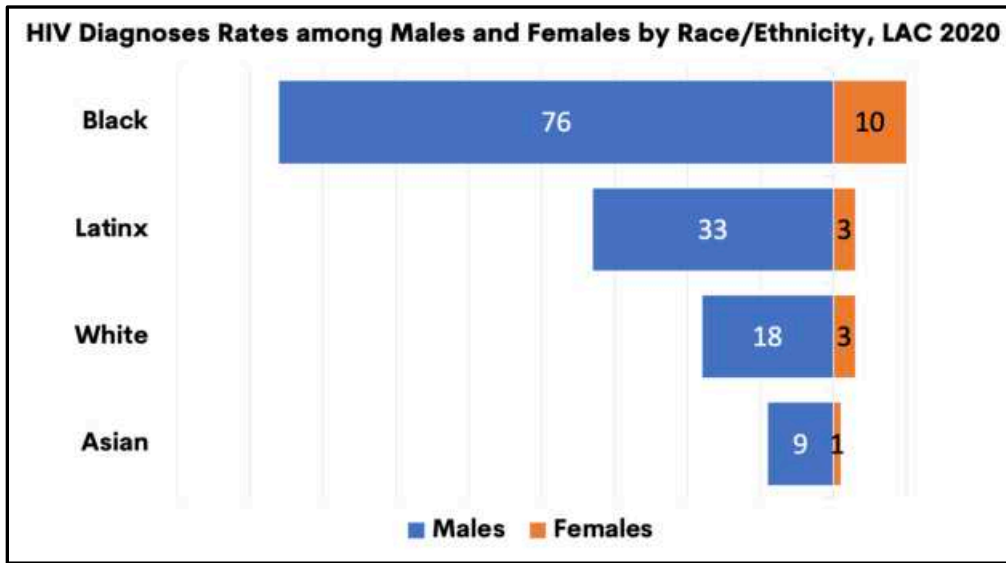
Figure 10: New HIV Diagnoses by Gender, LAC 2020

Cisgender men made up most of the new HIV diagnoses in 2020 (N=1,201, 86%). Cisgender women (N=143) and transgender persons (N=57) represented 10% and 4% respectively of new HIV diagnoses in 2020 (Figure 10). Among the 57 transgender persons newly diagnosed with HIV in 2020, notably, all identified as transgender women.

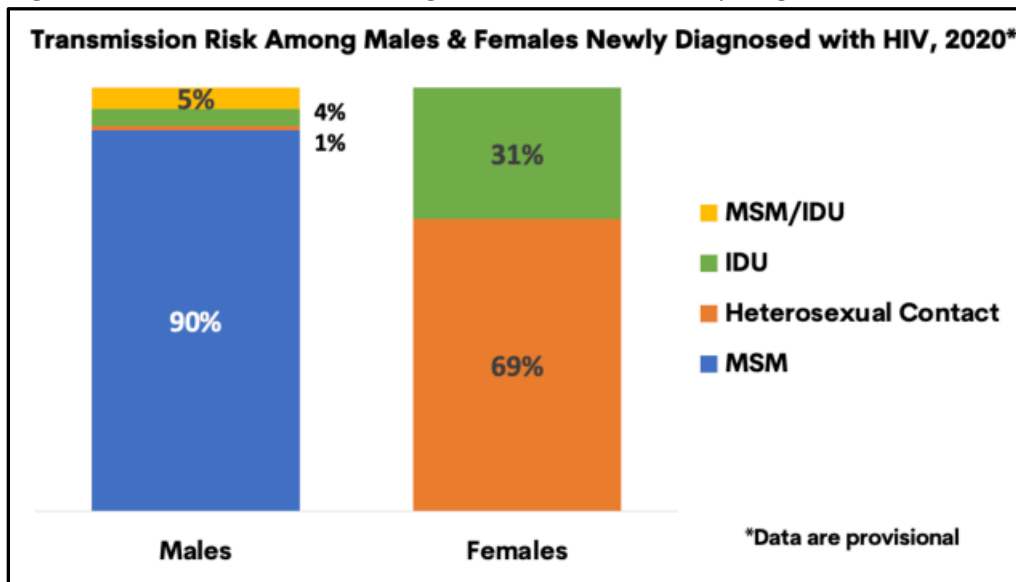
In 2020, among males, those aged 20-29 (65) and 30-39 (48); and Black/African Americans (76) had the highest rates of new HIV diagnoses. Among females, those aged 30-39 (7) and Black/African Americans (10) had the highest rates of new HIV diagnoses (Figures 11 and 12).

Figure 11: HIV Diagnoses Rates among Males & Females by Age Group, LAC 2020

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Figure 12: HIV Diagnoses Rates among Males & Females by Race/Ethnicity, LAC 2020

In 2020, the primary HIV transmission risk for newly diagnosed males was having sex with other men (90%), followed by IDU (5%), MSM/IDU (4%) and heterosexual contact (1%). The primary HIV transmission route among females newly diagnosed with HIV was heterosexual contact (69%). In 2020, the percentage of cases with IDU as the primary transmission route among females increased to 31% compared to 25% in the previous year (Figure 13).

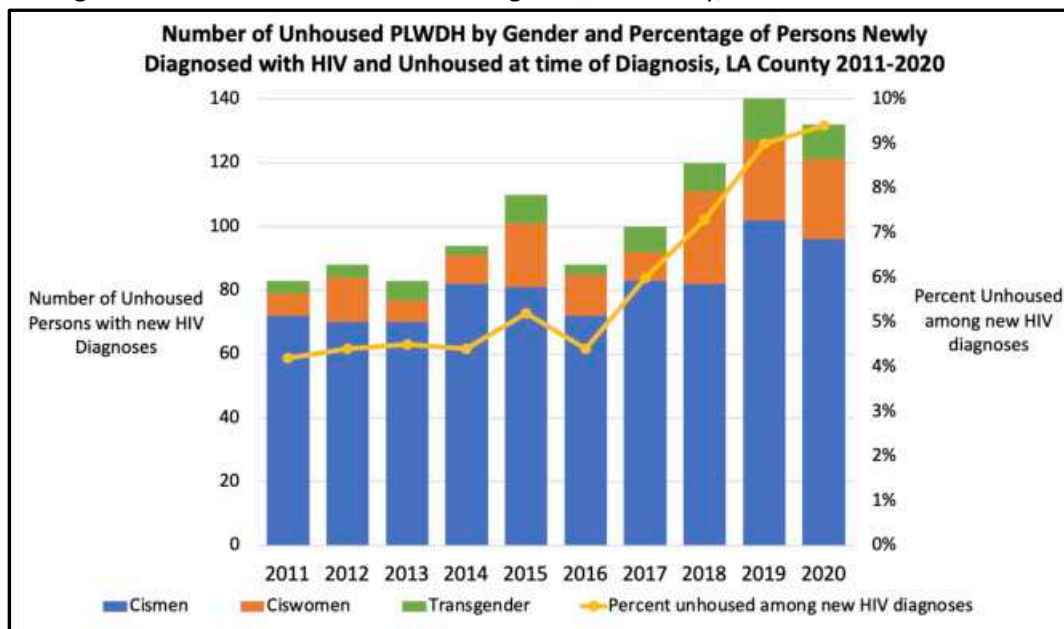
Figure 13: Transmission Risk Among Males & Females Newly Diagnosed with HIV, LAC 2020

Perinatal Transmission: In LAC, although the number of HIV-positive pregnant women has decreased over time, the number of perinatal HIV transmissions is increasing. In 2020 there were four infants who acquired HIV perinatally resulting in a rate of 8 per 100 HIV-exposed infants. Notably, common maternal risk factors included meth use (n=3), being unhoused (n=3), mental illness (n=3), syphilis (n=3) and a history of incarceration (n=2).

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Unhoused: Since 2011, the percentage of persons newly diagnosed with HIV who were unhoused has more than doubled from 4.2% to 9.4%. In 2020, among 132 unhoused persons with a new HIV diagnosis, 73% were cisgender men, 19% were cisgender women and 8% were transgender. However, the HIV diagnoses rates of the unhoused have been relatively stable over this time, indicating that the increase in the unhoused population likely explains the increases in HIV diagnoses (Figure 14).

Figure 14: Number of Unhoused PLWDH by Gender and Percentage of Persons Newly Diagnosed and Unhoused at time of Diagnosis, LA County, 2020

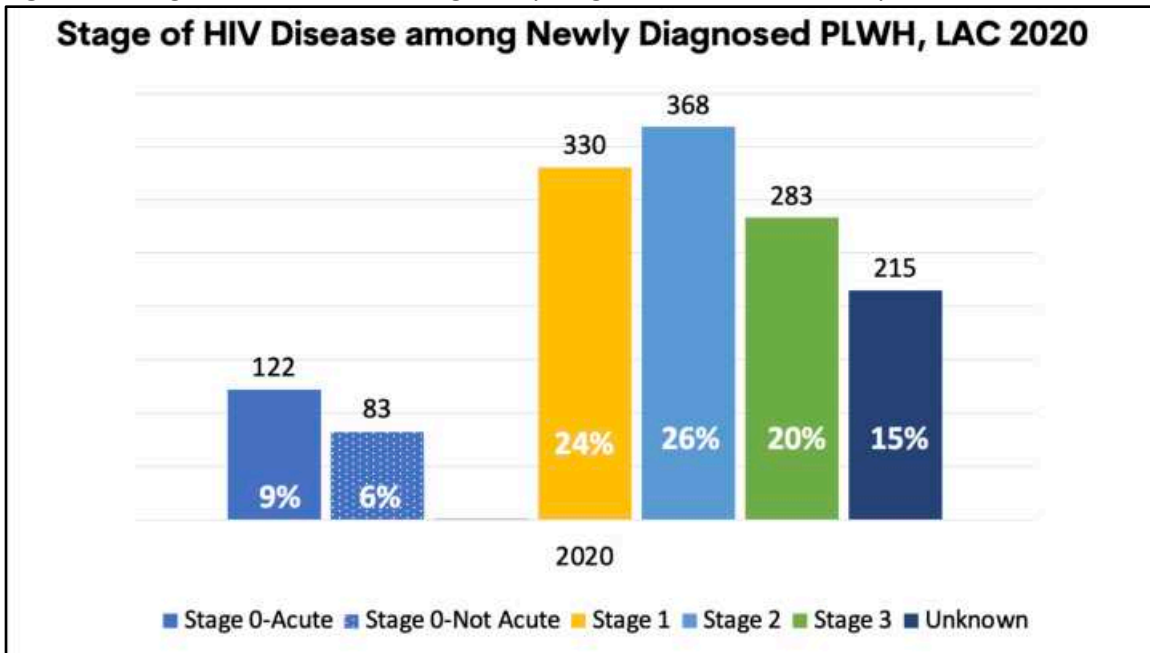
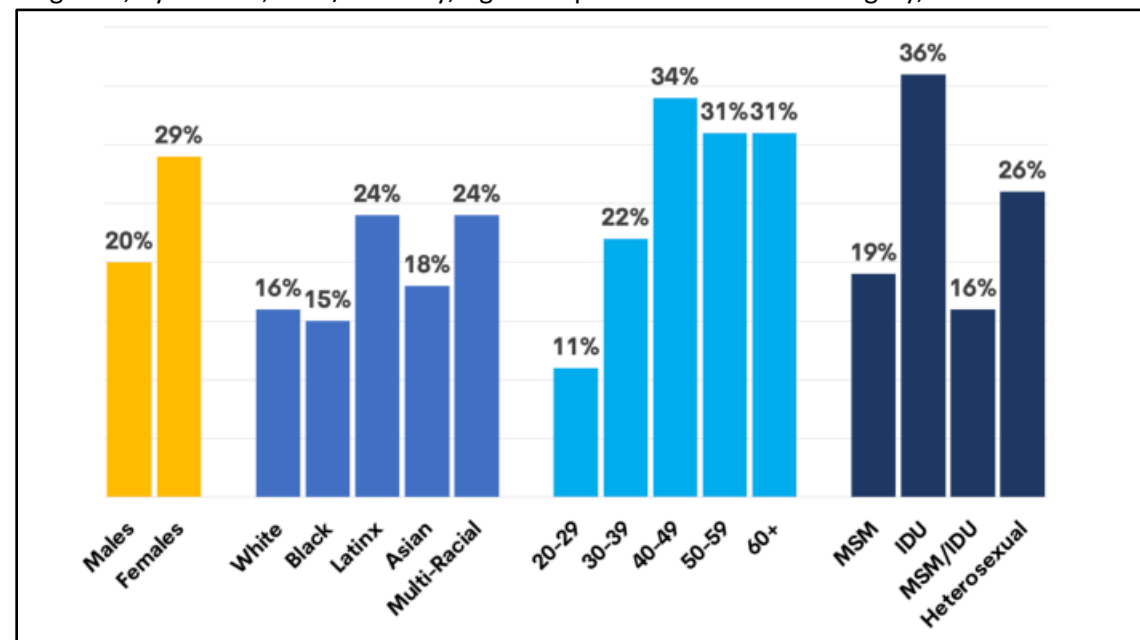


Stage of HIV disease among Newly Diagnosed: Information on stage of HIV disease at the time of diagnosis provides direct insight into the timeliness of an HIV diagnosis. The HIV surveillance case definition of HIV has four stages: Stage 0, 1, 2, and 3. Stage 0 includes those with acute infection at diagnoses (Acute HIV) and those with no evidence of acute infection at diagnosis. Acute HIV is based on the difference in days between the first HIV-positive test result and last HIV-negative test result. If the difference falls within 60 days, HIV is classified as acute HIV.¹⁸ The criterion for Stage 1 disease is CD4 $\geq$ 500 cells/ μ L within 90 days of diagnosis. Stage 2 is CD4 between 200-499 cells/ μ L within 90 days of diagnosis. Stage 3 criteria include either CD4 < 200 cells/ μ L within 90 days of HIV diagnosis or a diagnosis of an opportunistic illness within 90 days of HIV diagnosis.

In 2020, 15% of new HIV diagnoses were diagnosed at Stage 0, with over half of those diagnosed at Stage 0 having acute HIV at diagnosis (Figure 15). The proportion of PLWDH with acute HIV was highest among men, persons aged 20-29 years, and MSM. One in five new HIV diagnoses presented with CD4+ T-cells < 200 cells/ μ L at the time of diagnosis in 2020, indicative of late-stage HIV disease. The proportion of PLWDH with late-stage disease (Stage 3) was highest among females, those who identified as Latinx or multi-racial, those over 40 years of age, and those with IDU or heterosexual transmission risk (Figure 16).

¹⁸ The number of newly diagnosed persons with stage 0 are likely underestimated due to under-reporting of HIV-negative test results.

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Figure 15: Stage of HIV Disease among Newly Diagnosed PLWH, LA County 2020**Figure 16:** Percentage of Newly Diagnosed Presenting with Late-Stage Disease (Stage 3) at Time of Diagnosis, by Gender, Race/Ethnicity, Age Group and Transmission Category, LAC 2020

*Stage 3: Either CD-4 <200 w/in 90 days of diagnosis or diagnosis of opportunistic illness w/in 90 days

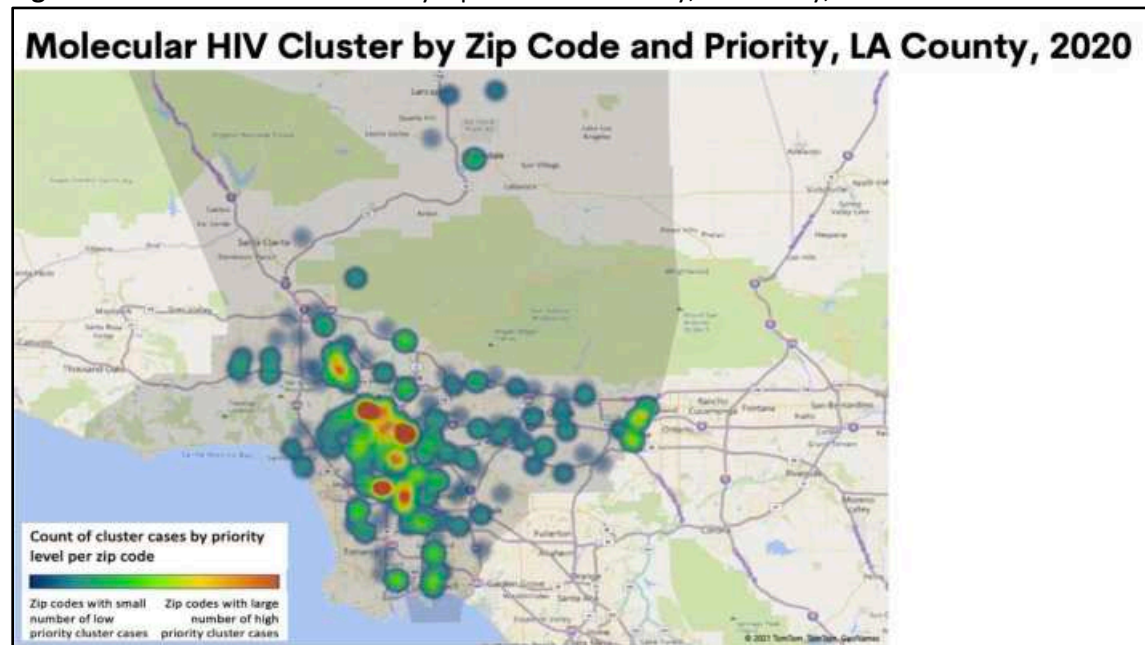
High Priority Cluster Areas: Federal guidelines for the care and treatment of PLWDH recommend HIV viral genotype testing at initiation of HIV care to determine whether an individual's HIV strain is resistant to certain drugs. The genotype testing, which results in a genetic sequence report reflecting an individual's HIV viral strain, is reported to DPH along with other HIV laboratory and clinical test results.

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Molecular HIV Surveillance is the collection and analysis of HIV genotype data generated through HIV drug resistance testing. Through a comparison of the viral genotype reports of PLWDH in the local area, it can be determined if there are multiple people with a highly similar HIV strain. Because HIV's genetic sequence constantly evolves, people whose viral strains are highly similar are likely to be in the same social HIV transmission network (i.e., transmission cluster).¹⁹ Transmission clusters with numerous newly HIV diagnosed individuals may indicate that recent and rapid HIV transmission is occurring among a group of individuals. When a cluster is identified, it can inform the delivery of services and interventions to minimize transmission in a geographic area and prioritize efforts to those who need them the most.

In 2020, 7% of persons newly diagnosed with HIV were associated with a priority transmission cluster. These persons were more likely to be aged 13-29 years, Latinx, and have MSM transmission risk compared with persons newly diagnosed with HIV who were not associated with a priority cluster. Persons associated with a priority transmission cluster were also more likely to reside in the Southeast, San Antonio, Northeast, and Antelope Valley Health Districts; report methamphetamine use and anonymous partners; and have syphilis co-infection. The geographic distribution of the transmission clusters and priority level for follow-up are presented below in Figure 17. The blue clusters are low priority (< 5 persons with new HIV diagnoses between 2018-2020), the green as medium priority (≥ 5 persons with new HIV diagnoses between 2018- 2020), and the red as high priority (≥ 5 cases diagnosed in 2020).

Figure 17: Molecular HIV Cluster by Zip Code and Priority, LA County, 2020



d) New HIV Infections²⁰: The annual number of new HIV infections reflect infections acquired in a

¹⁹ It is important to note that this information cannot be used to determine either direct transmission or the direction of transmission between any two individuals.

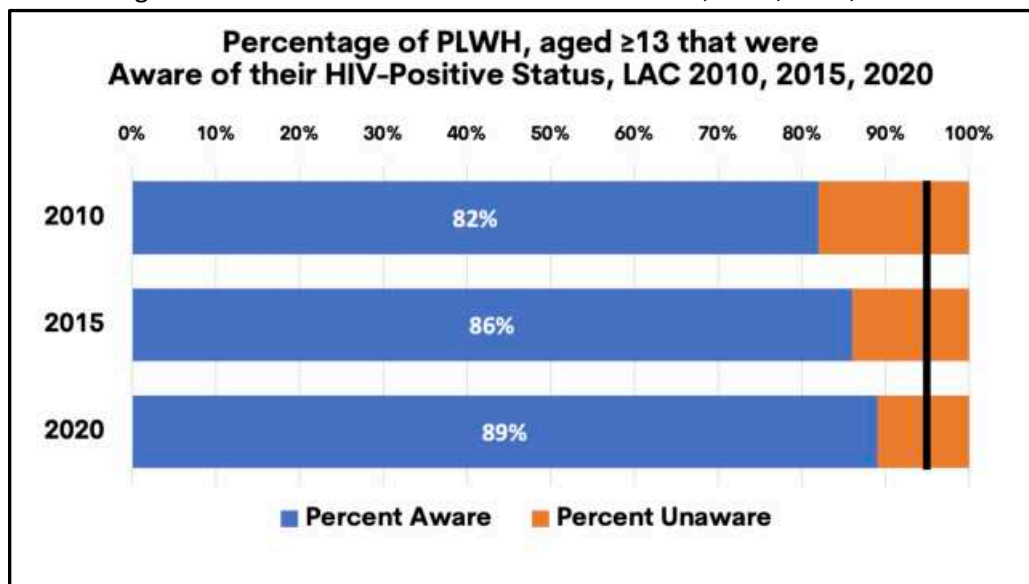
²⁰ HIV incidence is approximated using CDC's CD4 depletion model, which uses HIV surveillance data and the first CD4 value after HIV diagnosis to estimate HIV incidence, HIV prevalence, and percentage of undiagnosed HIV. The date of HIV acquisition is estimated for each person with a CD4 test using the model. To account for persons without a CD4 test result, persons with CD4 test results are assigned a weight based on the year of HIV diagnosis,

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

calendar year. Some new infections are diagnosed soon after acquiring HIV, but the majority are not. When the number of new HIV infections is high, HIV continues to spread, because most people with a new infection are not aware they are living with HIV. New infections provide information on recent transmission and serve as a barometer to assess whether HIV prevention strategies are reducing transmission. Trends in new infections generally track with trends in new diagnoses unless transmission is very low or high in the population. An estimated 1,400 persons aged 13 years and older acquired HIV in 2020. These new infections may or may not have been diagnosed that year.²¹ Estimates are not considered true values and should be interpreted along with a range of values that is likely to contain the true value with a certain degree of confidence (such as a 95% confidence interval). In 2020, the 95% confidence interval for the estimated number of new infections ranged from a low of 900 infections to a high of 1,990 infections. The number of persons newly diagnosed and the estimated number of persons who acquired HIV (new infection) have declined between 2010 and 2020. In 2010, there were an estimated 2,300 new infections and 2,186 new HIV diagnoses. In 2020, 1,404 persons were newly diagnosed with HIV, reflecting both new and old infections. An estimated 1,400 persons acquired HIV in 2020, reflecting new infections, some of whom were not diagnosed.

e) People Living with Undiagnosed HIV: In 2020, an estimated 11% of PLWH, or 6,800, were unaware of their HIV status.²² Since 2010, awareness of HIV has increased among PLWH from 82% to 89% (Fig. 18), however, since 2019, awareness of HIV-positive status decreased across all age, sex and race/ethnicity categories, with the largest decrease observed among cisgender women (-6 percentage points).

Figure 18: Percentage of PLWH that were Aware of their HIV Status, 2010, 2015, 2020



— Bolded line indicates the EHE Plan and Integrated Plan goal of 95% awareness by 2025

sex, race/ethnicity, transmission category, age at diagnosis, disease classification, and vital status at the end of the specified year.

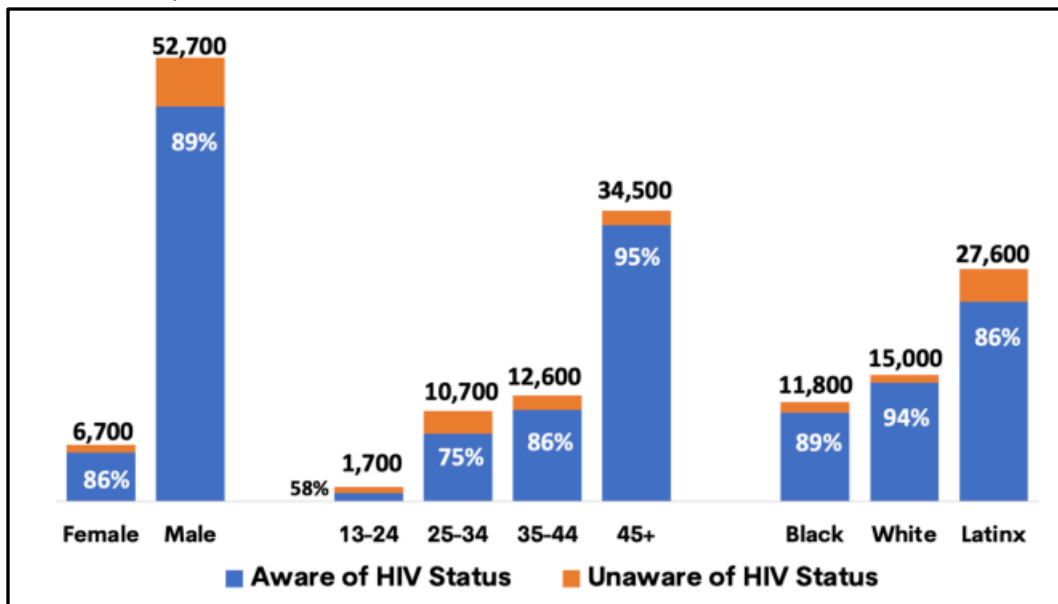
²¹ The annual number of new HIV diagnoses is the number of PLWH who received an HIV diagnosis in a calendar year. A new HIV diagnosis is *not* equivalent to a new infection that was acquired in a calendar year. Many people live years before they are diagnosed while some are diagnosed soon after acquiring HIV. Based on local data, the majority of new HIV diagnoses each year were infections acquired over a year ago.

²² Estimated using the CD4-based model developed by the Centers for Disease Control and Prevention.
https://journals.lww.com/jaids/Fulltext/2017/01010/Using_CD4_Data_to_Estimate_HIV_Incidence,.2.aspx.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

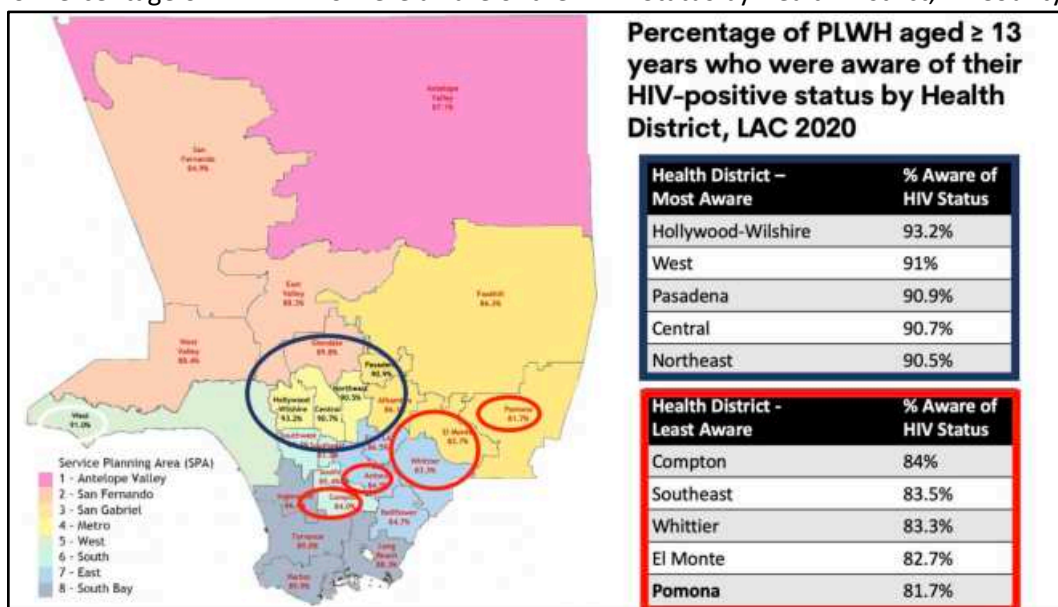
Among PLWH in 2020, the largest gaps in knowledge of HIV-positive status existed for younger persons, where approximately 42% of persons aged 13-24 years and 25% of persons aged 25-34 years with HIV were not aware of their HIV-positive status. Females and people who were Latinx or Black were also more likely to be unaware of their status compared to other groups (Figure 19).

Figure 19: Awareness of HIV-Positive Status among PLWH by Sex at Birth, Age Group and Race/Ethnicity, LAC 2020



The percentage of PLWH who were aware of their HIV-positive status also varied by location. There were five Health Districts with at least 90% of PLWH aware of their HIV status - Hollywood-Wilshire, West, Central, Northeast and Pasadena. Conversely, the five Health Districts with the least percentage of PLWH aware of their status were Compton, Southeast, Whittier, El Monte and Pomona (Figure 20).

Figure 20: Percentage of PLWH who were aware of their HIV Status by Health District, LA County 2020



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II. Clinical & Behavioral Characteristics of PLWH and People at Risk for HIV

Clinical and behavioral characteristics of PLWH and people at-risk for HIV are largely compiled through the use two biobehavioral surveillance efforts, the National HIV Behavioral Surveillance (NHBS) and the Medical Monitoring Program (MMP).

Since 2016, the NHBS has surveyed four different population groups: MSM, persons who inject drugs (PWID), heterosexuals at increased risk for HIV and transgender women. Across all NHBS participants living with HIV, 83% of MSM and 80% of transwomen were aware of their HIV-positive status. In contrast, only 63% of PWID were aware of their status²³.

MSM: Among MSM, over the course of five rounds of NHBS spanning over a decade, HIV prevalence has consistently been highest among Black MSM. In the most recent surveillance round (2017), 36% of Black MSM were living with HIV compared with 18% of Latinx MSM and 15% of White MSM. In 2017, HIV testing within the previous 12 months was high among MSM of all race/ethnicity groups, with 90% of White MSM reporting testing, and 83% of both Latinx and Black MSM reporting testing. Reports of condomless anal sex ranged from 71% among Black MSM to 79% among Latinx MSM. Twenty-eight percent of Black MSM, 25% of Latinx MSM and 24% of White MSM reported having an STD diagnosis. Exchanging sex for money or drugs was also highest among Black MSM (11%), compared to Latinx (7%) and White MSM (7%). Knowledge of PrEP was high (>92%) among MSM irrespective of race/ethnicity. Among participants who reported HIV-negative or unknown HIV status, 36% of White MSM had used PrEP within the past 12 months compared with 29% of Latinx MSM and 22% of Black MSM. Among MSM, the overlapping epidemic of meth use contributes to increased risk of HIV acquisition. Methamphetamine use is frequently associated with increased unsafe sexual activity and meth-using MSM are much more likely to have multiple sexual partners and report inconsistent condom use than MSM who do not use meth.

Transgender Women: NHBS data found that in 2019, transwomen had the highest HIV positivity rate (1 in 3 were HIV-positive) compared with other populations at elevated risk of HIV, with Black transwomen having the highest positivity rate (52%), compared with Latinx (30%) and White (9%) transwomen. Black transwomen were more likely to practice condomless anal sex and exchange sex for drugs or money but less likely to test recently for HIV than their Latinx and White counterparts. Meth use was also high among transwomen, with 33% of White transwomen, 28% of Black transwomen, and 17% of Latinx transwomen reporting use. PrEP knowledge was also high, however use of PrEP among HIV-negative transwomen in the past 12 months was low. The majority (91%) of HIV-negative transgender women had heard of PrEP and a little over half (55%) had discussed PrEP with a healthcare provider. Twenty-seven percent had taken PrEP in the last 12 months and 21% were PrEP persistent. Most respondents (70%) in the 2019 cycle reported a household income at or below the FPL and 42% were currently unemployed. Nearly 1 out of 2 participants (47%) reported being homeless at the time of the interview and 23% had been incarcerated in the previous 12 months. Over half of participants reported anal sex without a condom in the past 12 months (57%) and 35% reported having sex in exchange for food, shelter, money, or drugs. Nearly 2 out of 3 transwomen participating in NHBS reported having experienced verbal harassment over the last 12 months because of their gender identity or presentation. One out of 5 participants reported having seriously considered suicide. Recent sexual abuse was also reported by nearly 1 out of 5 respondents.

²³ Results for PWID may be unstable due to small numbers and should be interpreted with caution.

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People Who Inject Drugs (PWID): Substantial disparities exist among PWID along the diagnosis and care cascade. About one in three PWID living with HIV did not know they were infected (compared to one in five transwomen and one in six MSM). Once diagnosed, PWID had lower levels of receipt of care, retention in care and viral suppression than those with MSM and heterosexual contact transmission risk. A higher percentage of PWID aged 18-29 years reported sharing syringes or injection equipment (50% and 74%) compared with PWID aged >30 years (32% and 56%). Conversely, 15% of those 30 or older and 10% of those 18-29 reported exchanging sex for money or drugs. Injection of methamphetamines during the past 12 months increased from 59% in the 2015 IDU NHBS cycle to 68% in the 2018 IDU cycle. Non-injection use of methamphetamine also increased significantly (32% to 75%).

At-Risk Heterosexuals: In the 2016 heterosexual cycle, a total of 526 persons $\geq$ age 18 who reported having vaginal or anal sex with a partner of the opposite sex in the past 12 months were surveyed. Of these, 54% were male and 46% female. Of the women surveyed, 57% were Black, 36% Latina and 2% were White. Eighty-three percent reported no more than a high school diploma/GED and 82% reported a household income at or below the FPL. Eighty-four percent had health insurance, 11% reported being homeless at the time of the interview, and 14% had been incarcerated in the previous 12 months. Heterosexual cisgender women were more likely to have tested for HIV and STDs than heterosexual men. Among women, more Black women reported condomless sex with a casual partner, receiving money or drugs in exchange for sex, and having concurrent sexual partnerships than Latinx women. More recently, data suggest that meth is also contributing to increased HIV risk among heterosexual people with syphilis.

III. Other STDs²⁴

In recent years, STD rates have dramatically increased in LAC. According to provisional 2021 data, 28,115 gonorrhea cases and 5,746 early syphilis cases were reported to LAC - continuing the overall trend of increases in annual cases. In the last decade, there has been an 847% increase in syphilis rates among females and a 128% increase among males. Alarming, the number of reported congenital syphilis cases increased over 20 times between 2012 and 2021.

Chlamydia: In 2021, of the 52,121 cases, more than half were seen in cisgender females (56%) and 20-29 years old (54%). Hollywood-Wilshire (959 cases per 100,000), Central (1,035 cases per 100,000), South (987 cases per 100,000) and Southwest (956 cases per 100,000) Health Districts had rates about two times the rate of infection in LAC (545 cases per 100,000).

Gonorrhea: In 2021, the rate among African Americans (769 per 100,000) was more than four times that of Whites and Latinx people (168 and 185 per 100,000, respectively). The Hollywood-Wilshire and Central Health Districts had rates (906 and 796 per 100,000, respectively) that were approximately three times the rate of infection in LAC (294 per 100,000). Most of the gonorrhea case were among cisgender males (71%) and those aged 20-34 (63%).

Syphilis: In LAC, 5,746 early syphilis cases were reported in 2021 with a rate of 60 per 100,000, reflecting a 2% rate increase compared with the 2019²⁵ rate and a 161% increase compared with 2012. Rates were

²⁴ All 2021 data are provisional, and 2020 population estimates were used as a proxy for 2021

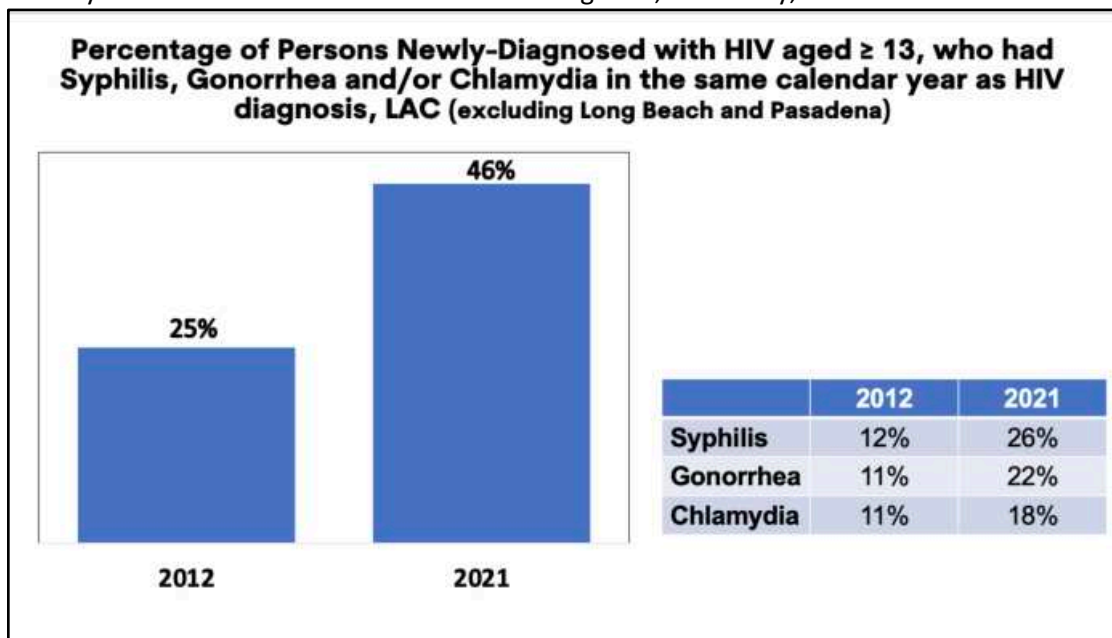
²⁵ Due to underreporting of STDs in 2020 due to the COVID-19 pandemic, a comparison with 2020 STD data may be unreliable.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

higher among males (99 per 100,000) compared to females (18 per 100,000); however, from 2019 to 2021, there was a 64% increase in early syphilis rates among females compared to a 5% decrease among males. Transgender individuals represented 3.4% of the early syphilis cases. Rates were highest in persons aged 25-29 among females (56 per 100,000) and among males aged 30-34 (265 per 100,000). The rate among African Americans (142 per 100,000) was more than three times that of Whites (46 per 100,000) and more than four times that of Latinos (60 per 100,000). Hollywood-Wilshire and Central Health Districts had a rate (205 per 100,000) that was more than three times the rate of infection in LAC (60 per 100,000). Increasing rates of syphilis among MSM/W, women and newborns (congenital syphilis) represent a concurrent epidemic with meth use disorder in LAC. As syphilis rates increase rapidly among women, LAC has reported 113 and 123 congenital syphilis (CS) cases in 2020 and 2021, respectively. After a rapid decline since 2006, LA County also had a perinatal HIV transmission rate of 7% in 2020, the highest ever seen, with three of the four babies also co-infected with CS. Maternal risk factors for congenital syphilis include meth use, unstable housing, mental illness, and lack of prenatal care.

STD and HIV Co-infection: Persons with syphilis, gonorrhea, and/or chlamydia are at an increased risk of acquiring HIV due to biological and behavioral factors. STDs among PLWH can also increase HIV viral load and the risk of forward HIV transmission. The percentage of persons newly diagnosed with HIV who had one or more STDs in the same year nearly doubled from 25% in 2012 to 46% in 2021. In 2012, 11% of those newly diagnosed with HIV had chlamydia in the same year; 11% had gonorrhea and 12% had syphilis. By 2021, those percentages grew to 18%, 22% and 26%, respectively. This reflects a rapid rise in the total number of syphilis cases in LAC over the same period (Figure 21).

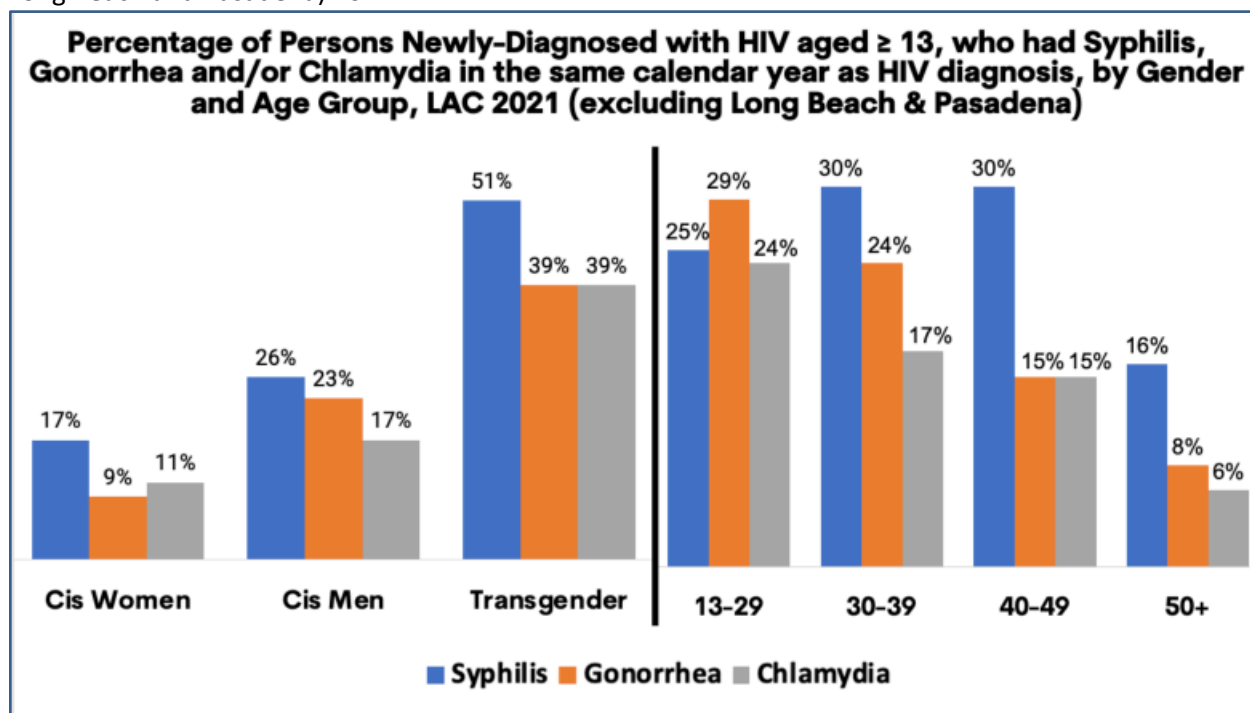
Figure 21: Percentage of Persons Newly Diagnosed with HIV who had Syphilis, Gonorrhea and/or Chlamydia in the Same Calendar Year as HIV Diagnosis, LA County, 2012 and 2021



In 2021, percentages of syphilis, gonorrhea and/or chlamydia co-infections among people newly diagnosed with HIV were highest in the transgender population. Among both cisgender women and cisgender men with newly diagnosed HIV, syphilis co-infection was higher than co-infection with other STDs. By age group, syphilis co-infection was highest among people aged 30-49 years old, while co-infection with gonorrhea and chlamydia was highest among people aged 13-29 years (Figure 22).

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Figure 22: Percentage of persons newly diagnosed with HIV who had syphilis, gonorrhea, and/or chlamydia in the same calendar year as HIV diagnosis by STD, gender and age group, LAC (excluding Long Beach and Pasadena) 2021



Hepatitis C Virus: In the U.S., the majority of persons become infected with hepatitis C virus (HCV) by sharing needles or other equipment used in injecting drugs.²⁶ In 2019, among the 1,952 (47%) reported acute cases in the U.S. that included risk information for injection drug use, 1,302 (67%) reported injection drug use. Since the early 2000s there have been notable increases in HCV incidence among young people (15–29 years old), mostly associated with increases in opioid and injection drug use (IDU).²⁷ Subpopulations with higher injection drug use typically include unhoused persons and criminal justice-involved individuals. In the most recent (2018) NHBS survey cycle targeting PWID, of the 510 people screened for HCV, HCV antibody prevalence was 58% and the prevalence of HCV and HIV co-infection was 1%. PLWDH who are co-infected with HCV are more likely than those with HCV alone to develop end-stage liver disease, and higher viral loads for both HIV and HCV results in increased transmission risks.

COVID-19: Between January 2021 to March 2022, there were 6,048 cases of COVID-19 among PLWDH, representing a rate of 1,249 cases of COVID-19 and HIV co-infection per 10,000 PLWD.³ Rates of COVID-19 and HIV co-infection among PLWDH were highest among females, persons aged 18-29 years, Latinx persons, residents of SPA 8 (South Bay), persons with MSM/IDU transmission risk and unhoused persons. Persons with HIV and COVID-19 co-infection had higher levels of hospitalization, intensive care

²⁶ <https://www.cdc.gov/hepatitis/statistics/2019surveillance/Introduction.htm>

²⁷ Gicquelais RE, Foxman B, Coyle J, Eisenberg MC. Hepatitis C transmission in young people who inject drugs: Insights using a dynamic model informed by state public health surveillance. *Epidemics*. 2019; 27:86–95. doi: 10.1016/J.EPIDEM.2019.02.003.

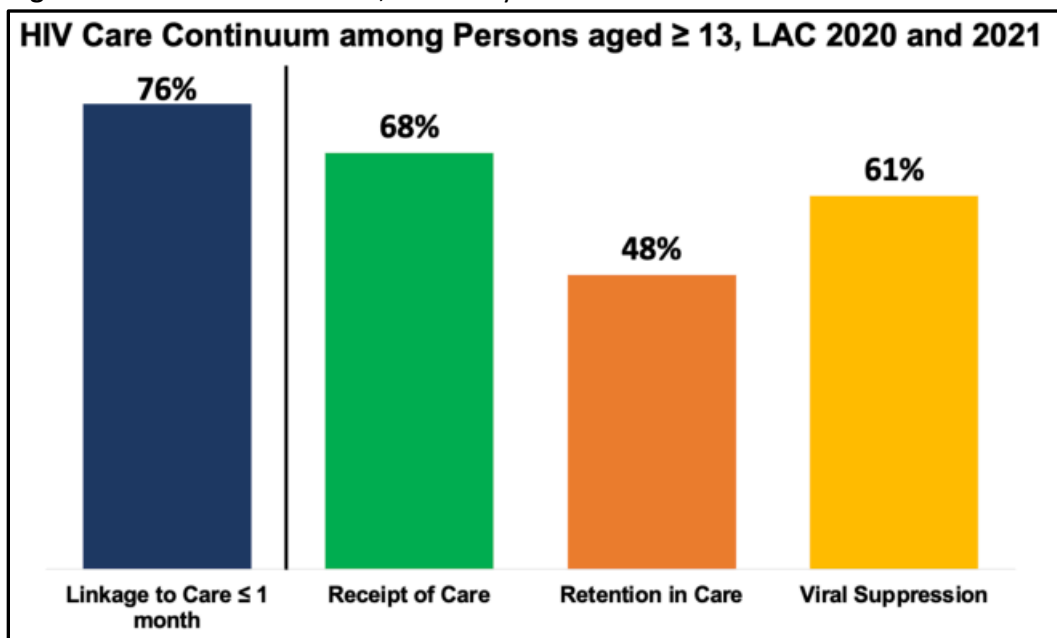
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unit admission, intubation, and death compared with all COVID-19 patients, regardless of COVID-19 vaccination status. However, COVID-19 vaccination reduced the risk of these severe outcomes for both HIV and COVID-19 co-infected patients and COVID-19 patients.

IV. HIV Care Continuum

The HIV Care Continuum is a series of steps starting from when a PLWH receives a HIV-positive diagnosis through the achievement of viral suppression. The HIV care continuum includes the following: (1) among persons receiving a diagnosis of HIV in a given calendar year, the percentage of persons who were linked to HIV care within 1 month of diagnosis (defined as ≥ 1 CD4/VL/Genotype test reported within 1 month of HIV diagnosis); and (2) among all persons living with diagnosed HIV, the percentage of persons who (a) received HIV care (defined as ≥ 1 CD4/VL/Genotype test per year)²⁸, (b) were retained in HIV care (defined as ≥ 2 CD4/VL/ Genotype tests at least three months apart per year), and (c) were virally suppressed (defined using most recent viral load) per year. The base population for measuring linkage to HIV care is persons who received a HIV-positive diagnosis in a given calendar year, whereas the base population for the downstream steps in the continuum of care is all persons who were diagnosed with HIV through the prior calendar year and living in LAC with diagnosed HIV in the current year. The latter ensures that there is at least one year of follow-up to measure receipt in care, retention in care, and viral suppression.

Figure 23: HIV Care Continuum, LA County 2020 and 2021



As depicted in Figure 23, 76% of people newly diagnosed with HIV in 2020 were linked to care within one month; and among all PLWDH in 2021, 68% received HIV care at least once in the calendar year, 48% were retained in care, and 61% were virally suppressed. Table 1 provides an overview of HIV Care Continuum outcomes across different characteristics of PLWDH, with the poorest outcomes in each group highlighted in red font.

²⁸ "Receipt of Care" and "Engagement in Care" are synonymous terms

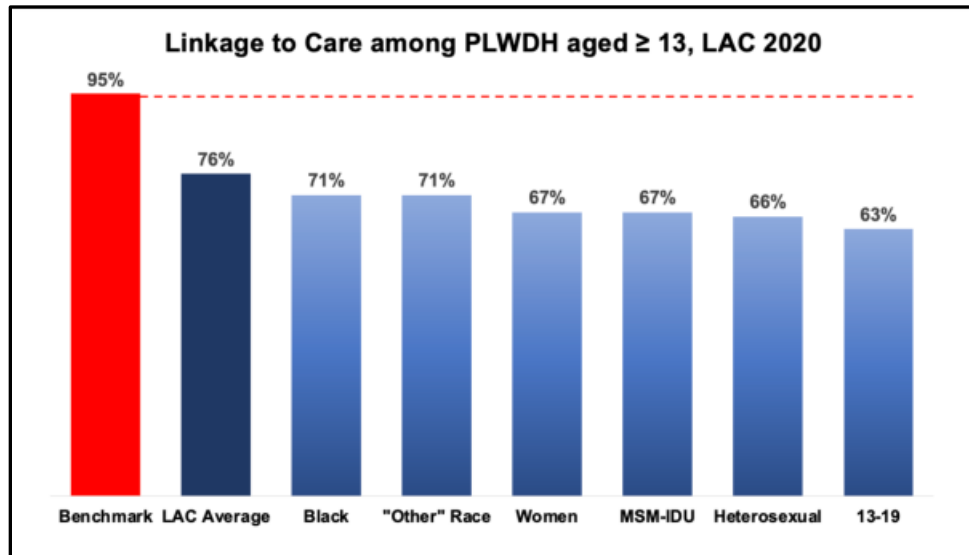
3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Table 1: HIV Care Continuum Outcomes among Select Characteristics of PLWDH, 2020-21

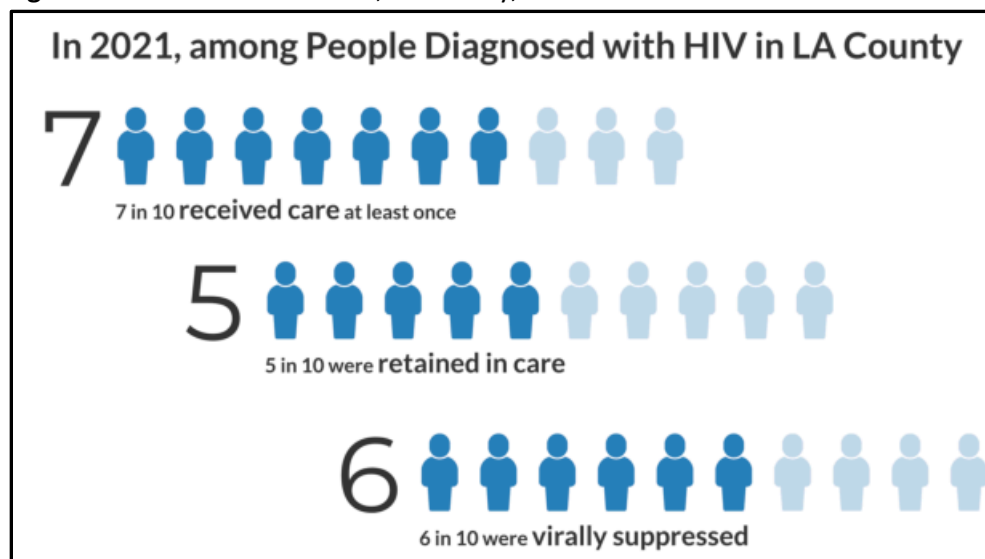
Characteristic	Linked to Care within 1 month	Engaged in Care	Retained in Care	Virally Suppressed
Men	77%	68%	48%	61%
Women	67%	67%	47%	59%
Transgender	81%	69%	49%	56%
13-19	63%	85%	59%	78%
20-29	76%	74%	45%	64%
30-39	78%	68%	43%	59%
40-49	73%	66%	47%	59%
50-59	78%	68%	50%	62%
60+	76%	67%	51%	62%
Black	71%	63%	42%	54%
Latinx	79%	68%	49%	61%
White	73%	69%	48%	63%
Asian	90%	72%	51%	68%
NH/PI	--	73%	47%	63%
AI/AN	86%	66%	42%	57%
Multi-race	69%	81%	55%	71%
MSM	78%	69%	48%	62%
IDU	75%	57%	40%	48%
MSM/IDU	67%	67%	47%	56%
Heterosexual	66%	66%	48%	60%
Total	76%	68%	48%	61%

Linkage to Care: Linkage to HIV care is typically tracked as being linked to HIV care within one month of HIV diagnosis. However, initiating HIV care services should occur faster, ideally within one week, to ensure that HIV treatment can start immediately. Though timeliness of linkage to care has improved, only 76% of persons who were newly diagnosed in 2020 were linked to HIV care within one month and only 54% were linked to HIV care within one week. Among persons aged 13 years and older newly diagnosed with HIV in 2020, groups that were least likely to be linked to care within one month of diagnosis were cisgender women (67%), Black/African Americans (71%), those whose race/ethnicity was classified as “Other” (71%), persons aged 13-19 years (63%), and persons with heterosexual (66%) and MSM/IDU (67%) transmission risk (Figure 24).

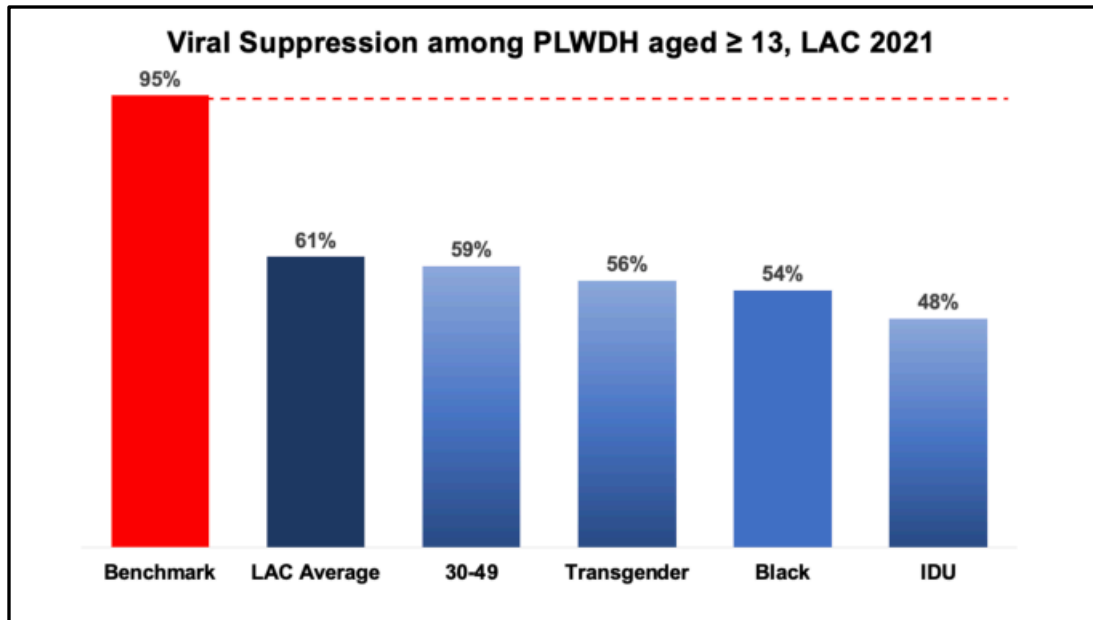
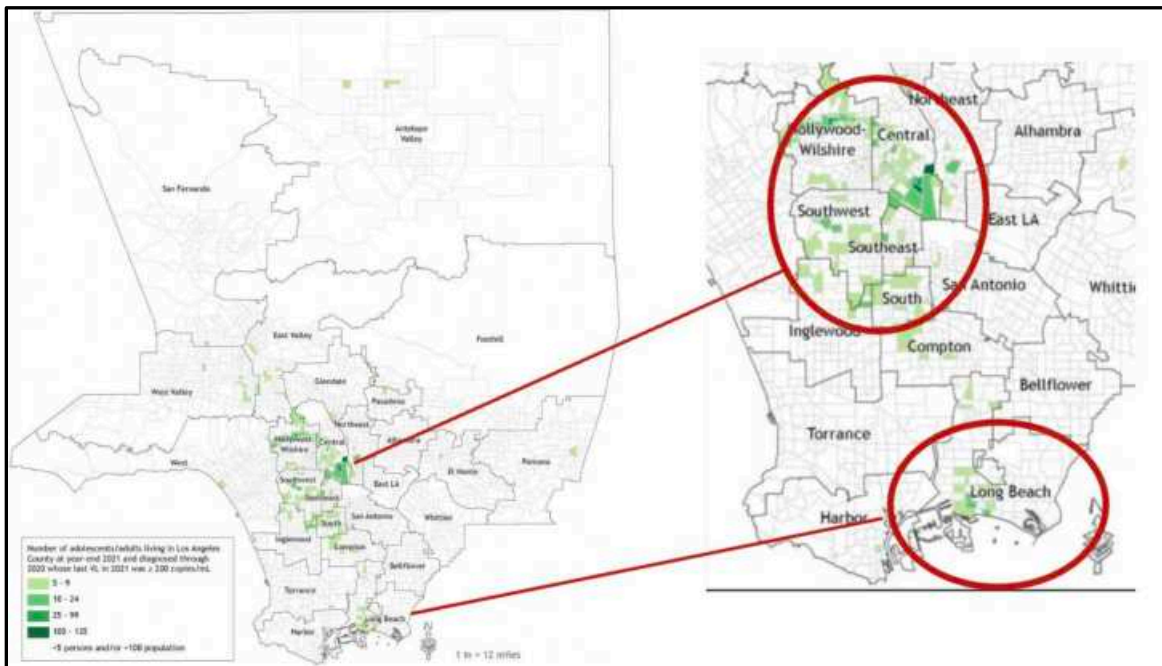
3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 24: Linkage to Care within 1 Month of Diagnosis, among PLWDH, LAC 2020

Receive Care/Retained in Care/Viral Suppression: Once linked to HIV care, performance along the HIV care continuum remains low. In 2021, only seven in ten PLWDH received care services, five in ten were retained in care, and six in ten were virally suppressed. The percentage of PLWDH who were receiving HIV care and retained in care were similar across gender groups, while the percentage who were virally suppressed was slightly lower among transgender persons. Adolescents had better HIV care outcomes than their counterparts, while persons aged 30-49 had the poorest outcomes across all age groups. With respect to race/ethnicity, Blacks/African Americans had the worst HIV care outcomes compared with other groups. Persons whose transmission risk was IDU had the lowest levels of receipt of care, retention in care and viral suppression. The greatest disparities in viral suppression were among Black sub-populations, cisgender women and transgender persons, persons aged 30-49 years, and persons whose transmission risk included injection drug use (Figure 26). By geographic area, unsuppressed viral load was highest in the Central Health District, followed by the South, Southeast, Harbor, Hollywood-Wilshire, West, and Northeast.

Figure 25: HIV Care Continuum, LA County, 2021

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 26: Viral Suppression among PLWDH, LA County 2021**Figure 27:** Unsuppressed Viral Load²⁹ by Census Tract among persons diagnosed through 2020 and living in LAC at year-end 2021 (N=1,687)*

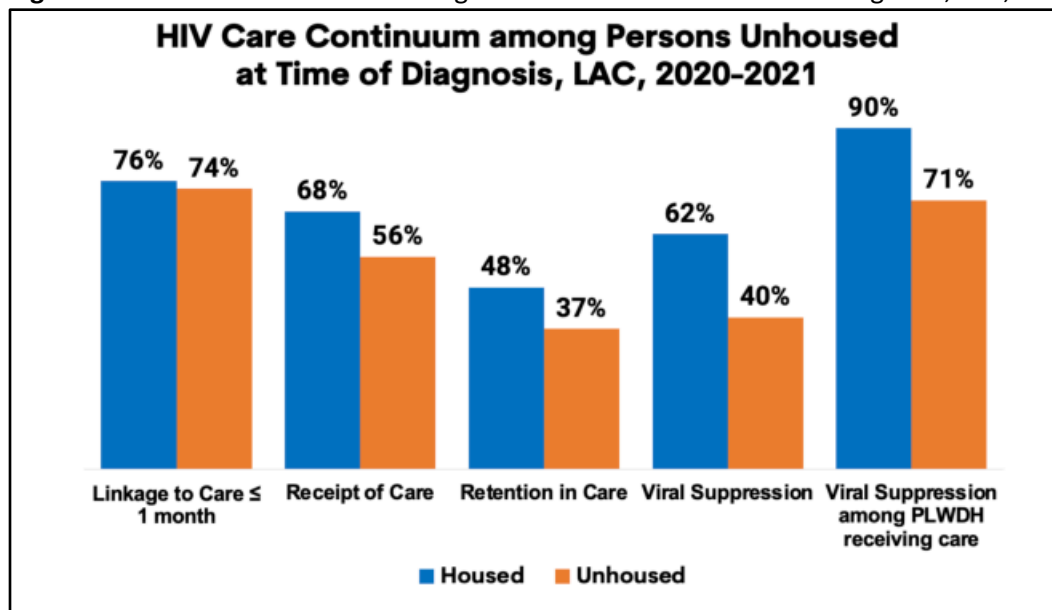
²⁹ Unsuppressed viral load: numerator includes PLWDH whose last VL test in 2021 was unsuppressed (HIV-1 RNA ≥ 200 copies/mL; denominator includes PLWDH diagnosed through 2020 and living in LAC at year-end 2021 based on most recent residence. PLWDH without a VL test in 2021 were considered virally unsuppressed. Analysis excludes PLWDH diagnosed through 2020 and living at year-end 2021 who (1) had missing census tract information, (2) were receiving care but never had a viral load test, (3) were not receiving care for >12 months at year-end 2021, or (4) were in census tracts with small sample sizes. Exclusions represented 68% of PLWDH diagnosed through 2020 and living in 2021 whose last viral load was unsuppressed.

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Timeliness of Care and Viral Suppression: Among persons newly diagnosed with HIV in 2020 with treatment information included in their case reports, 74% had initiated treatment within one month of diagnosis and 89% within three months of diagnosis. Timeliness from HIV diagnosis to viral suppression has improved over time, but early viral suppression is lagging. In 2021, only 51% of PLWDH were virally suppressed within three months of diagnosis while 76% of PLWDH were virally suppressed within 12 months of diagnosis.

Unhoused: Persons living with HIV who are unhoused continue to experience suboptimal outcomes along the HIV care continuum. Compared with housed persons, unhoused persons had lower rates of receiving HIV care, retention in care, and achieving viral suppression in 2021.

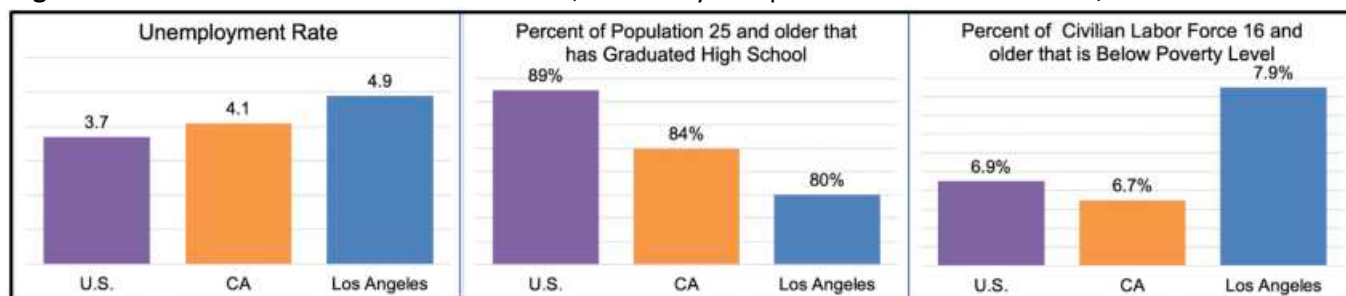
Figure 28: HIV Care Continuum among Persons Unhoused at Time of Diagnosis, LAC, 2020-21



V. Social Determinants of Health

Key social determinants of health including housing status, poverty, and recent incarceration, increase the risk of HIV acquisition and transmission. While data for social determinants of health are not as widely or consistently collected as demographic information, it is critically important to understand how these factors contribute to the experience of people at increased risk for HIV and those living with HIV. As depicted in the figure below, compared to both the state of California and the U.S., LAC fares worse with respect to key social determinants of health. LAC has a higher unemployment rate, a higher percent of its population living in poverty, and a lower percentage of its adult population that has graduated high school.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: EPI SNAPSHOT

Figure 29: Select Social Determinants of Health, LA County Compared to California and U.S., 2021

Limited socio-economic data is collected on the HIV case report forms that are used to populate the population-level case surveillance, therefore, additional data from the MMP, NHBS, and RWP Part A programmatic data are utilized to better understand the impact of social determinants of health on people at risk for and living with HIV in LAC. The MMP data is intended to be representative of all PLWDH in LAC. The RWP Part A data is representative of PLWDH in LAC who received at least one RWP-funded service in Year 31 (March 1, 2021-February 28, 2022). A total of 21,877 clients, or approximately two out of every five PLWDH in LAC, received at least one core or support RWP service in Year 31.

Poverty: Based on data collected in MMP, it was estimated that nearly half of PLWDH in LAC from 2015-19 were living at or below the Federal Poverty Level (FPL) in the past 12 months. Among RWP clients in Year 31, 64% were living at or below FPL. RWP subpopulations who were the most impacted by poverty were those recently incarcerated (85.4%), transgender persons (78.4%), and cisgender women (75.7%). Of the 501 transgender women who participated in the LAC NHBS in 2019, 70% reported living in poverty in the past year. Likewise, of the 511 PWID who participated in the LAC NHBS in 2018, 75% reported a household income below the federal poverty level.

Housing Status: Based on estimates from MMP, approximately 11% of PLWDH in 2015-19 experienced homelessness in the past 12 months. Among RWP clients experiencing homelessness, most (80%) were living at or below FPL in the past 12 months and nearly half were MSM of color (47%). The largest percentages of RWP clients experiencing homelessness were among recently incarcerated (33%), trans persons (25%), and PWID (23%). Among the transgender NHBS participants, 47% had experienced homelessness in the past year; and 64% of the PWID participants were currently homeless.

Experience with the Justice System: MMP estimates that approximately 2% of PLWDH in 2015-19 were incarcerated in the past 12 months. Information on experience with the justice system for RWP clients is collected as “recent incarceration” (in the past 24 months) and “ever-incarcerated,” and in Year 30 was reported for 16,656 clients. Of these, 8% were recently incarcerated and 18% were ever-incarcerated. Among clients who were recently incarcerated, 85% were living at or below FPL in the past 12 months and one-third were experiencing homelessness. The largest percentages of RWP clients recently incarcerated were among those experiencing homelessness, using injection drugs, and identify as transgender. Twenty-three percent of the transgender NHBS participants and 46% of the PWID participants reported recent incarceration (within past 12 months).

VI. Priority Populations

Based on HIV and STD disparities detailed above, the priority populations for the Integrated HIV Prevention and Care Plan, 2022-2026 are: Black MSM; Latinx MSM; Women of Color; Persons of Trans Experience; PLWH Aged 50 and Older; Persons Under 30; and PWID. This mirrors the EHE priority

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populations, with the added category of PLWH Aged 50 and Older. These priority populations are also aligned with the National HIV/AIDS Strategy: 2022–2025 priority populations: gay, bisexual, and other men who have sex with men, in particular Black, Latino, and American Indian/Alaska Native men; Black women; transgender women; youth aged 13–24 years; and people who inject drugs.

HIV PREVENTION, CARE AND TREATMENT RESOURCE INVENTORY

The LAC HIV Prevention, Care and Treatment Resource Inventory is depicted in Table 2. Los Angeles County has identified an estimated \$425,945,143 in HIV-related funding, 57% of which is attributed to Medi-Cal (\$242,424,556) expenditures. Although comprehensive in nature, the inventory is a point-in-time estimate and is still incomplete, given that some financial data are not available (e.g. Medicare and private insurance companies' financial data are not available). As local private fundraising can vary dramatically from year to year, this information was not collected and is also excluded from this report.

Organizations and Agencies Providing HIV Care and Prevention Services in Los Angeles County: There are at least 52 organizations/agencies that are not a part of the County system and at least 14 different County departments that provide HIV care and/or prevention services in LAC.

HRSA and CDC Funding Sources: HRSA and CDC funding is detailed in Table 2 and summarized below:

HRSA Funding:

- Part A: \$42,142,230 for RWP Year 32 -Year 1 of a 3-year award. The direct recipient of Part A funding, DHSP, contracts with 27 subrecipients to deliver Part A core and support services. All Ryan White funds are used as 'payor of last resort' and are designed to fill the gaps where other resources are insufficient or do not exist at all. Ryan White Part A funds are an integral part of LAC's safety net of services targeting PLWH at all stages of the HIV Care Continuum. Part A grant funds core and support services for PLWH including AOM, Oral Health, Early Intervention Services (EIS), Emergency Financial Assistance Services, Home and Community Based Health Services, Mental Health Services, Medical Case Management (Medical Care Coordination or MCC), Non-medical Case Management (Benefits Specialty), Food Bank and Home Delivered Meals, Housing Services - Residential Care Facility for the Chronically Ill (RCFCI) and Transitional Residential Care Facility (TRCF), Legal Services, Linguistic Services, Medical Transportation, and Outreach Services (Linkage and Reengagement Program). The Commission on HIV conducts a priority setting and resource allocation process in which they review existing and anticipated funding from all other public and private sources, including other Ryan White funds (Parts B, C, D, and F). DHSP manages funds from local, state, and federal sources to avoid duplication. Client eligibility screening for Ryan White services is entered into LAC's current Ryan White client database, Casewatch. This client-level data system enables service providers to ensure that Part A funds are used as a last resort. Using non-medical case management funding, LAC funds "Benefits Specialty" services, which help PLWH identify the non-Ryan White resources for which they are eligible.
- Minority AIDS Initiative (MAI) - \$3,780,205, March 1, 2022-February 28, 2023 - Year 1 of a 3-year award. DHSP, the direct recipient of MAI funds, contracts with subrecipients to provide Housing (permanent supportive housing), and Non-medical Case Management (Transitional Case Management) in LAC.
- Part B: \$5,446,809, April 1, 2022- March 31, 2023 - Year 4 of a 5-year award. DHSP receives Part B base grant funds, and contracts with subrecipients to fund Housing Services (RCFCI and TRCF), and Substance Use Residential services. The Commission on HIV allocates Part A and Part B funds

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together through its priority and allocation process.

- Part C-Early Intervention Services (EIS): \$5,859,855. HRSA provides Part C-EIS funds directly to 13 organizations throughout LAC. As many of these organizations also receive Part A funds, DHSP requires that they allocate Part C and Part A resources individually for services supported by both funding streams, and they are required to provide detailed budgets for each to prevent overlap. Part C EIS funds provide comprehensive outpatient primary health care to PLWH. Appropriate use of Part C funds includes HIV counseling and testing; monitoring of disease progression; treatment of HIV; diagnosis and treatment of related infections; and case management and assistance accessing other federal, state, and local programs that could provide needed health and support services to PLWH.
- Part D: Women, Infants, Children, and Youth: \$1,777,658. HRSA directly funds three organizations in Los Angeles County to provide Part D services targeting women, infants, children, and youth (Table 2). Part D funds can be used similarly to Part A and C funds with the difference being the intended target population of women, infants, children, and youth. Similar to Part C, the three organizations funded for Part D also receive Ryan White Part A funding. DHSP requires that funding allocations and services delivered are tracked separately to ensure there is no duplication.
- Part F – Dental Reimbursement Program: \$1,975,156. HRSA directly funds three dental schools in Los Angeles County. For the schools that also receive Part A funding for oral health services, DHSP requires that Part A and Part F funds do not duplicate services.
- Part F – AIDS Education and Training Center (AETC): \$788,056.00. The Los Angeles office of the Pacific AETC provides a wide variety of training and education to healthcare providers. DHSP and the Commission on HIV collaborate with the AETC in training sessions, conferences, and consultations on various topics, and plan on working closely with the AETC to build workforce capacity and educate providers about emerging issues as part of its work over the next five years.
- Part F – Special Projects of National Significance: \$410,000 – September 30, 2022 – September 29, 2023 – Year 3 of a 3-year grant. Two CBOs in LAC were funded with this grant: Building Capacity to Implement Rapid Start to Improve Care Engagement Initiative, the purpose of which is to accelerate the initiation of ART and entry into HIV medical care for people with HIV who are newly diagnosed, new to care, or out of care.
- Ending the HIV Epidemic - \$6,168,850, March 1, 2022-February 28, 2023 - Year 3 of a 5-year grant. HRSA's EHE grant awarded to DHSP supports 1) data system infrastructure development and systems linkages; 2) surveillance improvements and building organizational capacity, 3) emerging practices, evidence-informed and evidence-based interventions for diagnosis and rapid linkage to care; 4) reengagement in care and viral suppression; and 5) community engagement, information dissemination specifically calling attention to the activities for PLWH who are not virally suppressed.
- Ending the HIV Epidemic- Primary Care HIV Prevention - \$8,159,376 –April 1, 2022-March 31, 2023. Year 1 or Year 2 of a 2-year grant. In LAC, 17 FQHCs were awarded EHE funding in 2021 and 7 were awarded EHE funding in 2022 (15 other FQHCs were awarded funds in 2020, but those grant terms have ended). This grant is used to expand access to medication to prevent HIV (including PrEP and related services), connect people to care, and ensure care services are well coordinated. Funds are

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

also used to strengthen partnerships with community organizations such as HRSA's Ryan White HIV/AIDS Program-funded organizations and health departments.

CDC Funding:

- Ending the HIV Epidemic - \$3,360,658 – August 1, 2022-July 31, 2023 – Year 3 of a 5-year grant. This grant supports HIV prevention strategies, including 1) HIV self-testing; 2) community engagement; 3) increased access to syringe services; 4) increased screening for PrEP; 5) HIV prevention media campaigns; and 6) improved surveillance data for real-time HIV cluster detection and response.
- Integrated HIV Surveillance and Prevention - \$17,950,095 – January 1, 2022-December 31, 2022 – Year 5 of a 5-year grant. This grant awarded to DHSP supports 11 HIV surveillance and prevention strategies including active and passive surveillance; outbreak investigation; data management, analysis and reporting; comprehensive individual-level and community-level HIV-related prevention services; and data-driven planning.
- HIV Treatment Improvement Demonstration Project - \$597,083 - January 1, 2022-December 31, 2022 - Year 5 (1-year extension in 2022) of a 4-year grant. The two goals of this project are 1) increase infrastructure to improve classification of provider-level HIV surveillance data and 2) provide technical assistance on quality improvement to increase viral suppression, retention in care, and durable viral suppression among low performing providers in Los Angeles County.
- National HIV Behavioral Survey & TG supplement - \$716,168 - January 1, 2022-December 31, 2022 - Year 1 of a 5-year grant. This grant supports Los Angeles County's participation in this four-cycle national survey (MSM, IDU, Heterosexuals, and TG). Survey findings are used for the planning purposes, program development, and resource allocation.
- Medical Monitoring Project - \$728,648 - June 1, 2022-May 31, 2023 - Year 3 of a 5-year grant. This grant supports Los Angeles County's participation in the national surveillance project designed to learn more about the experiences and needs of PLWH (in and out of care).
- Strengthening STD Prevention and Control for Health Departments - \$3,356,049 - January 1, 2022-December 31, 2022 - Year 4 of a 5-year grant. This grant is used to support five strategy areas: STD surveillance, disease investigation and intervention, screening and treatment, promotion and policy, and data management and utilization. No more than 10% of grant funds support contracts.
- STD Prevention and Control for Health Departments –Disease Investigation Specialist (DIS) Workforce Development Infrastructure - \$6,598,516 - January 1, 2022-December 31, 2022 – Year 2 of a 5-year grant. This grant supports expanding, training, and sustaining local DIS workforce to support increased capacity to conduct disease investigation, linkage to prevention and treatment, case management and oversight, and outbreak response for COVID-19 and other infectious diseases.
- Gonococcal Isolates Surveillance Project - \$15,000 - August 1, 2019-July 31, 2020. This Epidemiology and Laboratory Capacity (ELC) grant supports participation in the national sentinel surveillance system to monitor trends in antimicrobial susceptibilities of *Neisseria gonorrhoeae* strains in the US among selected STD clinics and covers salary, fringe benefits and supplies.

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- Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic (CDC-RFA-PS22-2209) - \$500,000 – September 30, 2022 – September 29, 2023, Year 1 of a 4-year grant. This grant was awarded to St. John's Well Child and Family Center to develop a community-to-clinic model for integrated status-neutral HIV prevention and care services, gender-affirming services including hormone therapy, and primary health care. Navigation will also be used to link TG persons to services as needed for mental health and substance use disorder and other essential support services. This model will increase use of HIV prevention and treatment by TG persons to decrease HIV transmission and improve overall health and wellbeing.
- Comprehensive High-Impact HIV Prevention Programs for YMSM and YTG Persons of Color (CDC-RFA-PS22-2203) - \$2,500,000 – April 1, 2022 – March 31, 2023 – Year 1 of a 5-year grant. Four CBOs in LAC were awarded with funding to implement comprehensive high-impact HIV prevention programs to address health disparities among YMSM of color, YTG persons of color, and their partners with the goal of reducing HIV transmission and HIV-associated morbidity and mortality.
- Comprehensive High-Impact HIV Prevention Programs for CBOs (CDC-RFA-PS21-2102) - \$3,000,000 – July 1, 2022 – June 30, 2023 – Year 1 of a 5-year grant. Six CBOs in LAC were awarded with funding to implement comprehensive high-impact HIV prevention programs to enhance their capacity to increase HIV testing and referrals to Partner Services, link PLWH to HIV medical care and ART, provide or refer prevention and essential support services, including SSPs, for persons with HIV and persons at risk for acquiring HIV, and increase program monitoring and accountability.

Additional Funding Sources: Additional sources of HIV funding include HUD's HOPWA program, Substance Abuse and Mental Health Services Administration (SAMHSA) programs, and funding from the State of California:

HUD:

- HOPWA Program – \$27,323,580 - Fiscal Year 2021 -The City of Los Angeles receives HOPWA funding for Short-term Rent, Mortgage and Utility assistance payments, Tenant-based Rental Assistance, Transitional Housing Units and Permanent Housing Units.

SAMHSA:

- MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS - \$2,999,994 – September 30, 2022 – September 29, 2023 – Year 1 of a 5-year grant. Six CBOs in LAC are funded with this grant to increase engagement in care for racial and ethnic underrepresented individuals with substance use disorders (SUD) and/or co-occurring substance use and mental disorders (COD) who are at risk for or living with HIV/AIDS and receive HIV/AIDS services/treatment.
- MAI: High Risk Populations- \$1,500,000 – September 30, 2022 – September 29, 2023 – Year 1 of a 5-year grant. Three CBOs in LAC are funded with this grant to increase engagement in care for racial and ethnic underrepresented individuals with substance use disorders (SUD) and/or co-occurring substance use and mental disorders (COD) who are at risk for or are living with HIV/AIDS and receive HIV/AIDS services/treatment.
- The Substance Abuse and HIV Prevention Navigator Program- \$3,177,012– September 30, 2022 – September 29, 2023 – Year 1 of a 5-year grant. Fifteen CBOs in LAC are funded with this grant to provide services to those at highest risk for HIV and substance use disorders. The program proposes to use a navigation approach (Community Health Workers, Neighborhood Navigators, and Peer

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Support Specialists) to expedite services for these populations.

- Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults- \$1,582,000– August 30, 2022 – August 29, 2023 – Year 1 of a 5-year grant. Eight CBOs in LAC are funded with this grant to build solid foundations for delivering and sustaining quality and accessible state of the science substance abuse and HIV prevention services.
- MAI: Service Integration- \$485,000– September 30, 2022 – September 29, 2023 – Year 1 of a 5-year grant. One CBO in LAC is funded with this grant to reduce the co-occurring epidemics of HIV, Hepatitis, and mental health challenges through accessible, evidence-based, culturally appropriate treatment that is integrated with HIV primary care and prevention services.
- TCE-HIV: High Risk Populations- \$500,000– September 30, 2022 – September 29, 2023 – Year 1 of a 5-year grant. One CBO in LAC is funded with this grant to focus on high risk populations including racial/ethnic minority populations, such as black young men who have sex with men (YMSM) (ages 18-29), and other high-risk populations such as Latino YMSM and men who have sex with men (MSM) (ages 30 years and older), and gay, bisexual, and transgender individuals who have a SUD or COD who are HIV positive or at risk for HIV/AIDS.
- Harm Reduction Program- \$1,196,880 – September 30, 2022 – September 29, 2023 – Year 1 of a 3-year grant. Two CBOs and DPH-SAPC in LAC are funded with this grant to support community-based overdose prevention programs, syringe services programs, and other harm reduction services.

State of CA:

- DPH State Block Grant - HIV Surveillance CA Surveillance - \$1,972,378.00 - July 1, 2022-June 30, 2023. This grant supports active and passive HIV surveillance, data management, analysis and reporting.
- STD General Funds Allocation - \$547,050- July 1-June 30 - Year 4 of a 5-year grant. These funds support CT/GC Patient Delivered Partner Therapy (PDPT) Demonstration Project, condom distribution, training for PHNs and PHIs and DHSP staff.
- STD Management and Collaboration Project - \$1,952,013 - July 1, 2022-June 30, 2023 - Year 4 of 5-year grant. These funds support condom distribution, rapid syphilis test kits, and screening and treatment of new STD infections among persons at high risk for HIV. These include, but are not limited to; MSM, MSM that report substance use, Cis-gender women of color, Transgender Individuals and Young Men of color.

Strategy for coordinating the provision of substance use prevention and treatment services: DHSP works very closely with the Department of Public Health's Substance Abuse and Prevention Control (SAPC) division to coordinate the provision of substance use disorder prevention and treatment services. Examples of ongoing collaborations with SAPC include cross-training staff in integrating HIV and STD testing in harm reduction and substance use prevention and treatment programs; addressing methamphetamine and HIV in outreach, services, and policy interventions; and working with the City of Los Angeles to expand safe consumption sites.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Services and activities provided by organizations in the jurisdiction; and how services will maximize the quality of health and support services available to people at-risk for or with HIV: Collectively, the CBOs, FQHCs, clinics, faith-based organizations, universities, hospitals, and County departments provide comprehensive HIV prevention and care services including: HIV testing and treatment, STD screening and treatment, HCV screening and treatment, linkage to and reengagement in care, medication adherence, retention in care, PrEP/PEP, social marketing, health education and risk reduction, case management, partner services, medical care coordination, syringe services, sexual and reproductive health, substance use disorder treatment, harm reduction, mental health, housing, transportation, legal services, and more.

The Commission on HIV and DHSP are responsible for planning the continuum of HIV prevention and care services in Los Angeles County. As part of this responsibility, they conduct various needs assessment activities to understand the extent of need for services, as well as barriers to accessing those services. They also gather as much financial data that is available regarding HIV-related resources to identify gaps in current resources and are responsible for prioritizing and allocating Ryan White Part A and CDC funding to address service gaps, of which DHSP is the grantee. Through these oversight and coordination processes, DHSP and the Commission on HIV work in tandem to maximize the quality of health and support services available to people at-risk for or with HIV.

- a. **Strengths and Gaps:** The strength and resilience of the Los Angeles County HIV service system has been demonstrated over the past few years as we continue to weather complex public health and social challenges. These challenges include competing public health crises that tax our systems (e.g. COVID-19, Mpox, overdose, etc.); HIV and STD disparities across multiple domains; waning workforce capacity to meet the needs of the HIV, STD, behavioral health syndemic; and persistent social struggles, including the housing crisis and racial and reproductive injustice. In spite of these challenges, we have maintained high-quality HIV and STD continuity of care, we have tested and adopted new models of service delivery (e.g. HIV self-test kits, telehealth, etc.), and we have expanded the number and diversity of HIV service partners. We have also witnessed technological and administrative advances in the field, including the arrival of long-acting injectables, and the expansion of revenue streams (e.g. Medi-Cal and EHD funding).
- b. **Approaches and Partnerships:** Most of the data gathered to complete the HIV prevention, care and treatment inventory is publicly available online through various websites (e.g., CDC, HRSA, SAMHSA, etc.). The State of California Medi-Cal data for HIV positive individuals was also obtained online. Additional follow-up with individual grantees was conducted to obtain information regarding funding amount, contract period, services delivered, and/or impact along the HIV continuum to complete missing data. Additional information was obtained by talking to a number of key partners to understand the nature of some of their projects as well as to learn how they contribute currently to the continuum of services in Los Angeles County. These partners included the Cities of Los Angeles, West Hollywood and Long Beach, and the Pacific AIDS Education and Training Center, Los Angeles Region. The Division of HIV and STD Programs (DHSP) provided more detailed data on their funding for contracted services.

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Table 2: HIV Resources Inventory

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
HRSA	Ryan White Part A	DPH - DHSP	\$42,142,230.00	Home Health Care, Medical Case Management, including Treatment Adherence Services, Mental Health Services, Oral Health Care, Outpatient/Ambulatory Health Services, Food Bank/Home Delivered Meals, Housing, Linguistic Services, Medical Transportation, Non-Medical Case Management Services, Early Intervention Services, Substance Abuse Residential, Emergency Financial Assistance, Other Professional Services Outreach	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part B	DPH - DHSP	\$5,446,809.00	Housing, Substance Abuse Services (residential)			✓	✓	✓		✓		
HRSA	Ryan White Part C	AIDS Healthcare Foundation	\$299,983.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ryan White Part C	AltaMed Health Services Corporation	\$918,952.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Bartz-Altadonna Community Health Center	\$280,589.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Charles R. Drew University of Medicine and Science	\$403,977.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Dignity Health - St. Mary Medical Center	\$881,556.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	JWCH Institute, Inc.	\$262,990.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Northeast Valley Health Corporation	\$447,805.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	T.H.E. Clinic, Inc.	\$307,859.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Tarzana Treatment Centers, Inc.	\$356,514.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	University of Southern California, School of Medicine	\$325,259.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Venice Family Clinic	\$319,569.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Watts Healthcare Corporation	\$275,727.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part C	Los Angeles LGBT Center	\$779,075.00	Outpatient/Ambulatory Health Services, Testing	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part D	AltaMed Health Services Corporation	\$139,246.00	Outpatient/Ambulatory Health Services	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part D	University of California, Los Angeles	\$732,979.00	Outpatient/Ambulatory Health Services	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part D	University of Southern California	\$905,433.00	Outpatient/Ambulatory Health Services	✓	✓	✓	✓	✓	✓	✓		
HRSA	Ryan White Part F	University of California, Los Angeles	\$1,245,924.00	Oral Health Care			✓		✓		✓		
HRSA	Ryan White Part F	University of Southern California	\$728,752.00	Oral Health Care			✓		✓		✓		
HRSA	Ryan White Part F	Western University of Health Sciences	\$480.00	Oral Health Care			✓		✓		✓		
HRSA	Ryan White Part F AETC	University of California, Los Angeles	\$788,056.00	Capacity building/technical assistance		✓	✓	✓	✓		✓	✓	

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
HRSA	Ryan White Program Part F, SPNS	AltaMed Health Services Corporation	\$205,000.00	Capacity building/technical assistance			✓	✓	✓		✓		
HRSA	Ryan White Program Part F, SPNS	St John's Well Child and Family Center	\$205,000.00	Capacity building/technical assistance			✓	✓	✓		✓		
HRSA	Ryan White Minority AIDS Initiative	DPH-DHSP	\$3,780,205.00	Outreach, Housing, Non-Medical Case Management Services		✓	✓	✓	✓		✓		✓
HRSA	Ending the HIV Epidemic	DPH-DHSP	\$6,168,850.00	Medical Case Management, including Treatment Adherence Services, Surveillance, Data system infrastructure, EBIs for diagnosis and LTC, community engagement	✓	✓	✓	✓	✓	✓	✓		✓
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	All-Inclusive Community Health Center	\$342,098.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Center for Family Health & Education, Inc.	\$345,137.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Central Neighborhood Health Foundation	\$348,808.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Eisner Pediatric & Family Medical Center	\$365,537.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Harbor Community Clinic	\$341,063.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Health Access For All, Inc.	\$344,157.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Los Angeles Christian Health Centers	\$347,216.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Mission City Community Network, Inc.	\$342,198.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Pomona Community Health Center DBA Parktree CHC	\$345,963.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	San Fernando Community Hospital	\$340,405.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	South Central Family Health Center	\$353,475.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Southern California Medical Center, Inc.	\$346,672.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	The Los Angeles Free Clinic	\$348,195.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Universal Community Health Center	\$342,870.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Via Care Community Health Center	\$346,411.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Westside Family Health Center	\$345,390.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Yehowa Medical Services	\$336,781.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Community Medical Wellness Centers USA	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	The Children's Clinic Serving Children and Their Families	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Asian Pacific Healthcare Venture, Inc.	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	University Muslim Medical Association, Inc.	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Benevolence Industries, Inc.	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Chinatown Service Center	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
HRSA	Ending the HIV Epidemic-FQHC Primary Care HIV Prevention	Community Health Alliance of Pasadena	\$325,000.00	PrEP delivery, Testing	✓	✓	✓	✓	✓	✓	✓	✓	
CDC	Integrated HIV Surveillance and Prevention Programs	DPH - DHSP	\$17,950,095.00	PrEP delivery, Surveillance	✓	✓	✓	✓	✓	✓	✓	✓	✓
CDC	Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States	DPH - DHSP	\$3,360,658.00		✓	✓	✓	✓	✓	✓	✓	✓	✓
CDC	HIV Treatment Demonstration Project	DPH-DHSP	\$597,083.00	Capacity building/technical assistance, Surveillance			✓	✓	✓		✓		
CDC	National HIV Behavioral Survey and TG Supplement	DPH-DHSP	\$716,168.00	Surveillance	✓	✓	✓	✓	✓	✓	✓	✓	✓
CDC	Medical Monitoring Project	DPH-DHSP	\$728,648.00	Surveillance			✓	✓	✓		✓	✓	✓
CDC	Strengthening STD Prevention and Control for Health Departments	DPH-DHSP	\$3,356,049.00	STD screening, diagnosis and treatment, STD surveillance, Disease Investigation and Intervention									

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
CDC	STD Prevention and Control for Health Departments- DIS Workforce Development Infrastructure	DPH-DHSP	\$6,598,516.00	Disease Investigation and Intervention, STD Outbreak Response									
CDC	Gonococcal Isolates Surveillance Project	DHP-DHSP	\$15,000.00	STD surveillance									
CDC	Comprehensive High-Impact HIV Prevention Programs for YMSM and YTG Persons of Color	AltaMed Health Services Corporation	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for YMSM and YTG Persons of Color	APLA Health & Wellness	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for YMSM and YTG Persons of Color	Los Angeles LGBT Center	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for YMSM and YTG Persons of Color	Special Services for Groups	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	Via Care Community Health Center	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	Los Angeles LGBT Center	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	AltaMed Health Services Corporation	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	Bienestar Human Services	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	JWCH Institute, Inc.	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Comprehensive High-Impact HIV Prevention Programs for CBOs	APLA Health & Wellness	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
CDC	Transgender Status-Neutral Community-to-Clinic Models to End the HIV Epidemic	St. John's Well Child and Family Center	\$500,000.00	PrEP delivery, Prevention for persons living with diagnosed HIV infection, Testing, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	Bienestar Human Services	\$499,999.00	SUD Treatment	✓					✓		✓	

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	Special Services for Groups	\$499,995.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	Via Care Community Health Center	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	Children's Hospital Los Angeles	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	JWCH	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: SUD Treatment for Racial/Ethnic Minority Populations at High Risk for HIV/AIDS	St. John's Well Child and Family Center	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: High Risk Populations	St. John's Well Child and Family Center	\$500,000.00	SUD Treatment	✓				✓			✓	
SAMHSA	MAI: High Risk Populations	Tarzana Treatment Centers	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	MAI: High Risk Populations	Volunteers of America, LA	\$500,000.00	SUD Treatment	✓					✓		✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	AIDS Healthcare Corporation	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Center for Health Justice	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Los Angeles Gay & Lesbian Center	\$182,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Los Angeles Centers for Alcohol and Drug Abuse	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Public Health Foundation Enterprises	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Reach, LA	\$195,304.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Via Care Community Health Center	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Volunteers of America, Los Angeles	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Central City	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Children's Hospital Los Angeles	\$250,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Sunrise Community Counseling Center	\$250,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Special Services for Groups	\$250,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	St. John's Well Child and Family Center	\$250,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Azusa Pacific University	\$199,708.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	The Substance Abuse and HIV Prevention Navigator Program	Tarzana Treatment Centers	\$200,000.00	Prevention for persons living with diagnosed HIV infection, Navigation	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	AIDS Healthcare Corporation	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Center for Health Justice, Inc.	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Central City Neighborhood Partners	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Los Angeles Gay & Lesbian Center	\$182,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Los Angeles Centers for Alcohol and Drug Abuse	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Public Health Foundation Enterprises	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	

3. CONTRIBUTING DATA SETS & ASSESSMENTS: RESOURCES INVENTORY

Funder	Funding Source	Organization Receiving the Funding	Annual Award Amount	Services Delivered	HIV Care Continuum Steps Impacted					EHE Strategies			
					HIV Diagnosis	Linkage to Care	Engagement or Retention in Care	Prescription of ART	Viral Suppression	Diagnose	Treat	Prevent	Respond
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Via Care Community Health Center	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults	Volunteers of America, Los Angeles	\$200,000.00	Capacity building/technical assistance	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	MAI: Service Integration	Tarzana Treatment Centers	\$485,000.00	Mental Health Services, SUD Treatment	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	TCE-HIV: High Risk Populations	Behavioral Health Services, Inc.	\$500,000.00	Mental Health Services, SUD Treatment	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Harm Reduction Program	LA County Public Health Department - SAPC	\$398,960.00	Syringe services programs	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Harm Reduction Program	St. John's Well Child and Family Center	\$398,960.00	Syringe services programs	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	Harm Reduction Program	Tarzana Treatment Centers, Inc.	\$398,960.00	Syringe services programs	✓	✓	✓		✓	✓	✓	✓	
SAMHSA	SAMHSA Continuations	Special Services for Groups	\$257,354.00	Mental Health Services, SUD Treatment	✓	✓	✓		✓	✓	✓	✓	
HUD	HOPWA	City of Los Angeles	\$27,323,580.00	Mental Health Services, Housing			✓		✓		✓		
State of CA	State Block Grant - HIV Surveillance	DHP-DHSP	\$1,972,378.00	Surveillance		✓					✓		
State of CA	STD General Funds Allocation	DHP-DHSP	\$547,050.00	Condom distribution, CT/GC Patient Delivered Partner Therapy, Capacity building									
State of CA	STD Management and Collaboration Project	DPH-DHSP	\$1,952,013.00	Condom distribution, Rapid Syphilis test kits									
Los Angeles County DPH Substance Abuse and Prevention Control (SAPC)	SAPC Non-Drug Medi-Cal	DPH-SAPC	\$3,249,000.00	Substance Abuse Outpatient Care, Health Education/Risk Reduction, Substance Abuse Services - Residential	✓	✓	✓	✓	✓	✓	✓	✓	
Los Angeles County Net County Costs (NCC)	Net County Cost	DPH-DHSP	\$18,467,000.00	Medical Case Management, including Treatment Adherence Services, Health Education/Risk Reduction, Referral for Health Care and Support Services, PrEP delivery	✓	✓	✓	✓	✓	✓	✓	✓	✓

3. CONTRIBUTING DATA SETS & ASSESSMENTS: NEEDS ASSESSMENT

NEEDS ASSESSMENT

Needs Assessment Activities and Data/Information Used to Inform Goals and Objectives: To assess the needs of PLWH and persons at risk for HIV in LAC, multiple assessment activities and methods were utilized. In addition to the review and analysis of secondary data listed below, primary qualitative data were collected for planning purposes via facilitated listening sessions for six priority population groups; an online survey to assess the capacity of the HIV workforce and service system from both provider and community member perspectives (HIV Workforce Capacity and Service System Survey); and facilitated stakeholder meetings (see c. Approach, below). The numerous secondary data sources and reports that were reviewed include, but are not limited to:

- (1) Local and national HIV surveillance data, including various reports presenting data from LAC's National HIV Behavioral Survey (NHBS) and Medical Monitoring Project (MMP);
- (2) HIV Care Continuum measures for LAC by subpopulation;
- (3) Sexually Transmitted Disease (STD) surveillance data;
- (4) LAC PrEP data;
- (5) 2021 HIV testing data for DHSP publicly funded testing;
- (6) 2020 Unmet Need report;
- (7) Ryan White Program Year 31 Care Utilization Data;
- (8) Black/African American Taskforce PrEP Focus Groups Report³⁰;
- (9) DHSP-Funded Biomedical Prevention Services, Year 6 Report;
- (10) Project Fierce Community Survey on STD Prevention Needs of Young Women of Color;
- (11) Assessment of Unmet Mental Health Needs of PLWH; and
- (12) CHIPTS' Study on Optimizing PrEP Delivery to Immigrant Latino MSM

Informing a Status-Neutral Approach to Develop Goals and Objectives: LAC is committed to a status neutral approach to addressing the needs of PLWH and of those at high-risk for HIV. This means that although the *types* of services that both groups need may vary, the *commitment* to making sure that people are able to access and remain engaged in those services is equal and unwavering, regardless of their HIV status. *Status neutral* also means that LAC is committed to providing high-quality services, regardless of a person's HIV status. Summarized below are the needs and barriers related to the services necessary to access HIV testing, to engage in prevention activities (for those who test negative), and to link to and remain engaged in HIV care and prevention (for those who test positive). Data analysis also rendered needs and barriers that were applicable *across pillars*. These include the need to address mental health challenges, substance use disorders and social determinants of health; and build the capacity of the HIV workforce.

Services People Need to Access HIV Testing: The need for HIV testing is clear as it is the first step to accessing necessary and appropriate prevention and/or treatment services, ultimately resulting in reduced transmission and improved health outcomes. Analysis of LAC NHBS data tells us that 15% of transgender respondents had *not* tested for HIV in the past 12 months; nor had 16% of MSM; 45% of PWID and 70% of high-risk heterosexuals. Testing rates varied across race/ethnicities with lower testing rates found among Black transgender respondents (80%); Latino and Black MSM (83%); White PWID (47%); and Latino heterosexuals (27%). HIV status awareness also differed across population groups with 83% of MSM, 80% of trans persons, 63% of PWID and 0% of heterosexuals³¹ aware of their HIV-positive status (Table 3).

³⁰ Prepared by Equity & Impact Solutions

³¹ However, only 1 person in the HET category was HIV-positive

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Table 3: HIV Prevalence, Status Awareness, Testing & PrEP Use by NHBS Participants, LAC, 2017-19

	MSM	PWID	HET	TG
Survey Year	2017	2018	2019	2019
Sample Size	525	511	509	497
HIV Prevalence	21%	1.6%	0.2%	33%
Aware of Status Among HIV+	83%	63%	0%	80%
Tested Ever	99%	90%	73%	98%
Tested Past 12 Months	84%	55%	30%	85%
Current PrEP Use	29%	1%	0%	26%

In LAC, people living with undiagnosed HIV need low-barrier access to a variety of testing modalities in both clinical and non-clinical settings.

Clinical HIV Testing: HIV screening within clinical settings is crucial to increasing the number of PLWH who are aware of their status. In 2006, the Centers for Disease Control and Prevention (CDC) issued recommendations that screening for HIV should be performed routinely for all patients aged 13 to 64 years at least once in their lifetime, and at least once a year for those at higher risk. While typically the HIV positivity rates of routine screening programs in clinical settings is much lower than targeted HIV testing modalities that focus services on individuals with elevated HIV rates, they remain an important way to destigmatize HIV testing and infection. In LAC, clinical HIV testing takes place in primary care clinics, emergency departments, and sexual and reproductive health clinics.

Non-Clinical HIV Testing: Since the beginning of the epidemic, community members have advocated for non-clinical testing venues as settings in which individuals can seek HIV testing, sexual health education, and other services in a culturally affirming and confidential space. Settings include storefronts; mobile testing units; commercial sex venues, syringe service programs; and jails. Non-clinical HIV testing also increasingly relies on the distribution of HIV self-test kits. Targeted HIV testing identifies priority populations based on risk of acquiring HIV and often taps into social and sexual networks to do so. Through this model, community-based organizations (CBOs) leverage their relationships with community members and can utilize a wide range of outreach modalities to reach priority populations. County of Los Angeles-contracted HIV testing providers are selected for their expertise and strong track record of successfully reaching priority populations. All contracted providers are expected to provide 1) targeted HIV testing services, 2) hands-on assistance with linkage to HIV care for people testing HIV positive, and 3) education and referrals to PrEP and other prevention services for those who test negative but are at elevated risk of acquiring HIV. In 2021, DHSP-funded HIV testing had a 1.3% overall new HIV positive rate among the total 51,713 tests conducted in that year. However, this rate ranged by type of testing. Testing in healthcare settings rendered a 1.0% overall seropositive rate, while non-clinical testing rendered a 1.9% seropositive rate. Within the healthcare test setting, hospitals and primary care clinics had the highest positivity rates with 2.5% and 1.8%, respectively. Within non-clinical testing settings, HIV testing sites and community settings had the highest new positive rates, 2.4% and 1.3%, respectively (Table 4).

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Table 4: DHSP Contracted Agencies HIV Testing³² Volume, Positivity, Linkage to Care by Test Setting, 2021

Test Setting	HIV Test Events		Positive HIV Tests – All Diagnoses			
	No. Tests	%	No. Positive Tests	%	Test Positivity %	LTC w/in 30 days %
Healthcare Test Setting	31,884	62%	334	48%	1.0%	65%
Community STD Clinic	18,028	35%	153	22%	0.8%	69%
Community Health Center	6,843	13%	77	11%	1.1%	56%
Substance Abuse Treatment Facility	3,316	6%	35	5%	1.1%	43%
Primary Care Clinic	3,236	6%	58	8%	1.8%	78%
Hospital	444	1%	11	2%	2.5%	64%
Other	17	<1%	0	0%	0.0%	---
Non-healthcare Test Setting	17,188	33%	331	48%	1.9%	29%
HIV Testing Site	9,327	18%	228	33%	2.4%	27%
Community Setting	7,755	15%	102	15%	1.3%	33%
Correctional Facility	106	<1%	<5	0%	0.9%	0%-
Mobile Test Setting	2,641	5%	29	4%	1.1%	17%
Overall	51,713	100%	694	100%	1.3%	46%

HIV Self-Test Kits: Self-test kits provide an important low barrier option for individuals to confirm their HIV status. At the beginning of the COVID-19 pandemic, DHSP increased its investment in self-testing options by participating in a national self-test kit program, Take Me Home, and purchasing self-test kits for distribution through local providers. TakeMeHome provides an online platform by which health departments can provide free HIV self-tests. Between August 2020 to August 2022, 2,938 HIV self-test kits were requested via the TakeMeHome website. Among those that requested a test, over one-third reported to have never been tested for HIV; of those individuals, over 80% identified as men, and approximately 49% were under 30 years old. To date, over 15,000 self-test kits have been distributed.

Late Diagnoses: The number and percentage of late diagnoses among people newly diagnosed with HIV is indicative of a gap with respect to HIV testing. Late diagnosed HIV is based on the first CD4 test result (<200 cells/mL or a CD4 percentage of total lymphocytes of <14) or documentation of an AIDS-defining condition ≤ 3 months after a diagnosis of HIV infection. Among the 1,404 new diagnoses in LAC between January 1, 2020, and December 31, 2020, 286 (20.4%) were late diagnoses (Table).

- Among each of the three geographic epicenters of HIV: 15% of PLWDH in Hollywood-Wilshire Health District, in Central Health District, and in Long Beach Health District had a late diagnosis.
- The majority of late diagnoses were male (84%). Within each gender category 20% of males, 30% of females, and 7% of trans persons had a late diagnosis.
- Latinx were the largest racial/ethnic group among persons who were diagnosed late (62%); the highest percentages within each racial/ethnic group were among Latinx (24.1%) and those who identified as multiracial (23.8%).
- The highest number of late diagnoses were in people ages 25-34 years old, but the proportion of persons diagnosed late within each age group increased with age with 30% of persons 45-54, 31% of persons 55-64 years, and 44% of persons aged 65 or older being diagnosed late.

³² Data from DHSP Contracted Agencies HIV Testing Programs as of November 10, 2022

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Table 5: Numbers and Percentages of Late Diagnoses, Unmet Need and Unsuppressed Viral Load by Key Characteristics, LA County, 2020

	# PLWDH*	# New Diagnoses	# Late Diagnoses	# Unmet Need	# In Care, Not VS	Within Categories			Across Categories		
						% Late Diagnose	% Unmet Need	% In Care, Not VS	% Late Diagnose	% Unmet Need	% In Care, Not VS
LA County	44,090	1401	286	7279	4563	20.4%	16.5%	12.4%	100%	100%	100%
Priority Health Districts											
Central	5,097	128	19	973	695	14.8%	19.1%	16.9%	6.6%	13.4%	152%
Hollywood-Wilshire	7,925	171	26	1,312	891	15.2%	16.6%	13.5%	9.1%	18%	19.4
Long Beach	3,565	91	14	521	288	15.4%	14.6%	9.5%	4.9%	7.2%	6.3%
Gender Identity											
Male	38,464	1,201	239	6,319	3,937	19.9%	16.4%	12.2%	83.6%	86.8%	86.3%
Female	4,752	143	43	812	494	29.7%	17.1%	12.5%	15.0%	11.2%	10.8%
TG	871	57	4	146	132	6.8%	16.8%	18.2%	1.4%	2.0%	2.9%
Race/Ethnicity											
AI/AN	40	5	0	7	3	0.0%	17.5%	9.1%	0.0%	0.1%	0.1%
Asian	1,637	54	7	281	105	13.0%	17.2%	7.7%	2.4%	3.9%	2.3%
Black/AA	8,647	297	47	1,853	1,099	15.8%	21.4%	16.2%	16.4%	25.5%	24.1%
Latinx	19,315	735	177	2,673	1,867	24.1%	13.8%	11.2%	61.9%	36.7%	40.9%
NH/PI	43	1	0	13	4	0.0%	30.2%	13.3%	0.0%	0.2%	0.1%
White	11,772	261	44	1,851	1,179	16.9%	15.7%	11.9%	15.4%	25.4%	25.8%
Multi-Racial	2,182	42	10	340	266	23.8%	15.6%	14.4%	3.5%	4.7%	5.8%
Age											
13-24	1,063	226	16	220	155	7.1%	20.7%	18.4%	5.6%	3.0%	3.4%
25-34	7,643	571	97	1,735	954	16.9%	22.7%	16.1%	33.9%	23.8%	20.9%
35-44	9,279	298	77	1,834	1,072	25.8%	19.8%	14.4%	26.9%	25.2%	23.5%
45-54	10,875	199	60	1,622	1,062	30.2%	14.9%	11.5%	21.0%	22.3%	23.3%
55-64	10,889	84	26	1,363	996	31.0%	12.5%	10.5%	9.1%	18.7%	21.8%
65+	4,341	23	10	505	324	43.5%	11.6%	8.4%	3.5%	6.9%	7.1%

* Number of PLWDH reflects those who have had an HIV diagnosis, or any lab data reported over the last 5 years

To reach the estimated 6,800 people living with undiagnosed HIV, it will require at least 850,000 HIV tests at a 0.8% seropositive rate. This estimate, however, assumes that testing will reach undiagnosed individuals and that all have equitable access to HIV testing. Unfortunately, there are many barriers that prevent this equitable access, as described below in the *Barriers* section.

Services People At-Risk for HIV Need to Stay HIV Negative: For individuals who test negative for HIV, the testing encounter provides an opportunity to reenforce prevention behaviors and facilitate access to prevention tools and interventions including pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and syringe services programs (SSPs).

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PrEP/PEP: DHSP estimates that 76,000 people in LAC could benefit from PrEP, 72% of whom (54,500) are Black and/or Latinx. Using several data sources, DHSP estimates that, overall, 39% of people in priority populations with an indication for PrEP are currently prescribed PrEP.

An assessment of PrEP knowledge, attitudes and behaviors among Black MSM, Latino MSM, and transgender persons was conducted between 2016-2020 via an app-based survey for the CDC PrIDE initiative.³³ Participants were asked about their awareness of PrEP, willingness to use PrEP, and PrEP use in the past 12 months. Between 2016-2020, awareness of PrEP increased from 86% to 92%, willingness to take PrEP increased from 73% to 93% and PrEP use increased from 20% to 31% collectively. PrEP awareness significantly increased among Latino MSM and trans persons through 2020 but remained relatively unchanged among Black MSM.

PrEP/PEP Centers of Excellence: In 2016, DHSP funded nine PrEP/PEP Centers of Excellence (COE) across LAC with the primary goal of increasing access to and use of PrEP among Black/ African American and Latino MSM, transgender persons and cisgender women. Today, there are 12 COEs funded by DHSP that offer multiple services, including insurance application assistance, medication adherence support, primary medical care, and referrals to other services (Figure 30). Through March 2022, 9,810 unique clients had received biomedical services through one or more COEs with 73% receiving PrEP services, 21% receiving PEP services, and 6% receiving both PrEP and PEP (Figure 31).

Analysis of utilization data gives us insights into the PrEP/PEP needs of at-risk individuals in LAC. According to the DHSP-Funded Biomedical Prevention Services Year 6 Report, between July 1, 2020-June 30, 2021, 3,235 clients were prescribed PrEP at a COE, including 2,250 new enrollees. The majority of PrEP clients were Latino (53%), MSM (88%) (Table 6). Fifty-three percent of enrolled clients were retained in PrEP services at a COE clinic for at least six months. Retention rates were impacted by both the type and duration of services accessed. For example, those who were retained, on average, received 25 minutes of education activities, 34 minutes of adherence activities and 57 minutes of retention activities. Comparatively, those who were lost to follow-up only received about half as many service minutes with an average of 12, 13 and 28 minutes, respectively.

Figure 30: PrEP/PEP Centers of Excellence

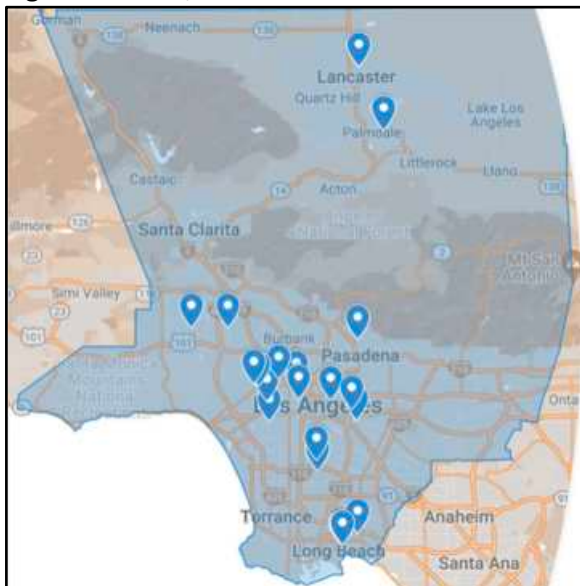
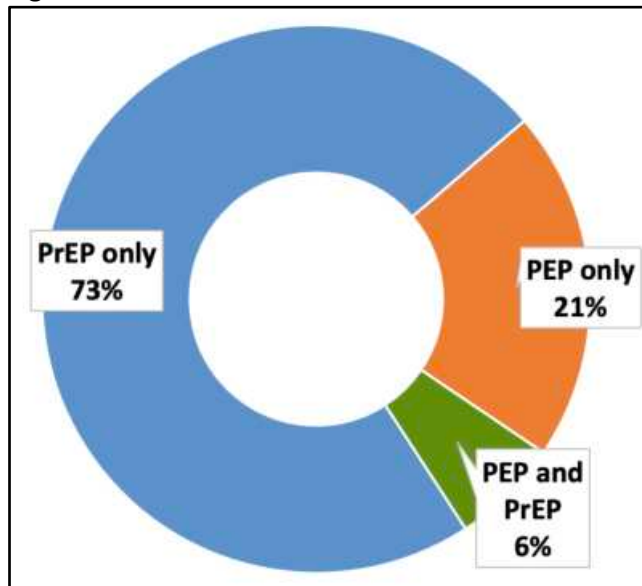


Figure 31: Biomedical Services Provided at COEs



³³ <https://www.cdc.gov/hiv/research/demonstration/projectpride.html>

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Table 6: Centers of Excellence: Clients Prescribed PrEP between 7/1/20-6/30/22 (N=3,235)

HIV RISK GROUP				AGE GROUP						RACE/ETHNICITY				
MSM	Trans	PWID	HET	13-19	20-24	25-29	30-34	35-39	40+	Latino	B/AA	White	Asian	Other*
88%	12%	1%	1%	<1%	7%	21%	27%	19%	25%	53%	18%	15%	12%	<2%

*“Other” includes American Indian/Alaskan Native (<1%) & Native Hawaiian/Pacific Islander (1%)

Among the PrEP priority populations, retention rates and adherence rates were worse for Latino MSM, trans persons and cisgender women than they were for Black MSM.

- Among Black MSM, 538 were screened for biomedical HIV prevention, including 465 screened for PrEP only, 32 screened for PEP only, and 41 screened for PEP and PrEP. The top three indicators for PrEP were multiple partners, condomless receptive sex and anogenital STD. Forty-three percent of Black MSM were retained in PrEP services at a COE for at least 6 months.
- Among Latino MSM, 1,560 were screened for biomedical HIV prevention, including 1,377 screened for PrEP only, 69 screened for PEP only, and 69 screened for PEP and PrEP. The top three indicators for PrEP were multiple partners, condomless receptive sex and anogenital STD. Forty percent of Latino MSM were retained in PrEP services at a COE for at least six months.
- Among trans persons, 462 were screened for biomedical HIV prevention, including 374 screened for PrEP only, 63 screened for PEP only, and 25 screened for PEP and PrEP. The top three indicators for PrEP were multiple partners, condomless receptive sex and previous PEP and ongoing behavioral risk. Thirty-six percent of trans persons were retained in PrEP services at a COE for at least 6 months.
- Of the 377 people between the ages of 14-24 that were screened for PrEP, the top three indicators were multiple partners; condomless receptive sex; and anogenital STD/syphilis.

Harm Reduction and Syringe Services Programs

Harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. It is also a movement for social justice built on a belief in, and respect for, the rights of people who use drugs.³⁴ Syringe Services Programs (SSPs) are excellent vehicles for harm reduction. Despite consistent evidence that SSPs, and needle-exchange in particular, work to reduce infections and save lives,³⁵ there remains a great deal of misinformation and stigma surrounding their existence. Contrary to some beliefs, SSPs do *not* increase the number of used syringes in communities, the use of drugs, or drug-related crimes. In addition to providing access to and disposal of syringes and injection equipment, SSPs are comprehensive community-based prevention programs that often provide vaccination, testing, education, case management and linkage to care, substance use treatment and PrEP. SSPs also serve as an important overdose prevention mechanism by providing low-barrier access to Medically Assisted Treatment (MAT) for opioid use disorder, and overdose prevention and response trainings; and distributing Naloxone kits and fentanyl information and test strips. Although there was a ban on using federal funds for syringe exchange until 2016, the City of Los Angeles has provided funding for syringe services since 1994 and the County of Los Angeles since 2006. Because SSPs provide a comprehensive set of services, as described above, the County now refers to the SSPs they fund as *Engagement and Overdose Prevention (EOP) Hubs* to more fully reflect the scope of the work they do. DPH-SAPC currently funds seven EOPs across the County that distribute close to a million sterile syringes and thousands of Naloxone kits every year. EOP services are provided through storefronts, street-based mobile sites and outreach efforts. In LAC, EOPs funded by the County are required to provide:

³⁴ <https://harmreduction.org/about-us/principles-of-harm-reduction/>

³⁵ Fernandes RM, Cary M, Duarte G, et al. Effectiveness of needle and syringe programmes in people who inject drugs – An overview of systematic reviews. BMC Public Health. 2017;17(1):309. doi:10.1186/s12889-017-4210-2.

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- Needs-based/low threshold access to syringes
- Sharps containers and education on disposal
- Naloxone
- Safe injection supplies (tourniquets, alcohol swabs, water, band aids, cotton balls, cookers)
- Safe smoking supplies (pipes, lip balm, straight shooters)
- Wound care supplies
- Direct or referred testing for: HIV and HCV
- Referrals for treatment for HIV/HCV, substance use treatment, specialized mental health, or medical care.

In 2021, among the six³⁶ EOPs that were operating in LAC:

- 924,164 clean syringes were distributed (a 32% increase from 2017)
- All provided injection supplies and safer sex supplies;
- 5 out of 6 provided overdose treatment (e.g. Naloxone), and HIV risk reduction counseling; a
- 4 out of 6 provided HIV testing

The majority of clients served were 30 years of age or older (90%) and cisgender males (76%). Thirty-nine percent were Latinx, 36% were White, 20% were Black/African American, and 5% were classified as “Other” race. In addition to the EOPs there are three SSPs in LAC that are certified by DPH-SAPC but not currently funded by them bringing the total amount of EOPs/SSPs operating in LAC to ten. Although the majority of EOPs and SSPs provide HIV testing, only two currently provide HIV, STD and HCV testing.

Services People Need to Rapidly Link to HIV Care: Linkage to care is an essential step to ensuring viral suppression. In 2020, 54% of people newly diagnosed with HIV were linked to care within seven days and 76% were linked within one month of diagnosis. Populations with lowest linkage to care rates were cisgender women (67%), Black/African Americans (71%) and those classified as “multi-racial” (69%), persons 13-19 years old (63%) and persons whose transmission risk included heterosexual contact (66%) or MSM/IDU (67%). Populations with the highest linkage to care rates were transgender persons (81%), those aged 30-39 and 50-59 (78%), Asians (90%), AI/ANs (86%) and those whose transmission risk was MSM (78%).

HIV testing providers assume primary responsibility for linking a newly diagnosed person to HIV care by setting up appointments and following up with the client until the first appointment is completed. As depicted in Table 4, the percentages of those newly diagnosed with HIV who were linked to care within 30 days varied by test setting. The highest percentages were found among primary care clinics (78%), followed by community STD clinics (69%) and hospitals (64%). Conversely, the test settings that had the lowest linkage to care percentages were mobile test settings (17%), HIV testing sites (27%) and community settings (33%).

In addition to HIV testing services, linkage to care is achieved through other targeted programs. One such program is DHSP’s Linkage and Re-engagement Program (LRP) designed to identify HIV-positive persons out of care, and their partners for linkage/re-engagement to HIV care. LRP receives referrals from a broad base of countywide partners and also uses data-to-care reports to identify potential LRP clients. LRP often works to locate persons hardest to find and acts as a service of last resort after all other outreach efforts have failed. Because LRP clients are not on ART it is essential that they are located and connected to care in order to improve their health outcomes and prevent transmission of HIV. With LRP clients reaching undetectable levels, partners are less likely to contract and further

³⁶ One more EOP was recently funded in 2022 to bring the total to seven.

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transmit HIV. Furthermore, partners are then able to receive support to get tested and take actions to address their status, whether negative or positive. LRP also supports Partner Services follow-up by taking on cases of clients who have been difficult to locate.

Services PLWH Need to Stay in HIV Care and Treatment and Achieve Viral Suppression: Once initially linked to care, it is imperative that HIV-positive persons remain engaged in care to improve their health outcomes and prevent transmission. Concerted efforts are also needed to re-engage into care PLWH who are diagnosed but not in care. The use of surveillance data to identify those who are lost to care is critical. Since the inception of the Ryan White Program, HRSA has funded a comprehensive set of medical and related services targeting low-income PLWH. Although the local utilization rates of Ryan White services don't tell us the complete picture of the needs of all PLWH, they serve as a starting point for examining needs related to engagement in care. Ryan White Program clients totaled 21,877 in Year 31 (3/1/21-2/28/22), representing 41% of all PLWDH in LA County. The services most utilized by RWP clients were Medical Outpatient (70%), Medical Care Coordination (38%), and Non-Medical Case Management (24%) (Table 7).

Table 7: Ryan White Program Services Utilization, 3/1/21-2/28/22

Service Category	Unique Clients	Percentage of RW Clients	Units Per Client
Total Unduplicated Clients*	21,877	--	--
Medical Outpatient	15,272	69.8%	3
Supplemental AOM Procedures	10,396	47.5%	25
Medical Outpatient	15,272	69.8%	3
Medical Care Coordination	8,244	37.7%	14
Non-Medical CM	5,181	23.7%	4
Benefits Specialty	4,658	21.3%	4
Transitional CM – Jails	563	2.6%	6
Oral Health Care	4,153	19.0%	11
General Oral Health	3,849	17.6%	7
Specialty Oral Health	3,477	15.9%	5
Nutrition Support	1,988	9.2%	193
Food Bank	1,582	7.2%	97
Delivered Meals	560	2.6%	410
Mental Health Services	756	3.5%	7
Home-Based Case Management	280	1.3%	321
Case Management	279	1.3%	43
Homemaker	184	0.8%	354
Nutrition	54	0.3%	108
Psychotherapy CM	70	0.3%	29
Attendant Care	20	0.1%	237
Durable Medical Equipment	4	0.02%	3
Housing Services	237	1.08%	287
Permanent Supportive Housing	151	0.7%	323
Residential Care Facilities for the Chronically	60	0.3%	238
Transitional Residential Care Facilities	28	0.1%	180
Substance Abuse Services – Residential	90	0.4%	123
Outreach Services (LRP Program)	26	0.1%	11

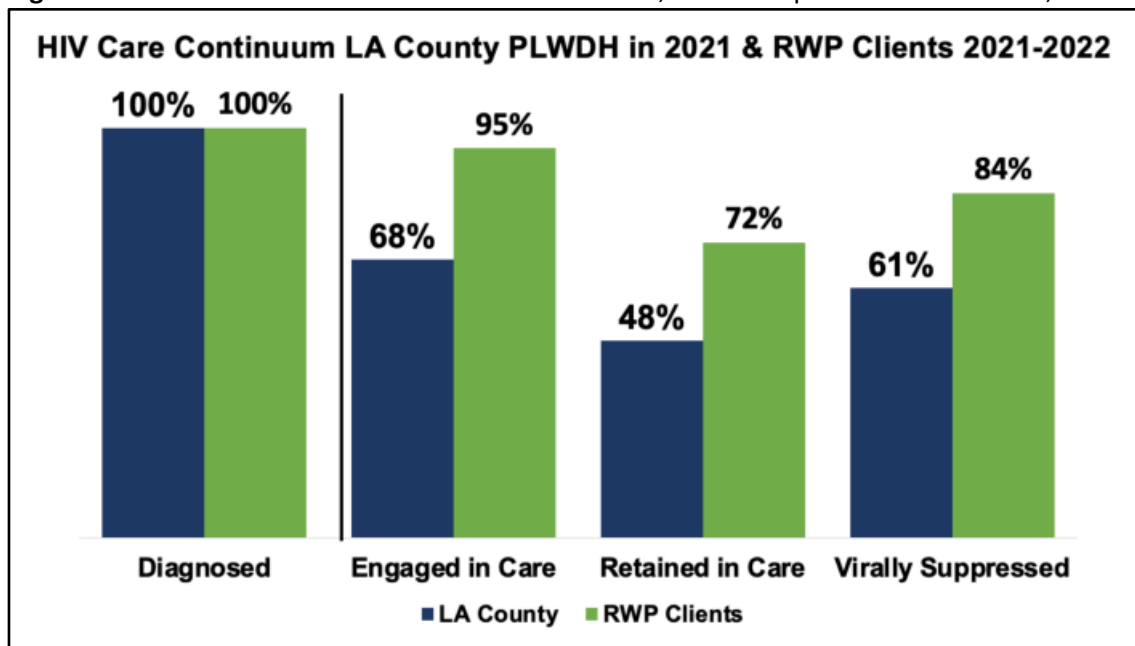
*Receiving Fundable RW Program Services

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Los Angeles County is also funded through HRSA's Minority AIDS Initiative (MAI) and has selected three subpopulations of focus based on local epidemiologic and programmatic data: cisgender men of color aged 30 or older who have sex with men (MSM of color); cisgender men of color aged 18-29 years who have sex with men (YMSM of color); and transgender persons of color (Trans clients). MAI subpopulations totaled 11,721, representing 55% of clients receiving at least one RWP service in Year 31. The top four services that were disproportionately utilized (compared to their population size) by the MAI population were benefits specialty (60%), mental health (58%), non-medical case management (58%), and oral health care (56%).

As depicted in Figure 32, HIV Care Continuum outcomes for RWP patients were better than for the larger population of PLWDH. However, disparities persist among certain subpopulations, again speaking to the need to target services to these populations. Among the RWP clients in Year 31, engagement in care rates were lowest for those who were homeless (90%), recently incarcerated (91%), people aged 18-29 (92%) and African Americans (92%). Retention in care rates were lowest for those between the ages of 18-29 (59%), currently homeless (60%), recently incarcerated (65%) and African American (66%). Viral suppression rates were lowest among currently homeless (67%), recently incarcerated (70%), people who inject drugs (77%) and people aged 18-29 (77%).

Fig. 32: HIV Care Continuum Outcomes: PLWDH in LAC, 2021 Compared to RWP Clients, 2021-22



Unmet Need (Not in Care): Based on the five-year population estimate (2016-2020) of 44,090 PLWDH in LAC, 7,279 (17%) were estimated to have unmet need (not in HIV medical care) as indicated by there being no evidence of a viral load or CD4 reported in 2020 (Table 5).

- Among each of the three epicenters of HIV: 19% of PLWDH in Central, 17% of PLWDH in Hollywood-Wilshire, and 15% of PLWDH in Long Beach had unmet need.
- The majority of persons with unmet need were male (87%). Within each gender category 16% of males, 17% of females, and 17% of trans persons were aware of their HIV status and did not receive recent laboratory testing.
- Within each racial/ethnic group, Native Hawaiian/Pacific Islander Non-Hispanic had the highest percentage of PLWDH with unmet need (30%), followed by Blacks/African Americans (21%), and American Indian and Alaskan Natives (18%).

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- The percentage of unmet need was highest within younger age groups; 23% of PLWDH 25-34 years, 21% of PLWDH 13-24, and 20% of PLWDH age 35-44 years.

In Care, Not Virally Suppressed (VS): Among the 36,811 PLWDH who were in care, 4,563 (12%) were not virally suppressed (viral load ≥ 200 copies/mL on the most recent test reported) between January 1, 2020, and December 31, 2021.

- Among the three epicenters of HIV: 17% of PLWDH in Central, 14% of PLWDH in Hollywood-Wilshire, and 10% of PLWDH in Long Beach were not virally suppressed.
- More than one out of five transgender persons (18%) were in care, but not virally suppressed compared to 12% of cisgender males and 13% of cisgender females.
- Within each racial/ethnic group, Black/African Americans had the highest percentage of PLWDH in care and not virally suppressed (16%), followed by multiracial (not Hispanic) group (14%) and Native Hawaiian/Pacific Islanders (13%).
- The percentage of unsuppressed viral load was highest within younger age groups; 18% of PLWDH 13-24 years, 16% of PLWDH 25-34 years, and 14% of PLWDH age 35-44 years.

Barriers to Services

The HIV Workforce Capacity and Service System Survey³⁷ respondents, both providers and community members, were asked to rank a set of barriers to accessing or remaining engaged in a variety of HIV-related services including HIV testing, PrEP and HIV care, and to add any other significant barriers not listed. Listening session participants were also asked to discuss any barriers related to diagnosing HIV and accessing HIV treatment and prevention services.

Top Five Barriers to Accessing HIV Testing

	Providers	Community
1	Lack of culturally appropriate services	Substance use
2	Substance use	Lack of accurate information about testing
3	Mental health	They don't believe they're at risk
4	They don't believe they're at risk	Mental health
5	Lack of accurate information about testing	Lack of culturally appropriate services

Other related barriers that respondents identified included:

- (Lack of) awareness of free services
- (Lack of) awareness of testing locations and hours
- Fear of finding out they're infected
- Isolation
- Stigma/Internalized homophobia
- PTSD

In addition to the barriers listed above, survey and listening session participants identified barriers relating to lack of urgency about HIV, not having enough testing sites, concern about HIV stigma and lack of health literacy or knowing they're at risk.

³⁷ Workforce Capacity and Service System Survey is described in more detail in the Approach section below.

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“We should learn from COVID – they had testing on every corner. Why can’t we do that with HIV?”

“I already experience stigma for being Black and Gay. I don’t want to add to that by being HIV positive.”

“A lot of people still don’t know they can get HIV – and once they’re positive, they don’t understand a lot of the language. U equals U means nothing to them.”

Top Five Barriers to Accessing PrEP

	Providers	Community
1	Mental health	Concern they won’t be able to pay for PrEP
2	Substance Use	Substance use
3	Lack of culturally appropriate services	Lack of accurate information about PrEP
4	Lack of stable housing	Mental health
5	Lack of accurate information about PrEP	Trauma

Other/related barriers included:

- Lack of social support and not having role models who take PrEP
- Stigma/Internalized homophobia

PrEP Needs among Black/African American MSM, Transgender and Cisgender Women

In 2019, the Commission on HIV’s Black/African American Task Force developed a set of recommendations that included developing a targeted PrEP marketing campaign for Black/African American communities, given less than optimal PrEP uptake. In response to this recommendation, a series of focus groups were held for Black/African American MSM, transwomen and cisgender women to inform the development of a PrEP campaign.³⁸

Among MSM, common barriers to accessing PrEP included:

- Provider barriers – difficulty getting a provider to prescribe PrEP; not having providers close by; and not a lot of people in the clinics who “look like us”
- Miseducation and mistrust – not knowing where and how to get PrEP and not fully understanding PrEP and its side effects
- Mental fatigue – having to constantly take medication can be overwhelming; having to take medications to have sex reinforces there is shame in having sex

Among transwomen, common barriers to accessing PrEP included:

- Discrimination - trans and nonbinary people face an extreme amount of discrimination in trying to not only utilize PrEP, but in every aspect of life
- Providers/Access – poor access to facilities; lack of eligibility for PrEP/cost; lack of Black trans/nonbinary people who work at facilities.
- Side effects: physical and mental – including a recognition that even preparing to take meds is challenging
- Stigma - association of PrEP use with being promiscuous

Among cisgender women, common barriers to accessing PrEP included:

- Stigma - questions about number of partners can feel shaming; scared family or friends might find out they’re taking it; they might be stereotyped for using PrEP

³⁸ Facilitated by *Equity & Impact Solutions*

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- Access - can't afford it if it's not free; not the same availability that MSM have
- Pill Burden - taking a pill everyday can be burdensome
- Social Determinants - having to deal with poverty, housing insecurity, etc., makes it hard to focus on PrEP
- Medical Mistrust - believing the medications only work for MSM; believing only HIV+ people take medications; not understanding why PrEP takes longer to work in women than men
- Lack of Support - no PrEP support groups in LA for Black cis women
- Messaging/Marketing - not enough campaigns with Black cis women in clinics and publicly
- Lack of holistic focus - not enough focus on general well-being, access to healthcare and social support services everyone deserves

Optimizing PrEP Delivery to Immigrant Latino MSM in LAC: The Center for HIV Identification, Prevention and Treatment Services (CHIPTS) recently led a collaborative research project to understand the barriers to PrEP access, and to develop strategies to enhance PrEP delivery, among immigrant Latino MSM (LMSM) in LAC. Given that LMSM comprised the largest percentage (51%) of all new HIV infections among MSM of all racial/ethnic groups in LAC in 2019, and that nationally, since 2010, foreign born LMSM have comprised the majority of new annual HIV infections among LMSM, researchers were intent to understand any additional barriers to accessing HIV prevention services immigrant LMSM may face that are not experienced by US-born LMSM. The study included in-depth interviews with 15 Spanish-speaking and 10 English-speaking immigrant LMSM, 7 key informant in-depth interviews and a concept mapping process³⁹ with 19 panelists.⁴⁰ Key barriers were identified at the agency-, and client-level, including:

Agency-Level Barriers

Language

- Lack of Spanish-speaking staff and PrEP navigators
- Lack of services offered in Spanish
- Lack of properly translated Spanish language materials
- Difficulty completing English language forms
- No standardized way to talk about PrEP in Spanish

Provider bias/knowledge/comfort

- Not receptive to providing PrEP services
- Hold perception that PrEP will lead to promiscuity
- Lack knowledge of PrEP
- Not proactive about offering PrEP to this population
- Not comfortable delivering PrEP to this population

Outreach doesn't reflect population

- Lack of PrEP outreach materials or public awareness campaigns tailored for immigrant LMSM
- Outreach materials are not intentionally created for immigrant Latino MSM

³⁹ Concept mapping is a mixed methods approach that integrates qualitative perspectives of individuals with multivariate statistical methods to visually depict the composite thinking of the group.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5451901/>

⁴⁰ Key informant and concept mapping participant inclusion criteria: Staff member from a medical care facility or community-based organization that provides PrEP services to immigrant Latino MSM; Person with experience working with or advocating on behalf of immigrant Latino MSM; Person with knowledge of issues affecting access to HIV prevention services such as PrEP among immigrant Latino MSM.

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Client-Level Barriers**Lack of knowledge about PrEP and available PrEP services**

- Unaware of PrEP
- Don't know that PrEP is for them
- Don't know where or how to access PrEP
- Unaware of medication assistance programs (e.g., Gilead's Advancing Access Program, PrEP-AP)

Structural/logistical barriers

- Lack of health insurance
- Cost of services not covered by assistance programs
- Lack of transportation
- Unable to get release time to attend medical appointments
- Clinic hours (i.e., no weekends or evening hours)

Language

- Difficulty communicating with non-Spanish speaking providers
- Not enough services offered in Spanish
- Unaware of where to access services in Spanish

Cultural

- Don't use healthcare services unless absolutely necessary and don't use preventive services
- Uncomfortable talking about sexual behaviors with providers
- Homophobia in the Latinx community (e.g., needing to hide sexuality)

Immigration status

- Fear that information about use of PrEP services and/or HIV testing will be reported to immigration authorities
- Fear that use of public benefits will impact immigration process
- Fear of deportation if accessing PrEP services

PrEP-related stigma

- PrEP is only for gay men or men who are promiscuous
- Fear of being outed when accessing PrEP
- Fear of family, friends, or partners finding a PrEP bottle
- Fear of being thought of as HIV-positive

Individual perceptions/beliefs

- Fear of side effects
- Don't recognize their own HIV risk
- Providers assume they are having sex with women because some immigrant LMSM identify as heterosexual

The concept mapping process was used to develop implementation strategies to enhance PrEP delivery to immigrant LMSM. After identifying a list of strategies, the top five that were determined to be most feasible and important were recommended for prioritization:

1. Provide immediate access to and enrollment in PrEP services (e.g., same-day PrEP, PrEP walk-in clinic), so that there isn't a delay in receiving services.
2. Gather testimonials from immigrant Latino MSM who have buy-in to PrEP services and are willing to showcase their stories on social media.

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3. Deliver comprehensive PrEP education and training to every staff member at the clinic, from front desk staff to providers.
4. Provide support to help undocumented individuals enroll in insurance programs that cover PrEP services.
5. Develop campaigns informing people that they can access PrEP (e.g., through PrEP-AP) regardless of their current documentation status and without affecting their future chances for documentation.

Additional themes identified from survey and listening session participants related to accessing PrEP included discomfort/ unfamiliarity with taking medication when you're not sick, thinking PrEP is for other people because of lack of authentic advertising, and not being able to store the medication because of being unhoused.

"We only go to the doctor when we're sick."

"I don't see any pictures of people that look like me on those billboards that I drive by every day."

"How can I take medication every day? Where am I supposed to keep it when I'm on the street?"

Top Five Barriers to Linkage to Care

	Providers	Community
1	Substance use	Substance use
2	Lack of accurate information about LTC	Mental health
3	Lack of culturally appropriate services	Concern that they won't be able to pay for HIV care
4	Lack of stable housing	Lack of accurate information about LTC
5	Trauma	Lack of stable housing

Other:

- Lack of HIV-positive peers to talk to
- Need a warm hand-off and walked to services without having to wait
- Stigma
- Transportation
- Unfriendly insensitive waiting rooms
- Fear of people thinking they're gay

Survey and listening session participants expressed not wanting to access care due to bad experiences with providers in the past and not feeling comfortable in the clinic's physical space. They also expressed concern over administrative hurdles.

"I've had bad experiences with providers before. Why would I go back to be judged again?"

"When I'm in the waiting room, I feel like I'm in someone else's space."

"If it were easy to see the doctor, I think more people would do it, but I think there are too many administrative and logistic barriers. Right now, it feels like the opposite of "express" linkage."

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Top Five Barriers to Remaining Engaged in Care

	Providers	Community
1	Substance use	Substance use
2	Mental health	They don't feel sick
3	Trauma	Mental health
4	Lack of stable housing	Lack of stable housing
5	Lack of accurate information about HIV care	Trauma

Other:

- Lack of appointment time options
- Don't want to take medication or go to doctor's office
- Lack of peer support and treatment advocates
- Lack of respect in waiting areas, reception for drug users, homeless and other downtrodden
- Stigma
- Transportation

Participants also identified barriers related to medical mistrust, not having providers who look like them, lack of transportation and childcare and the need for peer advocates.

"We need to have a list of providers that are people of color and LGBT and we need to have more of them."

"There are a lot of reasons why we don't remain in care – we need help with transportation and help with childcare. And I need to see a provider who gets me."

"Doctor appointments are fifteen minutes. If I want to know what my labs mean, or why I'm given a particular pill, or how to manage side effects, I go to my peer-led support group, which is not funded by the County or by my health insurance. We need peer advocates. We need treatment advocates."

Co-occurring Disorders, Social Determinants of Health and Stigma

Across all categories of service, the top two barriers identified were substance use and mental health challenges. We also recognize that HIV disparities in LA County, like the rest of the nation are fueled by stigma and social determinants, including housing instability and incarceration. Each of these is described in more detail below.

Mental Health Disorders: Mental health disorders can affect the progression of HIV disease, medication adherence and the likelihood of engaging in high-risk behaviors that may result in HIV transmission.⁴¹ Based on 2015-2019 Medical Monitoring Project (MMP) data, between 10.4% -16.5% of PLWDH in LA County report moderate to severe depressive symptoms. Effective treatment of mental health disorders requires regular screening and diagnosis. Using a subset of RWP clients, we compared diagnosis and screening data to describe the prevalence of undiagnosed depressive disorder among Medical Care Coordination (MCC) services patients from 2013- 2019. As part of routine assessment, patients were screened for depressive symptoms using the Patient Health Questionnaire (PHQ-9) and their medical record reviewed for any depressive disorder diagnosis. Among the 9,178 MCC clients, 29% met the screener criteria for a depressive disorder and 33% had

⁴¹ Remien RH, Stirratt MJ, Nguyen N, Robbins RN, Pala AN, Mellins CA. Mental health and HIV/AIDS: the need for an integrated response. AIDS. 2019 Jul 15;33(9):1411-1420.

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been previously diagnosed. Among those with depressive symptoms, only 57% had a corresponding diagnosis. Compared to patients with depressive symptoms and a concurrent diagnosis, those with symptoms and no diagnosis were more likely to be male, younger (12-24 years compared to 24- 39 years of age), higher assessed acuity, and have unsuppressed viral load in the past six months.

Assessment of Unmet Mental Health Needs of PLWH

A recent key accomplishment under the EHE Initiative was a formal assessment of the unmet mental health needs of PLWH and the LAC mental health services and delivery system. Conducted by HMA Community Strategies, the assessment sought to identify barriers at the systems-, provider-, and client-level. Key stakeholder interviews (15 agencies), surveys (35 provider and 29 client respondents), and a review of secondary data rendered the following key findings and recommendations:

KEY FINDINGS	RECOMMENDATIONS
DATA LIMITATIONS	
•There is a lack of access to data and a lack of integrated data across the BH system – prevents comprehensive analysis of service utilization among PLWH. •Within the DMH data set, SOGIE was unknown for a slight majority of patients with both HIV and a BH diagnosis. This SOGIE data gap make it more difficult to tailor public health messaging and interventions.	•Establish a data infrastructure that enables the extraction and analysis of client-level data across county departments to identify who and which subgroups are not receiving services •Develop data sharing protocols and/or platforms that would allow patient health information to be more efficiently shared between DMH, DHS and DPH to avoid delays in data request •Add sexual orientation/gender identity and expression (SOGIE) data fields to ongoing data collection and data systems •Collect comorbid health condition data as part of the data collection to track other major life stressors of PLWH in order to provide client-centered, whole person care.
ELIGIBILITY AND SERVICE UTILIZATION	
•The increase of health care coverage and decline in aggregate HIV incidence result in a decline of the number of individuals eligible for Ryan White; fewer PLWH are eligible under current guidelines. •The current system is more successful in reaching Hispanic/Latinx population despite the prevalence of HIV being more prominent in the Black community.	•Revise regulations to allow Ryan White services to individuals who are Medi-Cal eligible •Reduce the administrative burden on providers and clients by minimizing or streamlining intake and reporting requirements •Encourage and incentivize providers to hire peers, community health workers (CHWs) or navigators to assist with insurance and paperwork
SERVICE DELIVERY AND COORDINATION	
•Linkages between MH and primary care remain an issue for many providers. •Most providers have difficulty ensuring PLWH can receive timely referrals to MH services, as well as difficulties referring clients to both psychiatric and SUD services. •Many providers reported difficulty matching PLWH to a licensed clinician on their staff with whom they identify	•Modify screening tools to enhance alignment with Trauma Informed Care and Gender Affirming Care •Improve cross agency referrals by using the Los Angeles Network for Enhanced Services (LANES) to have more accurate patient data and facilitate referral communication. •Design and convene forums that bring together providers to discuss and plan improvements (e.g.,

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•Providers have difficulty coping with rules and regulations that limit how they can staff clinical care for PLWH. •Many MH service clients not currently accessing received MH services via telehealth indicated they would be interested in starting services via telehealth. •Clients often experience difficulties navigating the current MH system. •Clients lack awareness of the services available and experience long wait times and excessive paperwork to access these services.	how to strengthen implementation of “No Wrong Door”). •Develop a resource guide that provides detailed information on providers’ services, capacity, and specialty services to enhance cross-agencies referrals.
FINANCE AND FUNDING	
•Many MH providers do not receive Ryan White funding, nor do they have a DMH contract to provide MH services. •Providing wrap-around services is unsustainable for most providers. •Providers are challenged by the current billing system; the opaque nature of reimbursement poses a significant barrier for service providers.	•Develop and offer training to providers intended to clarify and standardize reimbursement policies, including guidance on CPT codes, rates, and proper documentation. •Advocate for subsidizing BH services for individuals who are above the RW eligibility threshold but do not have other sources as payment of last resort.
WORKFORCE AND STAFF CAPACITY	
•Staff retention is a significant issue at both the provider and systems levels; excessive turnover and inability to recruit and retain staff is a barrier to provision of MH services to PLWH. •Nearly all providers have difficulty assessing relevant staff training resources and/or staff training opportunities. •There is a need for more professional development of the MH workforce, as well as reconsideration of the content and emphasis of training efforts.	•Leverage current efforts of the <i>Zeroing In: Ending the HIV</i> consortium and other EHE capacity building organizations to provide better quality, relevant workforce training opportunities that prioritize the following: •Models of collaborative, holistic care •Co-occurring disorders (e.g., the intersection of HIV and SUD) •SMI/high acuity mental health conditions •Advanced trauma-informed care and practices •Innovations in telehealth •Resources to improve workforce retention •Coordinate training offerings among DHSP, DMH, SAPC, and the clinical provider organizations •Explore whether LMFTs could be cross credentialed to provide services now restricted to LCSWs •Collect data on the diversity and lived experience of staff working with PLWH •Expand Spanish-language providers

STDs: Project Fierce Community Survey

Project Fierce is a community-based project funded by the CDC designed to reduce STD disparities and promote sexual health among young (18-24) cisgender and transgender women of color in LAC. As a project of Community Health Councils and WeCanStopSTDsLA, the Project Fierce Community Advisory Board implemented a community survey in 2021 to better understand the sexual health

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needs of young women of color. The 27 survey respondents identified as cisgender women (82%) and transgender/gender non-conforming (18%); straight/heterosexual (63%), bisexual (19%), and pansexual/queer (13%); Latinx (70%), Black/African American (22%), Asian (7%), and American Indian/Indigenous (7%). Key findings included:

- 73% were offered an STD screening by a healthcare provider; 27% were not offered one
- 52% would be more likely to get screened for STDs if it was mailed to their home rather than walking into a clinic; 33% would be equally likely; and 15% would be less likely
- 26% would be more likely to get screened for STDs if it was offered through mobile services rather than walking into a clinic; 41% would be equally likely; and 33% would be less likely
- 33% had never been tested for STDs. Of those that were tested: 37% had previously been tested for chlamydia; 30% for HIV; 22% for gonorrhea; and 15% for HPV
- 30% reported that their healthcare provider had never educated them on STIs, associated risks, and ways to stay healthy
- 33% were not sure which questions to ask their provider during appointments
- Factors that influenced their likelihood of discussing their sexual health history and concerns with their provider included: having a consistent healthcare provider (67%); the healthcare provider's age (48%), gender identity (48%), race/ethnicity (33%), and experience (26%).
- 48% reported that they never (26%) or not very often (22%) have a consistent healthcare provider
- 52% reported that celebrities, social media, and media influencers shaped their view or understanding of sex and sexual relations
- 29% reported that they had felt/been pressured to have unprotected sex in a monogamous relationship

Substance Use Disorder (SUD) and the Meth Epidemic: In contrast to other parts of the U.S. where the HIV epidemic is driven significantly by sharing of needles and other equipment among PWID and other substances⁴², the nexus between substance use and HIV in LAC centers on unprotected sex while under the influence of alcohol or other drugs. Based on MMP data (2015-2019), it is estimated that between 33.9% and 42.1% of PLWDH used non-injection drugs, and 1.9% to 4.9% used injection drugs in the past 12 months. Among a subset of 9,021 RWP clients receiving MCC services in LAC from 2013-2018 who were screened, approximately one out of five had indication of a SUD.

In LAC an estimated 18% of young adults aged 18-25 and 8.4% of adults aged 26 and older were estimated to have a SUD. Based on data from the LAC SAPC program, approximately 1 in 5 people treated for SUDs in the county are treated for meth use disorder and only 47% of these clients successfully completed treatment.

In the U.S, the increased risk of adverse outcomes associated with meth use (vs. non-use), include depression (1.3 times), HIV infection (1.5 times) and HCV infection (3.4 times). Between 2010 and 2020, meth-related overdose deaths in LAC have increased 1,185% and percent of all drug deaths has increased by 345%. Latinos made up the majority of patients with primary meth problem admitted to a treatment facility (65%), while Blacks had the highest rate (223). Patients admitted to treatment whose primary drug problem was meth had higher rates of STDs than clients with other primary drug problems. The difference was greatest with respect to syphilis, with 1.2% of those with meth as a primary problem having syphilis compared to 0.3% of those with other drugs as a primary problem – a five-fold difference.⁴³ The connection between meth use and syphilis is further illustrated through the analysis of Partner Services (PS) data. Between 2011 and 2019: meth use

⁴² Syringes and equipment may also be shared to administer hormones, steroids and/or vitamins

⁴³ <http://www.publichealth.lacounty.gov/sapc/MDU/MDBrief/MethBrief.pdf>

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among the early syphilis cases referred to PS increased among men who have sex with women, by 7 to 22%, and women who have sex with men, by 0% to 21%.

Among MSM in LAC, meth use is frequently associated with increased unsafe sexual activity. Meth-using MSM are much more likely to have multiple sexual partners and report inconsistent condom use than MSM who do not use meth. Meth users have numerous clinical challenges such as poor treatment engagement rates, high drop-out rates, high relapse rates, severe paranoia, and declining oral health. The medical and psychiatric aspects of meth dependence often exceed the capabilities of existing SUD programs, requiring significant cost for training and education for staff to improve service delivery.

Homeless/Unstably Housed: There are more than 69,000 homeless persons in LA County on any given night.⁴⁴ Since 2019, there has been a 12.7% increase in the homeless population in LA County and over 70% of the homeless were unsheltered. Nearly half (44%) of the homeless people in the county were found in areas with the highest rates of HIV/ AIDS, poverty, and uninsured. Approximately 41% percent of LA County's homeless were chronically homeless, 2% had HIV/AIDS, 26% had a SUD, and 25% had a serious mental illness. Nine percent of RWP clients in Year 31 were experiencing homelessness. Among clients enrolled in MCC services at Ryan White clinics from 2013-2019 (n=8,438), 24% reported experiencing homelessness in the past six months at enrollment. Clients who reported recent homelessness were significantly more likely to be Black/African American, recently incarcerated (in the past six months), have depressive symptoms, and have used injection drugs in the past six months compared to clients who did not report recent homelessness. In addition, those who reported recent homelessness were more likely to be male and heterosexual, live below the federal poverty level (FPL), be US natives, and have less than a high school diploma compared to clients who did not report recent homelessness. These data suggest that MCC clients experiencing homelessness were from communities disproportionately impacted by HIV (e.g., persons of Black race/ethnicity), impacted by multiple determinants of health (e.g., experience with the justice system, low educational attainment, poverty) and comorbid conditions (e.g., mental health and IDU). Of particular interest is that these clients were more likely to be non-MSM and IDU – both populations in which HIV prevalence has historically been lower but could contribute to potential HIV clusters or outbreaks.

Incarceration: Incarceration is associated with harmful effects on viral suppression, lower CD4+ T-cell counts, and accelerated disease progression.⁴⁵ HIV prevalence among men in LA County jails is estimated to be between 1% and 2% and approximately 300 PLWH are housed in the jails at any one time. Based on the MMP data from 2015-2019, between 1.1% and 3.2% of PLWDH reported being incarcerated in the past year. Among RWP clients in 2021, 8% had been incarcerated in the past two years. High percentages of these clients were living at or below FPL (85%), experiencing current homelessness (33%), MSM of color (44%), and African American (36%). These clients also had some of the lowest levels of engagement and retention in care and viral suppression.

Beyond the direct association of incarceration and poor health outcomes among PLWH, we also recognize incarceration as a force in LA and across the country that destabilizes communities, disrupts family relationships, and magnifies the accumulation of health and social disadvantage for already marginalized populations. The LA County Sheriff's Department (LASD) operates the largest municipal jail system in the US, and the US, in turn "imprisons more people than any other nation on

⁴⁴ <https://www.lahsa.org/documents?id=6515-lacounty-hc22-data-summary>

⁴⁵ Fuge TG, Tsourtos G, Miller ER. A systematic review and meta-analyses on initiation, adherence and outcomes of antiretroviral therapy in incarcerated people. PLoS ONE. 2020;15(5):e0233355.

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Earth.”⁴⁶ There are more than 250,000 people who cycle through the county justice system annually, roughly 14,500 daily, and 500 inmates classified each day. In addition to the sheer volume of people in LA County jails, there are stark racial disparities. Black/African Americans, while making up only 9% of the LA County population, represent over 29% of the jail population. The justice system is clearly ill-equipped to deal with the thousands of people it imprisons who are typically struggling with poverty, homelessness, substance use disorders and mental health challenges. As a result, people cycle in and out of jail, not able to get the care they need to live healthy and productive lives.

In 2020, LA County voters approved Measure J, which dedicated no less than ten percent of the County’s locally generated unrestricted funding to address the disproportionate impact of racial injustice through community investments such as youth development, job training, small business development, supportive housing services and alternatives to incarceration.⁴⁷ As a result, the LA County Board of Supervisors adopted the Care First Community Investment spending plan⁴⁸ (aka Measure J), an unprecedented \$187.7 million spending package to advance its care first, jails last vision with a series of direct community investments and funding for alternatives to incarceration—accelerating the transformative process of creating a more just and equitable Los Angeles County for all residents. The plan was developed with an equity lens with a primary focus on chronically under-resourced communities to address negative outcomes caused by racially-driven criminal justice inequities and long-term community economic disinvestment. As such, the plan supports a wide range of programs including interim and permanent supportive housing, grants to community-based organizations, and employment opportunities for adults and youth. Highlights of the funding plan include:

- \$42 million to support the closure of Men’s Central Jail
- \$16 million for housing and related services to meet a variety of needs including for people experiencing homelessness with complex health needs and people with substance use disorder;
- \$15 million to support residents returning to the community after incarceration

Stigma: Since the beginning of the epidemic, stigma in all its forms has served as a constant barrier to people being able to access HIV care and prevention services. HIV-related stigma is compounded by stigma associated with LGBTQ identities and sexual behaviors, using drugs, injecting drugs, mental health disorders, being homeless and being incarcerated. Given its pervasiveness and sometimes insidious nature, stigma is hard to pinpoint and even harder to address. A recent example of how stigma impacts the lives of PLWH and the communities most impacted by HIV is the messaging and reaction to Monkeypox. In late 2022, LA County, like many urban areas across the country, is struggling to combat the monkeypox virus as we continue to grapple with COVID-19. To date, the vast majority of the 1,836 monkeypox cases have been identified among cisgender men (97%), most of whom identify as gay/bi or other MSM. However, risk is not limited to MSM, given that available evidence suggests that those who are most at risk are those who have had close physical contact with someone with monkeypox. Unfortunately, early messaging about monkeypox may have inadvertently led to people believing they are not at risk if they are not gay or transgender identified. There is also concern locally and globally that some communications and commentary on monkeypox have used language and imagery that reinforce homophobic and racist stereotypes and

⁴⁶ <https://www.lacounty.hiv/wp-content/uploads/2018/11/LACHAS2018-English.pdf>

⁴⁷ <https://ceo.lacounty.gov/ati/>

⁴⁸ In response to recommendations put forth by the *Measure J Reimagine LA Advisory Committee*, since transformed into the *Care First and Community Investment Advisory Committee*

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exacerbate stigma.⁴⁹ We recognize that such stigma and misinformation can severely undermine outbreak response. Indeed, we are reminded of the early days of the HIV epidemic when racism, homophobia, transphobia and stigma led to the failure to prioritize the communities most impacted by HIV/AIDS – gay men, people of color, trans persons and PWID - early on in the course of the epidemic. This resulted in the steady and deadly spread of HIV/AIDS most profoundly in these groups and a failure to - as of yet - end the HIV epidemic nationally.

The monkeypox outbreak creates both another health burden and another social burden for the LGBTQ population and for people living with HIV. The evolution of monkeypox remains to be seen, but even after the current wave of this particular health threat subsides, we likely will not be spared from future outbreaks, epidemics or pandemics of other infectious diseases. To protect PLWH and the communities most impacted by HIV from both the health and social burdens brought about by current and future pandemics, we urge public health leaders and elected officials to respond to outbreaks with an approach that avoids stigma and blame. To do so, we encourage the infusion of community voices and perspectives, particularly among those most impacted, in the development of such responses and messaging. We need to ensure that public health leaders and governments work with communities to find local solutions. Disproportionately impacted populations must not bear the brunt of increased stigma and discrimination as a result of any health threat or the response to it. Moving forward, we will work to ensure that these key principles⁵⁰ guide future public health responses in LA County:

- Affected communities must be actively engaged in identifying and implementing strategies in response to threats to their health and well-being.
- Stigma and fear are constant companions of infectious disease pandemics; proactive steps must be taken to minimize their negative consequences.
- To reduce health disparities, proactively identify groups and communities at disproportionate risk of developing disease or poor health outcomes and design interventions to reduce these disparities and to promote health equity.

Overall Service System and Workforce Capacity

Additional data were captured through assessment activities that pertained to the HIV service system and workforce capacity. Participants cited numerous strengths with the HIV service system in LA County, including addressing the epidemic through a social justice lens, multiple free and accessible services, and the dedication of those who work in the field.

“The HIV workforce tends to be comprised of passionate and committed workers. They feel their job is meaningful and believe in helping others to the best of their ability.”

“It’s beginning to acknowledge the impact of systemic racism in all aspects of care and as a driver of health disparities.”

Relatedly, community members who had received HIV-related services over the past year had mostly positive feedback about the services they received:

- 98% either strongly agreed or agreed that they were treated with respect;

⁴⁹https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2022/may/20220522_PR_Monkeypox

⁵⁰ Valdiserri, R.O., Holtgrave, D.R. Responding to Pandemics: What We’ve Learned from HIV/AIDS. *AIDS Behav* 24, 1980–1982 (2020). <https://doi.org/10.1007/s10461-020-02859-5>

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- 93% either strongly agreed or agreed that they did not feel judged;
- 97% either strongly agreed or agreed that the staff made them feel welcome and comfortable
- 97% either strongly agreed or agreed that the provider met their needs and answered their questions.

Needs/Areas for Improvement

Community members appreciated when their providers treated them more holistically, but some reported frustration with having to advocate to be screened for STDs, not being able to receive whole-person care, and not receiving culturally competent services.

"My clinic screen for other issues I may have and that was important to me."

"I used to be screened for STDs every three months. Now that I see my ID doc twice a year, the tests have been added to my labs once, at my request."

"My HIV provider used to be the only doctor I saw. My current and past physician is no longer willing to treat my cholesterol or other non-HIV issues. As an older person with HIV, I'm also dealing with other comorbidities. My healthcare is siloed, I'm taking ten different medications and I only see doctors who advocate for their disease, with no one advocating for the whole person."

"The location was cyberspace, so I didn't visit the therapist's office. I took three months to see the therapist. The therapist had no experience working with gay men, HIV, or cancer survivors."

"Case managers spend more time doing paperwork than servicing clients. LA County loves data driven programs, but all that paperwork means some people are denied access to services or have to wait three months."

The majority (79%) of respondents strongly agreed or agreed that there needs to be more people living with HIV delivering HIV-related services. Among those who identified as HIV-positive, the percentage jumped to 93%. Additionally, 80% of respondents strongly agreed or agreed that "there needs to be more people who look like me delivering HIV-related services." This included 86% of respondents who identified as Black/African American and 88% who identified as Latinx.

In addition to increasing the diversity of the workforce, the greatest needs with respect to the workforce and service system included addressing provider burnout; addressing turnover that stems from a variety of issues; the need for expedited services, especially for those with complex needs; training needs; building a better pipeline for providers; and addressing administrative barriers.

"Hire more people, more staff that look like us and can relate to our needs. Don't require a Master's degree in social work. Let people with an Associate's degree take a little training. If you hire more people that are HIV and give them training, you'll get better results."

"Do they employ members of the populations in positions other than outreach? For example, do they have trans front desk staff or a gay black MA? Or do these folks only get hired to do outreach to their "target" population?"

"They (providers) are overworked / forced to wear multiple hats and many of them have unhealed trauma that directly impacts the quality of their services."

3. CONTRIBUTING DATA SETS & ASSESSMENTS: NEEDS ASSESSMENT

“The turnover in organizations is high due to low pay and other factors. More free training is needed that offers certification and licensing. Experience is frequently underappreciated vs college degrees.”

“What we really need are housing resources, access to expedited mental health services and substance use disorder resources, linkage to care of vulnerable populations especially those experiencing homelessness.”

“The greatest need is to cross train programs regarding their services and systems to connect clients to services.”

“(There are) no clear pipelines or educational training programs (in colleges or in the community) to prepare for positions in the HIV field (HIV counselors, HIV prevention workers, PrEP navigators, Linkage to Care, Case Managers, Case Watch Data Managers, ADAP enrollers, Benefits Counselors, etc.).”

“At meetings, it often feels like there is adequate resource allocation especially for housing, yet as a provider, it feels that those resources are difficult to obtain or are not available in real time. There is so much red tape and ultimately, the patients suffer or there is delay in receiving care. This also applies to mental health resources.”

“(We need) one database for all services, once registered data like income can be updated and people get automatically enrolled for needed services like affordable housing.”

a. Priorities – The needs assessment process helped us to identify the following key priorities:

- Integration and streamlining of services
- Address mental health needs of PLWH and at-risk for HIV
- Address SUD, especially meth use disorder
- Address needs and gaps in the HIV workforce
- Clear marketing and messaging about services and risks to reach priority populations
- Need to increase health literacy

b. Actions Taken - In response to needs and barriers identified during the development of both the Integrated Plan and the EHE, LA County has undertaken a number of activities, including:

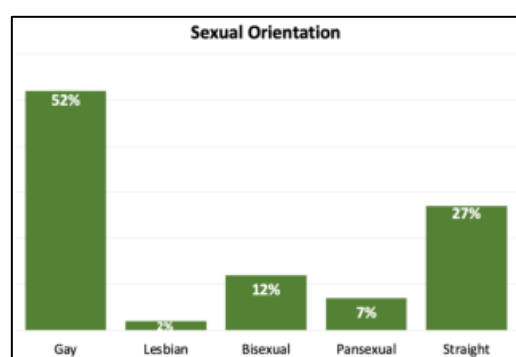
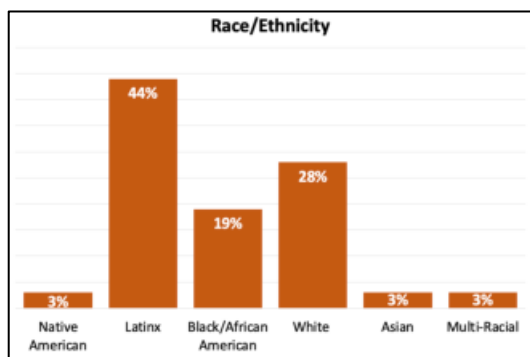
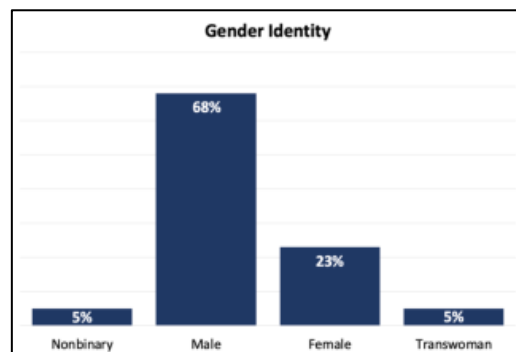
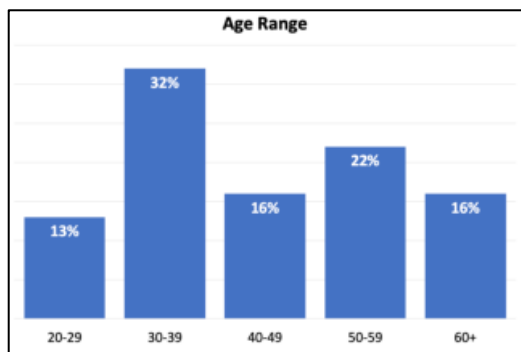
- Distributed over 15,000 HIV self-test kits
- An Assessment of Unmet Mental Health Needs of PLWH
- Assessment activities to develop PrEP campaigns in the Black/African American community
- Began initial activities for comprehensive workforce capacity assessment
- Increased Tele-PrEP capacity for PrEP/PEP Centers of Excellence
- DHSP began implementing *Addressing Implicit Bias & Medical Mistrust, and Cultural Humility* training
- Emergency Financial Assistance for PLWH – developed for clients at risk of losing housing or in need of one-time or short-term financial assistance
- Exploring ways to improve Partner Services efforts
- Development of a Cluster Detection and Response Community Advisory Board
- Community meetings and trainings on Cluster Detection and Response
- DHSP implemented EHE community mobilization project through a partnership with the AMAAD Institute, focused on highly impacted populations
- Implemented iCARE Contingency Management project
- Implemented Rapid and Ready Linkage to Care project

3. CONTRIBUTING DATA SETS & ASSESSMENTS: NEEDS ASSESSMENT

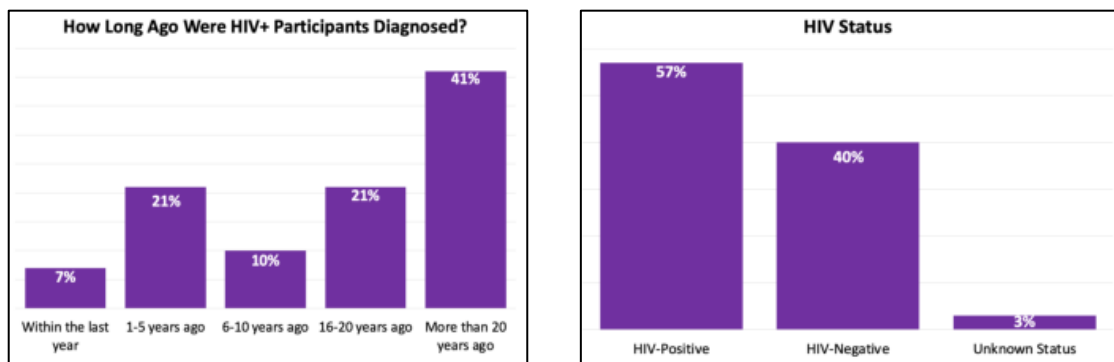
c. Approach - At the onset of planning, stakeholders expressed concern related to “over-assessing” both community members and providers, and that we should strive to utilize the data, recommendations and reports that had recently been collected and compiled through various means. For example, the recent development of the LA County EHE, the local *Act Now Against Meth* campaign; and the recommendations from the Commission’s Black/African American Task Force, Women’s Caucus, Transgender Caucus, Consumer Caucus, Prevention Planning Workgroup, and Aging Task Force rendered useful information for our planning purposes. In addition to the analysis of existing reports and data, we also collected primary qualitative data from priority populations, community members and providers through listening sessions, an online survey and facilitated stakeholder meetings.

Listening Sessions: To ensure the voices and perspectives of communities most impacted by HIV were used to drive the Integrated Plan’s goals and objectives, we conducted facilitated “listening sessions” with priority population groups. A total of 86 participants attended the listening sessions for Black MSM; People of Trans Experience; Cisgender Women of Color; People who Inject Drugs and their Stakeholders; PLWH 50 years of age and Older; and People Under 30 years of age. The listening sessions were 90-120 minutes long and included discussions about what the HIV service system does well; and barriers and solutions related to each pillar. Participants each received a \$25 gift card for their participation.

Survey: Two online surveys were also disseminated to capture perspectives from providers and community members (defined as anyone who had accessed any type of HIV-related service in LA County in the past 12 months). Community members each received a \$25 gift card for completing the survey and providers had the option of entering a raffle to win one of two \$50 gift cards. Both the provider and community surveys were available in English and Spanish. Fifty-one community members completed the survey, however, only 13 providers responded to the survey, which may be due to being “over-assessed” as described above. The demographic profile of community survey participants include:



3. CONTRIBUTING DATA SETS & ASSESSMENTS: NEEDS ASSESSMENT



Facilitated Stakeholder Meetings: To capture feedback from key stakeholders, the planning team (PP&A leadership, Commission staff and Consultant) facilitated a number of structured discussions to ascertain how to build upon the existing EHE to develop the new Integrated Plan. Stakeholders represented the following entities and/or population groups:

- EHE Steering Committee members
- Community-based organizations serving PLWH and at-risk for HIV
- Health department staff from LA County, the CA State Office of AIDS, and the Cities of Long Beach, and Pasadena
- People living with HIV, including members of a Federally recognized Indian tribe and individuals co-infected with hepatitis C
- Members from priority population groups including Black MSM, Latinx MSM, Women of Color, Trans and nonbinary persons, PWID, people 50 and older, people under 30
- Health department epidemiologists
- HIV clinical care providers including those who represent RWHAP Part C and D
- Providers from STD clinics
- Non-elected community leaders including faith community members and business/labor representatives
- FQHC and Community Health Centers
- Substance use treatment providers
- Hospital planning agencies and health care planning agencies
- Mental health providers
- Individuals (or representatives) with an HIV diagnosis during a period of incarceration (within the last three years) at a federal, state, or local correctional facility
- HOPWA Coordinator
- City of Los Angeles AIDS Coordinator
- Social services providers including housing and homeless services representatives*
- Service Planning Area (SPA) 2 (San Fernando Valley) HIV and social service providers
- SPA 4 (Metro) HIV and social service providers
- Long Beach HIV Community Planning members
- City of West Hollywood HIV service coordinators/staff
- Part F/AETC

Section IV: Situational Analysis

Overall, the LA County HIV prevention and care system has many strengths and providers, advocates, consumers and community members can be proud of key achievements over the course of the HIV epidemic that have undoubtedly saved lives and improved the quality of life for those living with or at-risk for HIV. More recently, although COVID-19 has devastated Angelinos and greatly stretched the public health infrastructure, the HIV system has shown great resiliency and continues to diagnose and treat people living with HIV and prevent HIV transmission through the provision of high-quality services. Although the number of people living with HIV continues to climb, the number of annual HIV infections continue to decrease, as does the HIV death rate.

Unfortunately, HIV-related disparities persist across race/ethnicity, gender identity, sexual orientation and age group. These disparities are driven largely by structural and systemic issues including housing status, poverty, recent incarceration, and co-morbid conditions such as STD coinfection, substance use disorders and mental health disorders. Our commitment to ending HIV means we must also be committed to confronting harmful practices and oppressive systems that fuel these disparities.

a. Diagnose all People with HIV as early as Possible: An HIV diagnosis as close to the period of infection as possible is a crucial first step to achieving optimal HIV-related health outcomes and reducing the likelihood of HIV transmission. In LA County, an estimated 6,800 people or 11% of all people living with HIV, are undiagnosed and therefore unaware of their status. Additionally, one out of five people who were newly diagnosed with HIV in 2020 were diagnosed in the “late stage” of the disease, increasing the risk of transmission and poorer health outcomes. To increase the proportion of people living with HIV who are diagnosed to at least 95%, and to increase the timeliness of diagnosis, LA County DPH, community health clinics, non-traditional community-based HIV testing partners, and other private and public entities must jointly support a robust and widespread HIV testing strategy, including testing in new and innovative ways. Critical in this effort is increasing the number of testing services access points to meet clients where they are in their readiness to engage in testing services in clinical, non-clinical and other community settings.

LA County DPH supports a cross-section of organizations to conduct HIV testing in a variety of settings, including non-clinical venues that serve priority populations, community-based HIV/STD clinics, social and sexual network testing programs, and commercial sex venues. Overall, DPH supports 42 HIV testing providers with annual goals to provide over 80,000 HIV tests and with the goal of diagnosing more than 800 individuals with HIV each year. In addition, LAC DPH staff directly provides HIV testing in the county jails and STD Clinics. These public-sector supported HIV testing and diagnosis efforts are an important complement to private sector HIV testing efforts supported by commercial health plans.

Routine HIV Testing: Expanding routine HIV testing within emergency departments, hospitals in highly HIV impacted geographic areas, FQHCs, and other clinical settings is crucial to meet HIV testing goals. While targeted testing often provides the highest positivity rate, implementing routine testing in health care settings is an important component to not only move towards destigmatizing HIV, but also allowing individuals who do not recognize their HIV risk to be tested for HIV. Given the co-occurrence of HIV and other STDs and substance use, it is essential that we continue to promote HIV testing as a part of routine STD screenings and at substance use disorder treatment facilities and SSPs. Routine testing in a subset of clinical settings can have an acceptable yield while leveraging multiple revenue streams, including public and private health plans, to cover testing costs. Despite these opportunities and benefits, launching new routine HIV testing programs in healthcare settings in LAC has been difficult. To catalyze routine HIV testing, a variety of policy changes are needed

4. SITUATIONAL ANALYSIS

including changes that require low barrier reimbursement for HIV screening and strong annual screening mandates. In addition, we must address several non-financial routine HIV testing barriers, including broad scale training and technical assistance of routine HIV testing staff, broad scale adaptation of electronic medical records to incorporate HIV testing prompts and export critical HIV testing data, the development of protocols to ensure the immediate linkage of newly-diagnosed HIV- positive persons to care, and incentives to recruit and maintain a county-wide cadre of health care settings based routine HIV testing “champions.”

Primary Care Clinics: As part of the national EHE initiative, since 2020 39 FQHCs and community health clinics were funded directly by HRSA’s Bureau of Primary Health Care to adopt routine HIV screening, increase PrEP provision, and implement other HIV prevention services within their clinics. LA County DHSP works with the funded clinics in partnership with the Community Clinic Association of Los Angeles County to support these efforts.

Emergency Departments (EDs), Urgent Care Centers and Hospitals: EDs are entry points into healthcare services for many individuals, including people living with diagnosed and undiagnosed HIV. Thus, EDs, urgent care settings, and hospitals are important locations to offer HIV testing, especially for those who don’t access primary care. Routine HIV screening in these settings is also conducive to the identification of persons with acute HIV infection and high linkage to care rates. In 2020, DPH received HIV case reports for a total of 2,338 new HIV diagnoses, and 2,006 cases were matched to a reporting health care facility. Approximately three out of every five new diagnoses were identified at one of the top eight HIV diagnosing hospitals or outpatient clinics.

Sexual & Reproductive Health Clinics: Screening sexually active persons for HIV when they present for STD testing is imperative, particularly given that HIV and other STDs often co-occur. Sexual health providers in LA County include community and DPH STD clinics, family planning providers, and HIV PrEP clinics. DPH currently operates 11 STD clinics and funds four community-based LGBT focused STD clinics that provide no-cost specialized STD and HIV services in a confidential, non-judgmental setting. Family planning providers include Planned Parenthood as well as a network of many smaller clinics. These providers have and continue to provide comprehensive STD and family planning services to patients of all genders for uninsured or underinsured persons. Since 2012, the number of clinics offering PrEP either in a separate PrEP focused clinic or integrated into their regular services has increased. Increased PrEP use results in increased HIV testing given CDC guidelines that clients prescribed PrEP should be tested for HIV every three months. The top six sexual and reproductive health clinics diagnosed nearly one-third (30%) of all new diagnoses in 2020.

In the past, DHSP has conducted Public Health Detailing (a method of targeting and reaching providers who will benefit from a short, focused public health message) related to HIV, PrEP, and syphilis among women to influence practice patterns for established community medical providers. This effective intervention, however, remains both resource and time intensive for a jurisdiction the size of LAC. A more targeted approach of connecting with medical schools and training programs, including residency programs, nurse practitioner and physician assistant training programs, may be a more cost- effective way to support sustained clinical practices with public health benefit. By reaching clinicians at the beginning of their healthcare training and careers, the importance of HIV prevention and HIV testing can be included as a fundamental element of routine clinical practice that spans the life of medical careers and can be used to identify and develop HIV champions.

Rescreening individuals with elevated HIV risk: Both national and local data indicate that many people at higher risk for HIV infection are not screened according to clinical guidelines (e.g. CDC recommendation of at least once per year). Among CDC’s NHBS participants, 15% of transwomen, 16% of MSM and 45% of PWID had not had a test in the past 12 months; and a lower proportion of

4. SITUATIONAL ANALYSIS

persons with ongoing HIV risk received an HIV test every three or six months as recommended by the CDC.

The link between STDs and elevated HIV risk is clear, and we must ensure that health care providers are not missing opportunities to conduct HIV testing with clients who are seeking STD screening, diagnosis and treatment services. The wide-scale adoption of technology to allow HIV testing providers to track and communicate with clients via text or a secure portal when they are due for repeat testing in an automated fashion and could accelerate efforts to ensure that clients who are newly diagnosed are promptly linked to care. The adoption of this technology and the use of digital forms of communications is congruent with how younger individuals prefer to exchange information, particularly given their ease and the higher levels of confidentiality they provide.

Self-Test Kits: Alternative HIV testing approaches are necessary to ensure that HIV diagnoses continue among individuals who may be HIV-positive but who may be less inclined to seek in-person services. The U.S. Food and Drug Administration (FDA) has approved HIV self-test kits, that while less sensitive than other rapid tests, provide an important low barrier option for individuals to confirm their HIV status. In response to this alternate testing strategy, LA County DHSP joined the multi-jurisdictional Take Me Home initiative. Take Me Home is a timely and innovative HIV self-test kit ordering program that centralizes advertising, data collection, and test kit distribution to clients, relieving health departments from coordinating and hiring staff during the COVID crisis. As a strategy to promote linkage to care efforts, DHSP has also made available HIV self-test kits to community-based partners who also offer video or phone assistance and support by trained test counselors and who prioritize providing linkage to care services to persons testing HIV-positive. TakeMeHome is working to expand its reach and diversify its users by implementing active social media strategies and partnering with local credible messengers to increase the recognition of and trust in the program. Providing the opportunity for no-cost self-test kits is a strategy to increase access to HIV testing services with minimal staff support. Since January 2021, Public Health has distributed over 15,000 kits to contracted HIV prevention agencies, other community partners, and through community events. DPH plans to expand self-test kit distribution through programs that serve people who inject drugs, transitional aged youth, and people experiencing homelessness. LA County is also pursuing distribution options through non-traditional partners such as barbershops, religious institutions, mutual aid groups, as well as through large scale community events.

In addition to HIV self-testing, the “I Know” program (dontthinkknow.org), first developed by LAC DPH in 2009, was the second free home STD testing program in the U.S. offered by a public health agency, and the very first to offer clients online access to test results. The program offers free testing for chlamydia and gonorrhea to females and trans males in LAC ages 12-24, using the Aptima Combo 2 vaginal swab. Chlamydia and gonorrhea together cause more than 25,000 infections in young women in LA County annually. Most of these infections are asymptomatic, making routine testing essential to timely treatment and preventing further transmission. “I Know” expands testing by removing common barriers to clinic-based testing, including time, stigma, and lack of nearby facilities. Re-launched in April 2022 on a new more powerful software platform, “I Know” has now also expanded to six other CA counties, with support from CA Department of Public Health.

The County welcomes traditional and non-traditional partners to further explore HIV testing opportunities that allows for the highest impact in increased testing access points, reduced barriers for clients, and integration of routine “syndemic” testing that includes viral hepatitis and STDs. DHSP will continue to expand or support the existing HIV testing portfolio especially for populations where HIV rates are rising and is committed to partnering with agencies such as homeless service providers conducting street outreach to further increase HIV testing opportunities, given their expertise of the communities and clients they serve.

b. Treat People with HIV Rapidly and Effectively to Reach Sustained Viral Suppression: By leveraging a combination of federal, state, and local funds, LA County supports a network of HIV providers and more than 30 DHSP funded HIV medical homes, where referrals, linkage assistance, medical care, and medications are available regardless of insurance status. For years, DHSP, the Commission and a network of providers have worked to reduce barriers to care so that PLWDH can be readily linked to and be retained in HIV medical care. Despite these efforts, at the end of 2020, linkage to care, engagement in care, and viral suppression rates remain far below targets for a significant subset of patients.

Linkage to care: Since 2011, DHSP has incentivized timely linkage to HIV medical care for its network of community-based HIV testing providers. HIV testing providers assume primary responsibility for linking a newly diagnosed person to HIV care by setting up appointments and following up with the client until the first appointment is completed. While this incentive structure initially produced significant improvements in initial linkage to care, more recently performance has generally plateaued. Only 76% of persons who were newly diagnosed in 2020 were linked to HIV care within one month and only 54% were linked to HIV care within one week. This is likely due to a combination of factors, such as denial or competing life demands, and structural barriers, such as lengthy financial screening requirements and administrative paperwork. The current system must evolve to make rapid initiation of antiretroviral therapy (ART) the easiest choice for both the provider and the patient. DHSP, together with HIV prevention and medical providers, must restructure its approach to linkage to care, must treat new HIV diagnoses with more urgency, and must ensure that providers receive technical assistance to make same day linkage referrals a standard practice. In addition, DHSP will utilize its position as funder to provide technical assistance to clinics to reduce unnecessary administrative barriers for patients and improve the client experience. An exciting LTC project recently launched by DHSP is the Rapid and Ready program focusing on same-day linkage to care which has received 52 referrals to date, of which, 50% have been linked to care.

Engagement and Retention in Care: In 2013, LAC DHSP implemented the *Medical Care Coordination (MCC)* program in Ryan White Program-funded HIV medical homes with the goal of addressing the unmet psychosocial and medical needs of patients at risk for or already experiencing poor health outcomes. Comprised of a Registered Nurse, a Social Worker, a Case Manager, and a Retention Outreach Specialist, the MCC teams help patients with a range of psychosocial, behavioral, and medical issues that may impact their treatment adherence. A robust evaluation of the MCC program demonstrated that PLWH who utilize MCC services experience significantly improved health outcomes after 12 months. In 2016, DHSP established the *Linkage and Re-engagement Program (LRP)* as a complement to the MCC program to identify, reach, and re-engage patients who have fallen out of care, and then expanded MCC to additional HIV clinics in 2017. Given that the path to consistent, ongoing HIV care and reaching viral suppression is not always a linear experience for clients (for multiple reasons), the Linkage and Re- engagement Program was developed as a specialty linkage program to work with clients who have had challenges linking to care or have fallen out of care and cannot be reached. LRP utilizes experienced DHSP-based health navigators, who have access to a wide-range of LA County data systems in order to locate and follow-up with clients who are often not well served by traditional medical and support service models, including those without a cell phone or who are unstably housed, or who have not been located or responsive to service providers' attempts to engage them in care. While the engagement and retention in care of clients remains a primary responsibility of the clinic, the LRP program is intended to serve as a complementary option of last resort to focus efforts on locating and connecting with clients and subsequently facilitating a warm hand-off to clinics and MCC teams.

In August of 2022, a contingency management program known as iCARE (Incentives for Care, Adherence, Retention, and Engagement) was launched. iCARE is an incentive-based program that seeks to support engagement in care and viral suppression among youth and young people under the age of 30 using principles of contingency management, an evidence-based behavioral intervention. This pilot program consists of two cohorts (youth under 30 years and women from DHSP's Linkage and Re-engagement Program).

It is clear that despite the availability of these programs, many PLWH struggling with financial concerns, housing instability, mental health diagnoses, and SUDs, also struggle to not only access care, but remain in care and achieve viral suppression over long periods of time.

Cal-AIM⁵¹: The California Department of Health Care Services (DHCS) has recently begun rolling out a multi-year initiative to improve the quality of care provided to Medi-Cal members by implementing broad delivery system, program, and payment reform across the Medi-Cal Program. The goals of the California Advancing and Innovating Medi-Cal (CalAIM) initiative are to identify and manage member risk and need through whole-person care approaches and addressing social determinants of health; move Medi-Cal to a more consistent and seamless systems by reducing complexity and increasing flexibility; and improve quality outcomes, reduce health disparities and drive delivery systems transformation and innovation through value-based initiatives, modernization of systems, and payment reform. Under CalAIM, Enhanced Care Management (ECM) is a care coordination benefit for the highest need and/or high-cost members. This new Medi-Cal managed care plan benefit would provide intensive care management for both medical and non-medical needs for high-need Medi-Cal members. Eligible populations include people experiencing homelessness, people at risk of institutionalization and people transitioning from incarceration with complex health needs. Because a key focus of CalAIM is addressing the challenges facing people with complex and unmet needs, we are hopeful that CalAIM will help support the needs of PLWH who have fallen out of care or are at risk of falling out of care. For these reasons, we will carefully monitor the roll-out of the new initiative and work to ensure the system supports the needs of PLWH.

Addressing the Meth Epidemic: In LA County, the SAPC Program leads and facilitates the delivery of prevention, treatment, and recovery support services intended to reduce the impact of substance use, abuse, and addiction county-wide. The LAC DPH Division of HIV and STD Programs collaborates with SAPC to connect clients to HIV and STD-related services. Given the consistent increase in methamphetamine use over time and its well-established intersection with HIV, syphilis, and poor HIV-related health outcomes, it is imperative that LA County facilitates greater integration and synergy of HIV and substance use disorder services. Stronger partnerships among HIV service providers and SUD providers must include strategies that address meth use and its role with sexual HIV risk behavior, must promote adherence to PrEP or ART, and must prioritize the expansion of contingency management services coupled with these biomedical HIV prevention tools. More broadly across the substance using spectrum, programs that promote harm reduction, mitigate the sharing of injection equipment and promote syringe services programs must be prioritized, including geographic areas with high rates of HIV transmission but devoid of SSPs. The LA-based Act Now Against Meth Coalition, a long-standing community mobilization and awareness effort launched to address the alarming increase in meth use among gay and bisexual men has recently developed the Los Angeles County Platform Addressing the Meth Epidemic. The platform includes a list of recommendations for meth prevention, treatment, and policy, some of which we have folded into our goals and objectives. Separately, SAPC has launched a Countywide Meth Task Force to inform meth prevention and treatment strategies and address both the upstream drivers of meth use and abuse. DHSP actively participates in both the Prevention and Treatment Committees of the Meth

⁵¹ <https://www.dhcs.ca.gov/calaim>

Task Force.

Aging with HIV: As we enter the fifth decade of the HIV epidemic, those who are aged 50 and older make up an increasingly larger percentage (51%) of PLWDH, with people 50-59 years old making up 30% of all PLWHD and people 60 and older making up 21%. By comparison, people 50 and older make up only 33% of LA County's general population. It is estimated that by 2030, people 50 and older will comprise 70% of all PLWH. Additionally, among new HIV diagnoses in 2020, 34% of people aged 50-59 and 31% of people 60 and over were diagnosed at Stage 3 of HIV disease, indicative of late HIV disease (compared to 20% among all diagnoses).

Advances in treatment have greatly improved the health and well-being of all PLWH. As HIV treatments continue to improve and the general population continues to age, the number of older PLWH will continue to increase. Relatedly, according to a recent modeling project,⁵² by 2030, over 25% of people taking HIV treatment will be over the age of 65; over half will be over the age of 53; and 36% of people taking ART are expected to have multimorbidity – at least two physical co-morbidities in addition to HIV. A recent study finds that accelerated aging occurs within just two to three years of infection.⁵³ With age and the cumulative effects of HIV, older PLWH and some long-term survivors experience exacerbated age-related health vulnerabilities and comorbid conditions. Older PLWH face a range of challenges to their physical and mental health, in addition to the usual effects of aging, even when HIV disease is well-controlled.^{54, 55}

Physical challenges may include exacerbation of widespread, chronic inflammation associated with normal aging; multimorbidities and their interactions, and side effects of ART and other medications. Mental challenges and challenges to overall well-being may include HIV-associated neurocognitive disorders; depression; trauma and loneliness.

As the needs of older PLWH and long-term survivors come more into focus and grow more urgent, it is imperative that our service system adapts to ensure strategies for long-term viral suppression, continuous access to ART, and prevention and care for comorbid physical and mental conditions. In 2020, the Commission on HIV's Aging Task Force (now Caucus) developed a set of recommendations to address the broad health needs of those over 50 years old living with HIV and long-term survivors. The Task Force is currently revisiting the recommendations to better respond to the aging needs of long-term survivors under 50 and individuals who acquired HIV perinatally. Aligned with these recommendations, as well as California's Master Plan on Aging, DHSP has begun to develop plans to address the needs of those PLWH 50 and older, as reflected in our goals and objectives.

The current safety net in LAC to address the needs of PLWH with multiple health and/or life circumstances (e.g., substance use disorder, homeless, mentally ill, other co-morbidities, and chronic health conditions) persons living with HIV is fraught and complex. Navigating the healthcare system and identifying accessible and quality mental health and SUD services, particularly for low-income persons, can be difficult; at the same time, mental health services specifically designed for PLWH remain underutilized in parts of LAC. To ensure that we improve the health outcomes of PLWH who have not achieved viral suppression, disruptive programming that provides supportive services with an emphasis on education, emotional support, trauma informed care and stigma reduction; and improves the lives of people experiencing financial hardship, homelessness, mental illness, and SUD are greatly needed. New and unconventional programming, such as conditional financial incentives,

⁵² Kasaie P et al. *Multimorbidity in people with HIV using ART in the US: projections to 2030*. Conference on Retroviruses and Opportunistic Infections, abstract 102, 2021.

⁵³ Crabb Breen, et al. *Accelerated aging with HIV begins at the time of initial HIV infection*. Published: 6/30/22 DOI: <https://doi.org/10.1016/j.isci.2022.104488>

⁵⁴ <https://www.hiv.gov/hiv-basics/living-well-with-hiv/taking-care-of-yourself/aging-with-hiv>

⁵⁵ <https://www.medicalnewstoday.com/articles/growing-old-with-hiv>

also known as contingency management, must be expanded, as well as advances in antiretroviral therapy such as long acting injectables, particularly for individuals facing the most complex life circumstances. For communities most impacted by HIV, the importance of addressing barriers to care and ensuring PLWH are informed and able to easily access various programs and resources will be important.

c. Prevent New HIV Transmissions by Using Proven Interventions, Including PrEP/PEP & SSPs

PrEP/PEP: Increasing the number of people who take advantage of and have access to clinical preventive services, such as PrEP, continues to be a major public health challenge. Despite widely available PrEP resources and providers, less than four in ten persons with an indication for PrEP report taking it. Significant progress has been made to limit PrEP associated costs as a barrier to uptake; most health insurance plans now cover most PrEP associated health care costs, with public and private programs available to cover out-of-pocket costs based on income. Unfortunately, assistance programs require eligibility screening and paperwork, which can deter some clients. Clear and direct messaging about PrEP from appropriate community stakeholders is greatly needed to address mistrust and combat misleading information. Health care systems must adapt to make PrEP initiation and its continued use as easy as possible so that individuals with a continued indication are retained in care.

Mistrust of new pharmacologic interventions and medical providers in communities of color are understandable and justifiable given the history of mistreatment of Black Americans, Native Americans, and other people of color, as unwilling subjects of medical research and continued racial biases in access to and the delivery of health care services. Unsurprisingly, the uptake of PrEP among Black and Latinx MSM and transgender persons has consistently been lower compared to their White counterparts. In addition, many individuals incorrectly believe that PrEP will be too expensive and therefore inaccessible. While federal, state, and local programs that support PrEP at low to no-cost remain in place; community-based organizations, medical providers, and public health departments all have a role to play to help address misinformation and mistrust as a step towards deconstructing institutional racism and improving healthcare access patterns. The Commission's *Black/African American (AA) Community Task Force*⁵⁶ recommended increasing culturally sensitive PrEP advertising designed with input from the very communities it is attempting to reach, including Black/African American cisgender women, transgender individuals and MSM. In addition, voices of influential individuals through social media and marketing may help destigmatize both HIV and PrEP use and could potentially activate some individuals to take action.

For PrEP to reach the individuals who would most benefit from this prevention tool, health care partners across all sectors and disciplines must not only understand its clinical use, but, more importantly, be mindful and comfortable in their approach to discussing sexual behaviors with patients, ideally in an open non-judgmental manner. The network of LAC PrEP Centers of Excellence (COEs) was launched in 2016 with the goal of creating culturally competent access points where patients can also receive assistance navigating PrEP-related cost and health insurance coverage issues. Since the FDA approval of PrEP, the number of medical providers in LAC who report being a PrEP provider has steadily increased.¹² Recently, 39 Federally Qualified Health Centers (FQHCs) in LAC were funded directly through the federal Ending the HIV Epidemic initiative to expand their PrEP and HIV prevention efforts. Additionally, recent California legislation and policy changes have further expanded PrEP access points to include pharmacies⁵⁷ and telemedicine providers.

⁵⁶ Now the Black/African American Caucus of the LA County Commission on HIV

⁵⁷ With the passing of California's Senate Bill 159, pharmacists are now allowed to directly provide PrEP and post exposure prophylaxis (PEP).

An outstanding concern regarding PrEP uptake is its duration of use among individuals with continued risk. Discontinuation of PrEP is likely due to multiple factors, including pill fatigue, administrative barriers, and competing life demands. To ensure consistent, sustained access for clients at highest risk for HIV and other STDs in sexual health and prevention services and PrEP services, providers must develop more systematic and innovative ways of staying engaged with their clients. PrEP providers can reduce barriers to care for follow up appointments by offering telemedicine visits and allowing patients to come in only when laboratory work is needed. Expansion of technology to allow for accurate and sensitive home or self-collected HIV and STD tests will be a significant step toward further minimizing the frequency and length of time for medical visits and ensuring PrEP adherence. Many clients, especially younger individuals, prefer digital forms of communication and care, yet many community health centers still lack secure technology platforms to facilitate easier communication with patients.

DHSP and stakeholders must continue to promote all PrEP access points to further increase uptake. Studies have demonstrated that the “2-1-1” PrEP regimen⁵⁸ (where an individual takes two pills 2 to 24 hours before sex, one pill 24 hours after the initial dose, and one final pill 24 hours later), as well as long-acting injectable PrEP options, are important alternatives to oral daily PrEP. These alternate regimens have the added benefit of being attractive for individuals with pill fatigue or those struggling with adherence issues. Lastly, providers must be aware of clients who have or continue to utilize PEP, the use of antiretroviral drugs for people who are HIV- negative after a single high-risk exposure to stop HIV acquisition. Clients utilizing PEP should be connected to PrEP service providers to further prevent HIV transmission and acquisition. Although providers must acknowledge that for some clients, repeated use of PEP overtime may be the most beneficial form of biomedical prevention.

Syringe Services Programs: Historical data in LAC have shown injection drug use (IDU) to be a consistent, but less common risk factor for HIV transmission, accounting for less than 5% of HIV cases annually. However, recent increases in opioid and methamphetamine use via both injection drug use and non-injection drug use is concerning. Additionally, the rise of conditions that contribute to drug use, such as economic inequality, homelessness and untreated mental illness are pervasive in LAC, increasing our susceptibility to an IDU outbreak. Fortunately, syringe services programs (SSPs) are legal under California law, but programs in LAC experience fragmented or insufficient support from County and City of Los Angeles partners. In addition, LAC DPH funded SSPs continue to be small in scale, including only nine agencies funded at modest levels through the DPH SAPC program. Of the nine currently funded EOP agencies, only two currently provide HIV, STD, and hepatitis C (HCV) testing. Unfortunately, there is limited data and an absence of an in-depth analysis to confirm the impact of the LAC DPH-supported SSP programs, including data tied to linking clients to testing, other HIV prevention and care resources as well as Hepatitis and substance use disorder services. LAC has recently increased our investment in this area and we plan to continue to enhance the SSP service portfolio to ensure clients are linked to HIV prevention and treatment services and allow for more robust data collection. Despite recent legislative setbacks, we will also continue to support the creation of supervised drug consumption sites and services. Supervised Consumption Sites (SCS) are designated sites where people can use pre-obtained drugs under the safety and support of trained personnel. SCS have been implemented across over 200 sites in countries around the world and have been proven to save lives.⁵⁹

⁵⁸ There is scientific evidence that the “2-1-1” schedule provides effective protection for cisgender MSM when having anal sex without a condom, however, to date, we don’t know how “on-demand” PrEP works for heterosexual cisgender men and women, people who inject drugs, and transgender persons.

⁵⁹ Gostin LO, Hodge JG, Gulinson CL. Supervised injection facilities: legal and policy reforms. *JAMA*. 2019; 321(8):745-746.

d. Respond Quickly to Potential HIV Outbreaks to Get Needed Prevention and Treatment Services to People who Need Them:

The use of client-level data reported to the public health department to identify and target PLWH for contact tracing and linkage to services has a long precedent that continues today. The use of this client data for expanded HIV prevention and outreach efforts, however, is relatively recent. For decades, national guidelines and state laws restricted access and use of client-level HIV surveillance data to traditional surveillance functions, such as generating aggregated reports to describe population-based trends among PLWDH. While these limits on the use of surveillance data in the early days of the HIV epidemic as a way to protect the privacy of PLWH were understandable, these laws severely limited the ability of public health staff to use available information to further advance outbreak investigation efforts. Fortunately, we find ourselves in a different era where data driven HIV public health strategies, such as data-to-care, the use of geospatial analysis, and molecular cluster analysis are available (and required) and can be leveraged to ensure that the HIV public health response is more targeted and timely, and has the greatest impact. These activities require real-time access to client-level surveillance data and will be carried out regularly to not only identify individuals who need enhanced services, but to also detect and rapidly respond to early clusters or outbreaks of HIV in the community.

Partner Services: The CDC describes Partner Services as a continuum of clinical evaluation, counseling, diagnostic testing, and treatment designed to increase the number of infected persons brought to treatment and to reduce transmission among sexual networks.⁶⁰ Partner services is a key strategy for identifying people with HIV infection—those with undiagnosed infection and those with diagnosed infection who are not receiving HIV medical care—and helping them access care and treatment. All persons with newly diagnosed HIV infection should receive Partner Services to help them identify sex and needle-sharing partners who may also be infected or may be at very high risk for becoming infected. These partners can then be notified of their potential exposure and offered HIV testing. Those who test positive for HIV can then be linked to HIV medical care and other services. Those who test negative can then be linked to PrEP, SSP and other prevention services.

DPH employs Public Health Investigators (PHI, aka Disease Intervention Specialists) to implement both HIV and STD Partner Services (PS) activities. Currently, LAC's integrated HIV/STD disease investigation and PS program is implemented by staff who work within two separate divisions within the Department of Public Health: DHSP and Community and Field Services (CFS). DHSP PHIs, based at a centralized office, focus on syphilis and HIV partner services while CFS PHIs, based in 12 district offices throughout LAC, focus on HIV/STD and other communicable diseases assigned by the DPH.

While the Partner Services program in LAC has been mostly successful in interviewing newly diagnosed clients, there is opportunity to further expand the program's capacity to ensure all newly diagnosed clients and their partners are being interviewed in a timely and more efficient manner. In LAC, improved data system integration, easier data access, and increased staffing will improve the ability of LAC DHSP to reach all newly diagnosed persons with HIV. The latest estimate suggests that 73% of newly diagnosed persons with HIV in LAC receive an offer of Partner Services around the time of their diagnosis, but only 46% of those newly diagnosed are interviewed and only 10% name contacts. There is an opportunity to build staff capacity within the Partner Services program as well as expand partnerships with providers at high volume HIV/STD clinical testing sites to 1) establish more on-site counseling and education for persons testing positive within clinics, 2) promote rapid linkage to care and treatment efforts, and 3) reinforce community driven service sites that support and empower clients to prioritize their wellness and connect identified partners with critical HIV testing and/or PrEP. In addition, Partner Services will need to adapt to new technologies in order to respond to the use of web-based platforms, mobile apps, and other internet-based modalities that facilitate identifying and connecting with partners to testing, prevention, or care.

⁶⁰ <https://www.cdc.gov/std/treatment-guidelines/clinical-partnerServices.htm>

4. SITUATIONAL ANALYSIS

In response to the steady increase of syphilis cases and the increasingly scarce human and financial resources available to aggressively investigate all cases and interrupt the transmission of new infections, DPH has employed and implemented a priority setting process to further improve local disease investigation efforts, in particular HIV partner services. The three-point plan to improve HIV partner services includes HIV surveillance system improvements, organizational restructuring and enhanced HIV training for PHIs.

In 2021, DHSP hired seven new Public Health Investigator Trainees. The County will also hire additional PHIs to move closer towards meeting the large needs based on the high HIV and syphilis rates. Key to expanding and improving the local infrastructure is updating the existing training curriculum and adding more mentoring and hands-on training to provide better disease intervention for the very complex, high priority HIV and syphilis cases. Additional improvements are planned in quality improvement and epidemiological analysis to inform the current needs and practices as well as to inform incident trends; ultimately, to use data-to-care/action strategies in real time to detect, intervene, and prevent new cases. One other important upgrade is a new data management system, IRIS, which will enhance the workflow and case management system in comparison to the current system, STD Casewatch. IRIS will also integrate data systems that allows for efficiencies in conducting searches in HIV surveillance and other key databases.

Linkage Re-engagement Program: At DHSP, the Linkage and Re-engagement Program (LRP) is staffed by a team of health navigators and supervised by a social worker. LRP provides intensive case management and longitudinal support to PLWDH who are out of care, who are facing challenging life circumstances, and who have multiple co-morbid, mental health or SUD conditions. While linkage and re-engagement activities are the primary contracted responsibility of clinics and organizations that provide direct services to clients, LAC DHSP offers LRP as a complementary service designed to locate and connect the hardest to reach clients to the health care system. The majority of clients served by LRP are referred by their medical provider after they have fallen out of care and have been lost to follow-up. Other clients in need of LRP services are identified through data-to-care analyses, because they are high need for intensive case management such as pregnant women, individuals recently released from jail, and individuals who are identified as part of a growing HIV transmission cluster.

HIV Molecular Cluster Detection: In 2018, LAC adopted the use of the CDC's HIV TRACE program to identify priority molecular clusters (defined as a group of 5 or more persons whose HIV genotype is identified as being highly similar and a transmission cluster requiring additional review and intervention.) Because HIV has a high mutation frequency, individuals whose HIV genotypes are highly similar are likely connected through recent sexual or social networks where there is ongoing HIV transmission. In addition, there is a high likelihood that persons who may be part of new cluster are unaware of their HIV status or know their status but are not virally suppressed. LAC staff perform molecular cluster analysis of available surveillance and programmatic data to determine if the individuals are in care, virally suppressed, and if they need contact and engagement from linkage to care, re-engagement or partner services/notification teams. Given the novel nature of molecular cluster detection, in late 2019 LAC DPH launched an effort to engage community stakeholders regarding its use and assess potential unintended consequences. LAC DHSP provided an overview of molecular surveillance to the Commission on HIV to provide background information, address community concerns, address misperceptions related to the use of data, and review the potential legal ramifications and privacy issues. Planned activities for further community dialogue were put on hold due to the deployment of staff to the local COVID-19 response, however they have recently resumed. As a part of continued community engagement and awareness on molecular cluster detection and the monitoring of cluster outbreaks, DHSP will develop a communication strategy for community members and organizations in 2022 and beyond.

More recently, LAC DHSP has begun to identify emerging HIV diagnosis trends using a complementary methodology called time-space cluster analysis using case surveillance data. Time-space alerts determine whether the number of new cases in the prior 12 months is greater than expected baseline levels across different geographic areas and sub-populations, providing insight into where and among whom to prioritize early investigation and interventions to prevent onward transmission.

As we continue to move forward with EHE and develop new or strengthen existing partnerships with community stakeholders and service providers, LAC DHSP will continue to adopt common language and improve understanding of the Respond Pillar. This will be important to advance strategies designed to support the adoption of this new technology, more efficiently serve clients in need, and prevent outbreaks. Successful EHE efforts are strongly dependent on the extensive partnerships between LAC's HIV medical homes, Medical Care Coordination teams, vast network of HIV support services providers, leaders from the most impacted communities, and a broad-based coalition of non-traditional service partners. An integrated data management system for case management and surveillance data is foundational to future programmatic enhancements. LAC DPH's Informational Technology branch has begun to add HIV and STDs to its new surveillance data system for all communicable diseases; the new system will offer large-scale improvements to overall data management, facilitate data linkages across diseases, and improve timely access to surveillance data for staff working with clients. We are hopeful that the social acceptance of contact tracing for COVID-19, and the societal shift in understanding its importance in disease investigation will translate into improved HIV case-finding efforts under the Respond Pillar.

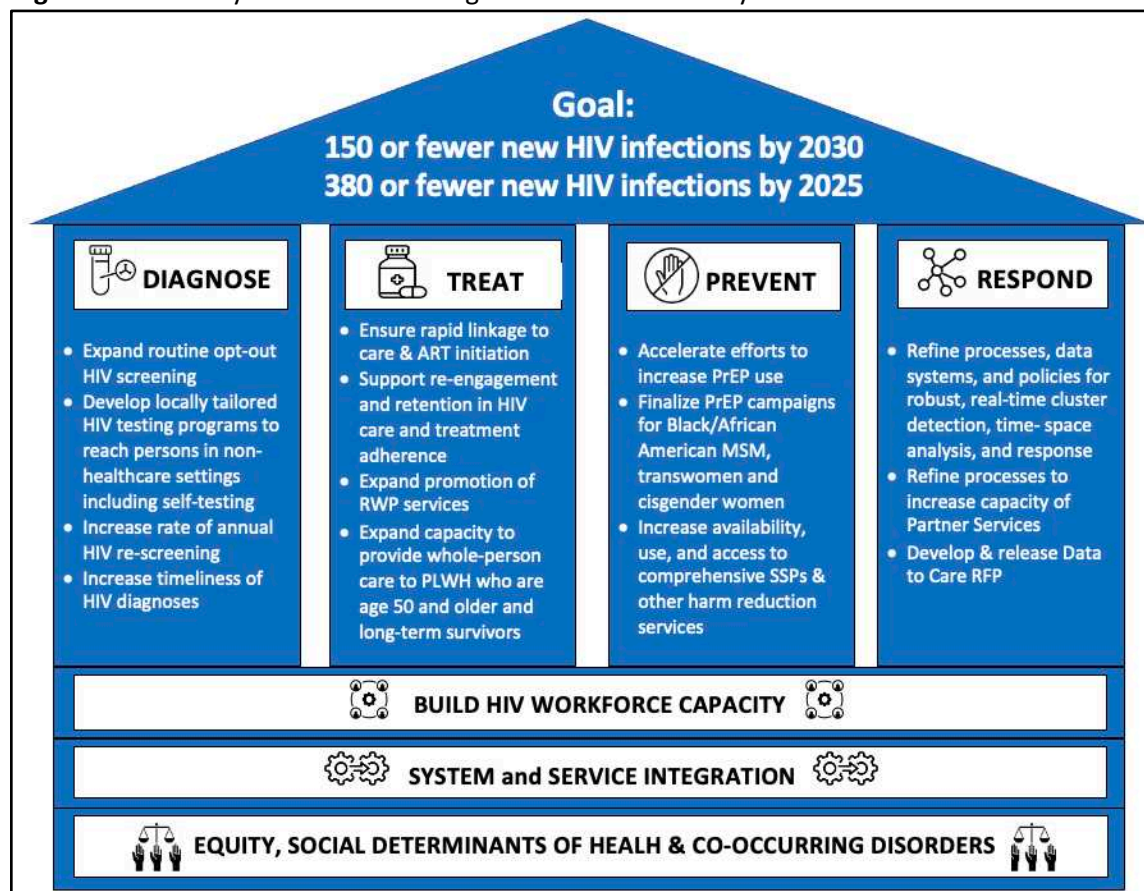
Priority Populations: Based on epidemiologic and needs assessment data, the priority populations for the Integrated Plan are: Black/African American MSM, Latinx MSM, women of color, people who inject drugs, transgender persons, youth under 30 years of age and PLWH aged 50 and older. These populations are inclusive of the priority populations in the EHE with the addition of the 50 and older population group. Although these populations will be prioritized, the County's HIV portfolio will continue to support *all* populations affected by HIV and will not diminish efforts to prevent, diagnose, and treat HIV for populations who remain a critical concern, including people experiencing unstable housing or homelessness, among others.

Capacity Building & HIV Workforce: For many years, there has been a resounding call from frontline HIV service providers and others to provide the HIV workforce with the tools, resources, and support to maintain their health and wellbeing while continuing to diligently serve people affected by and living with HIV. The jurisdiction is committed to exploring additional opportunities to support frontline workers by addressing staff burnout, identifying and addressing training needs, and supporting continued professional development and advancement, all of which will improve the quality of services and strengthen the local HIV response. LAC DHSP will continue to work with the AETCs and the California Prevention Training Center to identify trainings to support the HIV workforce, with a particular focus on client-centered and trauma-informed approaches to HIV care. Given recent events and persistent social injustices, including COVID-19, a housing crisis, and worsening economic, racial and social injustice, the emotional and physical capacity of individuals, organizations, and the HIV workforce continues to be strained and tested. We recognize the need to support programs and services that 1) address intersectional issues that go beyond HIV prevention, care and treatment needs, 2) support PLWH with meeting basic human needs and 3) better support the HIV workforce. We will continue to encourage organizations to diversify the HIV workforce by hiring diverse employees to promote cultural competency, mirror the populations most impacted by the HIV epidemic, and combat systemic racism as we operationalize all Pillars.

Section V: Goals and Objectives

The EHE Plan forms the core of the Integrated Plan's goals, objectives and strategies. In addition to the four pillars: diagnose, treat, prevent and respond, we have added key foundational and cross-pillar elements that are essential to supporting each pillar's strategies and activities and our broader HIV-related goals. As depicted in Figure 33, these foundational elements include Building Workforce Capacity; System and Service Integration; and Equity, Social Determinants of Health and Co-Occurring Disorders.

Figure 33: Four Key Pillars and a Strong Foundation Necessary to Achieve HIV-Related Goals



Pillar I: Diagnose

Goal: Diagnose all people with HIV as early as possible

Objectives:

1. By 2025, increase the percentage of PLWH who are aware of their status to 95%, from a baseline of 89%.
2. By 2025, reduce the number of undiagnosed PLWH from an estimated 6,800 to an estimated 3,067.⁶¹
3. By 2026, decrease the proportion of people newly diagnosed with HIV who are in the late stage⁶² of HIV disease at time of diagnosis from 20% to 15%.

Strategy 1A: Expand or implement routine opt-out HIV screening in healthcare and other settings, such as emergency departments (EDs) and community health centers (CHCs) in high prevalence communities.

Activity 1A.1: Assess and monitor the degree that HIV testing is occurring county-wide. Identify infrastructure and healthcare system issues to determine the feasibility of expanding routine opt-out testing.

Activity 1A.2: Expand the number of EDs and CHCs in high prevalence communities performing routine opt-out HIV screening.

Activity 1A.3: Identify additional opportunities in healthcare and non-healthcare settings where HIV testing can be included, such as routine STD screening sites and substance use treatment centers, among others.

Strategy 1B: Develop locally tailored HIV testing programs to reach persons in non-healthcare settings including home/self-testing.

Activity 1B.1: Assess and monitor the degree that HIV testing is occurring county-wide (see Strategy 1A). Identify infrastructure and healthcare system issues to determine the feasibility of launching a county-wide rapid HIV self-test program.

Activity 1B.2: Develop guidance on HIV self-testing, including linkage to care and prevention services, a quality assurance protocol, and assess readiness of providers to implement self-testing.

Activity 1B.3: Assess Take Me Home self-testing initiative utilization, barriers and facilitators and make improvements as necessary.

Activity 1B.4: Expand use of HIV self-testing among at risk individuals unlikely to receive traditional in-person HIV testing by developing and expanding other types of self-testing (in addition to Take Me Home) to ensure equitable access.

Strategy 1C: Increase the rate of annual HIV re-screening among persons at elevated risk for HIV in both healthcare & non-healthcare settings. Implement technology to help providers identify clients due for HIV re-screening & increase ways of maintaining communication with clients.

Activity 1C.1: Develop provider-to-patient communication tools to support providers in identifying at risk clients who are due for HIV re-screening and increase systematic ways of maintaining communication with clients.

Activity 1C.2: Develop a plan for evaluating impact of the provider-to-patient communication tools on client re-screening.

Activity 1C.3: Expand implementation & use of provider-to-patient communication tools among LAC DHSP funded HIV prevention providers.

⁶¹ Estimated based on 59,400 PLWH in 2021 and assuming 4,450 new infections and 2,500 deaths by 2025 = $\sim 61,350 \times 5\% = 3,067$ Undiagnosed PLWH in 2025

⁶² Late stage is Stage 3 HIV disease, the criteria being either CD4 < 200 cells/ μ L within 90 days of HIV diagnosis or a diagnosis of an opportunistic illness within 90 days of HIV diagnosis

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Activity 1C.4: Explore the use of client incentives to maintain re-screening adherence.
Strategy 1D: Increase the timeliness of HIV diagnoses from point of infection by increasing access to testing and increasing awareness of risk
Activity 1D.1: Increase integration of HIV testing/screening with other STDs and HCV
Activity 1D.2: Increase the number of STD & HIV express clinics in LAC, especially in Health Districts disproportionately impacted by HIV
Activity 1D.3: Increase community awareness of HIV testing options through advertising and promotional events in multiple languages
Activity 1D.4: Work with SAPC to ensure that all syringe service programs (SSPs) provide integrated testing/screening (HIV, STDs, HCV) and linkage to care
Activity 1D.5: Explore utilizing a Promotores/Community Health Worker model to increase sexual health literacy and awareness of HIV risk in priority populations
Activity 1D.6: Increase the capacity of Partner Services and Cluster Detection and Response to quickly identify and contact people who may be at risk of HIV/STD/HCV and direct them to testing services (see Respond Pillar activities)
Key Partners: FQHCs & Community Health Centers, Emergency Departments, HIV & STD testing providers, HIV prevention providers, private providers, academic medical provider training programs including colleges and universities, LAC Dept. of Health Services (DHS), LAC Dept. of Mental Health (DMH), LAC Sherriff's Department, homeless service providers, City of Long Beach and City of Pasadena Health Departments, LAC DPH Substance Abuse Prevention and Control Program (SAPC) and other DPH programs and divisions.
Potential Funding Resources: CDC EHE Program Implementation; HRSA RWP Part A; CDC Integrated HIV Surveillance and Prevention; State OA HIV Surveillance; SAPC Non-Drug Medi-Cal; EHE funding to FQHCs, Academic Institutions/Research, and AIDS Education and Training Centers
Outcomes: • Increased routine opt-out HIV screenings in healthcare and other institutional settings • Increased local availability of and accessibility to HIV testing services • Increased HIV screening and re-screening among persons at elevated risk for HIV infection • Increased knowledge of HIV status • Increased HIV diagnoses • Improved timeliness between HIV infection and diagnosis
Monitoring Data Source: DHSP HIV Surveillance (eHARS)
Expected Impact on HIV Care Continuum: Increase the percentage of PLWH who know their HIV status by 6% (89% to 95%).
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☒ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☐ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

Pillar II: Treat

Goal: Treat people with HIV rapidly and effectively to reach sustained viral suppression	
Objectives:	
1. By 2025, increase the proportion of people diagnosed with HIV who are linked to HIV care⁶³ within one month of diagnosis from 76% to 95%. 2. By 2026, increase the proportion of people diagnosed with HIV who are linked to care within 7 days from 54% (2020) to 65%. 3. By 2025, increase the proportion of PLWDH who are virally suppressed from 61% to 95%.	
Strategy 2A: Ensure rapid linkage to HIV care and antiretroviral therapy (ART) initiation for all persons newly diagnosed with HIV.	
Activity 2A.1:	Increase county-wide capacity to provide same-day rapid linkage to care during expanded hours and days for persons newly diagnosed with HIV.
Activity 2A.2:	Develop a network of HIV care providers who offer same day appointments with rapid ART disbursement.
Strategy 2B: Support re-engagement and retention in HIV care and treatment adherence	
Activity 2B.1:	Expand the use and capacity of peer navigators and/or community health workers for PLWH to increase health literacy, access services and address social determinants of health (housing, food insecurity, etc.)
Activity 2B.2:	Increase knowledge & awareness among both providers & community members about long acting injectables and other biomedical advances
Activity 2B.3:	Create and distribute list of clinical providers of color and LGBTQ culturally competent providers
Activity 2B.4:	Create and expand medical and supportive services for cisgender women living with HIV/AIDS. This includes services such as family housing, transportation, mental health, childcare, and substance abuse
Activity 2B.5:	Create and expand medical and supportive services for transgender persons living with HIV/AIDS
Activity 2B.6:	Advocate for appropriate allocation and maintenance of funding for the Trans, Gender Nonconforming and Intersex (TGI) Equity Fund created by the passage of AB-2521
Strategy 2C: Support re-engagement and retention in HIV care and treatment adherence, especially for persons who are not eligible for Ryan White Program-supported services, persons with mental illness, persons with substance use disorders, and unhoused persons.	
Activity 2C.1:	Comprehensively assess unmet mental health needs of PLWH and identify gaps and areas of improvement in the mental health provider network in LAC.
Activity 2C.2:	Develop partnerships to meet the SUD (particularly meth use disorder) needs of persons at risk for HIV or PLWH and improve the capacity of SUD providers to address the sexual health needs of clients and ensure access to HIV-related services, as needed.
Activity 2C.3:	Develop a report that summarizes critical gaps in the current system and makes recommendations for improvement and investment of County resources, including Ryan White Program funds.

⁶³ Linked to HIV care is defined as ≥ 1 CD4/VL/Genotype test reported

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Activity 2C.4: Leverage and monitor CalAIM to ensure their programs are appropriate and effective for PLWH
Activity 2C.5: Develop transitional case management programs that help PLWH transition from Ryan White Program into Medi-Cal, Medicare and CalAIM, and develop case management services that can monitor if care and support services are meeting the needs of PLWH post-transition.
Activity 2C.6: Expand the use of street medicine for unhoused PLWH and at-risk for HIV
Strategy 2D: Expand the promotion of Ryan White Program services to increase awareness, access to, and utilization of available medical care and support services for PLWH
Activity 2D.1: Assess how clients are currently learning about available RWP services. Identify existing and new resources to assist with promotion and educational outreach including, but not limited to, print materials and online resources
Strategy 2E: Develop and fund a housing service portfolio that provides rental subsidies to prevent homelessness among PLWH
Activity 2E.1: Determine processes and program operations for housing assistance that are aligned with federal funding guidance and restrictions
Activity 2E.2: Identify potential housing partners positioned to serve PLWH and implement an expanded housing program.
Strategy 2F: Explore the impact of conditional financial incentives to increase adherence to treatment for high acuity out-of-care PLWH
Activity 2F.1: Develop processes and program operations for a pilot program that is acceptable to clients and is aligned with federal funding guidance and restrictions
Activity 2F.2: Identify potential clinical sites, train staff on pilot processes, and implement program
Activity 2F.3: Develop a robust evaluation plan to determine continued use of financial incentives and potential for expansion to other populations
Strategy 2G: RFP: EHE Priority Populations Interventions
Activity 2G.1: Develop and release RFP to fund 7-10 contracts for identified interventions
Strategy 2H: Expand capacity to provide whole-person care to PLWH who are age 50 and older and long-term survivors⁵⁹
Activity 2H.1: Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services ⁶⁴
Activity 2H.2: Identify and implement best practices related to addressing psychosocial and behavioral health needs of older PLWH and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation ⁵⁹
Activity 2H.3: Review/update diagnostic screenings to include age-related conditions (i.e. screen for loneliness, ACEs, depression, anxiety, experiences of discrimination), using LA County Commission on HIV's Aging Task Force recommendations as a guide
Activity 2H.4: Screen patients for comprehensive benefits analysis and financial screening; and assess access to caregiving support

⁶⁴ Adapted from the NHAS, 2022-2025

Activity 2H.5: Review Home-Based Case Management service standards for alignment with OT and PT assessments
Key Partners: RWP-supported HIV service providers, HIV medical providers outside of RWP network, FQHCs and Community Health Centers, HIV and STD Testing Providers, HOPWA, CA Dept. of Healthcare Services; LAC DHS Housing for Health program, LAC Homeless Services Authority (LAHSA), additional housing and homeless service providers, immigrant rights groups, public and private health plans, LAC DMH, LAC DHS, and City of Long Beach and City of Pasadena Health Departments.
Potential Funding Resources: HRSA EHE; HRSA CARES; HRSA RWP Part A; HRSA RWP Part B; HRSA RWP Minority AIDS Initiative; CDC Medical Monitoring Project; EHE funding to FQHCs, Academic Institutions/Research, and AIDS Education and Training Centers.
Outcomes: • Increased rapid linkage to HIV medical care • Increased early initiation of ART • Increased support to providers for linking, retaining, and re-engaging PLWH to care and treatment • Increased capacity to serve PLWH 50 and older and long-term survivors • Increased utilization of RWP core services among PLWH • Increase viral suppression among PLWH
Monitoring Data Source: HIV Casewatch, DHSP HIV Surveillance (eHARS), Medical Monitoring Project (MMP)
Expected Impact on HIV Care Continuum: Increase the percentage of PLWDH who are linked to HIV care within 90 days by 19% & and who are linked to HIV care within 7 days by 11%. Increase viral suppression rate by 34% (from 61% to 95%).
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☒ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☐ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

Pillar III: Prevent

Goal: Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs)	
Objectives:	
1. By 2025, increase the proportion of persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 39%. 2. By 2025, increase the proportion of Black/African American persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 25%. 3. By 2025, increase the proportion of Latinx persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 38%. 4. By 2026, increase the percentage of EOPs and SSPs that provide HIV/STD testing and HCV screening from 20% to 80%.	
Strategy 3A: Accelerate efforts to increase PrEP use (particularly for populations with the highest rates of new HIV diagnoses and low PrEP coverage rates) by adopting new strategies at LAC funded PrEP Centers of Excellence tied to client retention, PrEP navigation, community education, supporting alternatives to daily PrEP, and expanding PrEP support groups; and promoting recent innovations	
Activity 3A.1:	Conduct an in-depth landscape analysis of current PrEP resources and services among primary care providers in high morbidity areas, among providers who serve transgender persons, women's health providers, and SUD providers.
Activity 3A.2:	Implement systematic and innovative strategies at LAC DHSP-funded PrEP Centers of Excellence for enhanced client communication to promote retention in PrEP and sexual health services.
Activity 3A.3:	Increase capacity of LAC DPH staff to provide more robust PrEP navigation services to clients served through County STD clinics, Partner Services, and those receiving PrEP/PEP at community pharmacies.
Activity 3A.4:	Disseminate simple fact-based social marketing PrEP messaging to increase knowledge and awareness of PrEP, alternatives to daily PrEP, how to access PrEP/PEP under SB 159, ⁶⁵ and help combat misinformation regarding cost, access, and safety.
Activity 3A.5:	Work with local stakeholders to identify the potential role for PrEP support groups or PrEP ambassadors to support new and continued PrEP use in affected communities.
Activity 3A.6:	Finalize PrEP campaigns for Black/African American MSM, transwomen and cisgender women, per the LA County Commission on HIV's Black/African American Community Task Force's Recommendations.
Activity 3A.7:	Increase knowledge & awareness among both providers & community members about long acting injectables and other biomedical advances (See 2.B.2).
Activity 3A.8:	Help build the capacity of pharmacies to prescribe PrEP/PEP and create a directory of pharmacies that have capacity to prescribe PrEP/PEP under SB159, potentially to be integrated into the GetPrEPLA website.
Activity 3A.9:	Develop a public health detailing campaign to expand the number of oral PrEP prescribers in LAC.

⁶⁵ SB 159 authorizes pharmacists to furnish PrEP and PEP without a physician prescription and prohibits insurance companies from requiring prior authorizations in order to obtain PrEP coverage.

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Strategy 3B: Increase availability, use, and access to comprehensive syringe services programs (SSPs) and other harm reduction services.	
Activity 3B.1:	Collaborate with the Los Angeles County Substance Abuse Prevention and Control Program to identify opportunities to increase the capacity of SSPs, improve the provision or linkage of SSP clients to HIV and STD prevention and treatment services, and expand the availability of contingency management services to persons with substance use disorder, including meth use.
Activity 3B.2:	Explore ideas for alternate models of prevention service delivery (e.g., vouchers which can be taken to pharmacies in exchange for clean syringes and HIV self-test kits).
Activity 3B.3:	Distribute information about the efficacy of SSPs to increase the health literacy of HIV providers and community members
Activity 3B.4:	Destigmatize syringe services/needle exchange and further integrate SSP providers into HIV-related work
Activity 3B.5:	Promote safe consumption/injection sites
Key Partners: FQHCs and Community Health Centers, PrEP Centers of Excellence, HIV and STD Testing Providers, LAC STD clinics, LAC SAPC; County of Los Angeles and City of Los Angeles-funded SSPs, pharmacies, general practitioners and private healthcare providers, family planning clinics (including Planned Parenthood), schools and colleges, community leaders and advocates, and Region IX PACE Program.	
Potential Funding Resources: CDC EHE Program Implementation; HRSA RWP Part A; HRSA RWP Part B; HRSA RWP Minority AIDS Initiative; CDC National HIV Behavioral Survey & TG Supplement; CDC Integrated HIV Surveillance and Prevention; State OA HIV Surveillance; SAPC Non-Drug Medi-Cal; County/City of LA SSP Funding; EHE funding to FQHCs, Academic Institutions/Research, and AIDS Education and Training Centers.	
Outcomes: • Increased referral and linkage of persons with indications for PrEP • Increased PrEP prescriptions compared to number with indications overall and in areas with high HIV diagnosis rates • Decreased racial and ethnic disparities in PrEP uptake • Increased capacity of SSP service providers to directly provide or link clients to HIV prevention and care services • Reduced new HIV infections	
Monitoring Data Source: Multiple PrEP monitoring and evaluation data, DHSP HIV Surveillance (eHARS), National HIV Behavioral Surveillance.	
Expected Impact on HIV Care Continuum: Increase the percentage of people with an indication for PrEP who access PrEP by 11%.	
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☐ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☐ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties	

Pillar IV: Respond

Goal: Respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them	
Objectives:	
1. By 2026, provide/disseminate at least 5 educational trainings/workshops or educational materials to increase awareness/knowledge related to cluster and outbreak detection and response 2. By 2025, increase the total proportion of persons newly diagnosed with HIV who are assigned for Partner Services (PS) to 95% from a 2021 baseline of 73% 3. By 2025, increase the total proportion of persons newly diagnosed with HIV who are interviewed for PS to 75% from a 2021 baseline of 46%	
Strategy 4A: Refine processes, data systems, and policies for robust, real-time cluster detection, time- space analysis, and response	
Activity 4A.1:	Develop a protocol, training materials, and standard operation plan.
Activity 4A.2:	Continue community engagement regarding the use of HIV molecular surveillance for cluster detection to inform its best use and identify and mitigate any unintended consequences.
Activity 4A.3:	Expand routine epidemiological analysis of recent infection by person, place, and time to identify hot-spot locations and sub-populations associated with recent infection to inform rapid investigation and intervention.
Activity 4A.4:	Educate HIV providers about the use and effectiveness of cluster detection
Strategy 4B: Refine current processes to increase capacity of Partner Services to ensure people newly diagnosed are interviewed and close partners are identified and offered services in a timely and effective manner.	
Activity 4B.1:	Increase capacity of LAC DHSP to provide Partner Services to all newly diagnosed persons in LAC.
Activity 4B.2:	Implement new STD surveillance system to enhance the identification and assignment of new HIV cases to LAC DPH staff for timely follow-up and Partner Services.
Activity 4B.3:	Educate HIV providers about the use and effectiveness of Partner Services
Activity 4B.4:	Explore increased use of community-embedded Partner Services
Strategy 4C: Data to Care RFP	
Activity 4C.1:	Develop and release RFP to fund up to 5 contracts for Data to Care activities.
Key Partners: California Office of AIDS, City of Long Beach and City of Pasadena Health Departments, HIV and STD Service Providers; CBA	
Potential Funding Resources: HRSA EHE; CDC Integrated HIV Surveillance and Prevention; EHE funding to Academic Institutions/Research	
Outcomes:	
• Increased number of newly diagnosed people with HIV interviewed by Partner Services staff • Improved data systems and surveillance data for real-time cluster detection and response • Improved policies and funding mechanisms to respond to and contain HIV clusters and outbreaks • Improved knowledge of networks to contain HIV transmission clusters and outbreaks	

5. GOALS & OBJECTIVES

• Increased number of testing providers offering HIV recent infection testing • Increased new HIV diagnoses
Monitoring Data Source: Partner Services data (STD Casewatch), Local HIV clusters
Expected Impact on HIV Care Continuum: Increase the number of people in networks affected by rapid transmission who know their HIV status, are linked to HIV medical care, and who are virally suppressed, and/or who are engaged in appropriate prevention services.
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☒ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☐ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

Workforce Capacity

Goal: Increase the capacity of the HIV workforce to diagnose and treat PLWH, prevent new HIV infections and reduce HIV-related disparities
Objectives: 1. By 2024, conduct a comprehensive assessment of the HIV workforce identifying strengths, needs and potential solutions, including an assessment of the true costs of services and how those services might be financed. 2. By 2026, implement training, technical assistance and necessary policy changes to increase workforce capacity as outlined in assessment findings and guided by the strategies below.
Strategy 5A: Increase the diversity and capacity of the workforce that delivers HIV prevention, care and supportive services to optimally reflect and serve the populations most impacted by HIV
Activity 5A.1: Conduct an assessment of Black/African American led agencies providing HIV services to identify training/technical assistance (TA) needs
Activity 5A.2: Provide TA and/or training for Black/African American led agencies to provide a more equitable playing field to successfully compete for solicitations, based on assessment findings
Activity 5A.3: Increase inclusion of peers/paraprofessionals in the workforce through training, mentorship, certification, supervision, reimbursement, and team functioning to assist with HIV, STD, HCV, and mental health and SUD service provision ⁵⁹
Activity 5A.4: Develop inventory of both formal and informal pipeline programs to prepare workers to work in the HIV/health field
Activity 5A.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations ⁵⁹

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Activity 5A.6: Based on results of workforce capacity assessment, review and revise service standards as necessary
Activity 5A.7: Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV
Strategy 5B: Ensure that the workforce is adequately prepared to deliver high-quality services in a culturally responsive manner
Activity 5B.1: Include harm reduction principles and the provision of trauma-informed care across provider trainings
Activity 5B.2: Provide gerontology training to Ambulatory Outpatient Medical, Oral Health, Medical Care Coordination and Mental Health services providers to improve awareness and understanding of age-related inequities in care and treatment
Activity 5B.3: Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work ⁵⁹
Activity 5B.4: Identify and make available succession planning and leadership development trainings/programs
Key Partners: AETC; CBAs; FQHCs and Community Health Centers, HIV and STD Testing Providers, HIV prevention providers, private providers, academic medical provider training programs including colleges and universities, LAC DHS, LAC DMH, LAC SAPC.
Potential Funding Resources: CDC, HRSA, SAMHSA
Outcomes: • Increased capacity to provide culturally responsive services to PLWH and people at-risk for HIV
Expected Impact on HIV Care Continuum: Increased number of PLWH who know their status; Increased number of PLWDH that are linked to care within 30 days, retained in care and virally suppressed.
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☒ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☒ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

System and Service Integration

Goal: Integrate systems and services to address the syndemic of HIV, STDs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence⁵⁹

Objectives:

1. By 2026, the LA County Division of HIV and STD Programs (DHSP) and/or the Commission on HIV (COH) will implement at least three internal (within LAC system) efforts to advance system and service integration
2. By 2026, DHSP and/or the COH will implement at least three external efforts to advance system and service integration

Strategy 6A: Increase cross-training and TA opportunities across fields/disciplines

Activity 6A.1: Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs⁵⁹

Activity 6A.2: Expand opportunities and mechanisms for information sharing and peer-to-peer technical assistance amongst HIV/STD/MH/SUD/Housing providers⁵⁹

Activity 6A.3: Support training for housing service providers on needs of PLWH and LGBTQI persons to improve cultural competencies among staff

Activity 6A.4: Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services⁵⁹

Activity 6A.5: Increase capacity of FQHCs that provide HIV-related services to screen for and treat HCV / Increased integration of HIV and HCV services

Strategy 6B: Leverage the Alliance of Health Integration initiative to integrate services within LA County publicly funded care systems.

Activity 6B.1: Strive to align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, and local partners⁵⁹

Activity 6B.2: Optimize RWP, Medicaid, Medicare, and other health systems to ensure they are used in a manner to deliver the highest quality of care for PLWH.

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Key Partners: RWP, Medi-Cal, Medicare, LAC Acute Communicable Disease Control (ACDC); LAC DHS, DMH, SAPC and other DPH programs
Potential Funding Resources: CDC, HRSA, SAMHSA
Outcomes: • Increased system and service integration
Expected Impact on HIV Care Continuum: Increased number of PLWH who know their status; Increased number of PLWDH that are linked to care within 30 days, retained in care and virally suppressed.
Alignment with NHAS Goals: ☒ Prevent New HIV Infections ☒ Improve HIV-Related Health Outcomes for PLWH ☒ Reduce HIV-Related Disparities & Health Inequities ☒ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

Equity, Social Determinants of Health and Co-Occurring Disorders

Goal: Achieve health equity by addressing social determinants of health, stigma, & co-occurring disorders that fuel the HIV epidemic and HIV disparities
Objectives: 1. By 2026, increase the number of services and programs available to address meth use disorder by at least 25% 2. By 2026, increase the availability of mental health services for PLWH and at-risk for HIV by at least 25% 3. By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV in LA County by at least 25% 4. By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV among Black/African Americans in LA County by at least 25% 5. By 2026, increase the number of evidence-based or evidence-informed practices/programs that address SDH by at least 20%.
Strategy 7A: Advocate for an effective countywide response to SUDs, especially methamphetamine disorder
Activity 7A.1: Assess providers' ability to recognize and address meth use disorder
Activity 7A.2: Advocate for services and programs associated with methamphetamine use and HIV transmission
Activity 7A.3: Expand and enhance mental health services for people living with, affected by, or at risk of contracting HIV/AIDS.
Activity 7A.4: Support the building of community-based mental health services.
Strategy 7B: Advocate for an effective countywide response to the Sexually Transmitted Disease (STD) epidemic
Activity 7B.1: LA County Commission on HIV Public Policy Committee (PPC) will submit a letter to the Board of Supervisors (BOS) that will outline priorities/recommendations to improve the countywide STD response (based on a DPH report previously submitted to the BOS)
Activity 7B.2: The PPC will request a formal letter of support from the BOS to support the EHE budget request to the State of California
Strategy 7C: Address social determinants of health and stigma
Activity 7C.1: Create funding opportunities that specifically address social & structural drivers of health as they relate to BIPOC communities

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Activity 7C.2: Implement effective, evidence-based and evidence-informed interventions that address stigma and SDHs among PLWH or at risk for HIV
Activity 7C.3: Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors. ⁵⁹
Activity 7C.4: Ensure that the voices/perspectives of PLWH and people at-risk for HIV are represented in pandemic planning and response (
Activity 7C.5: Monitor and advocate for policies that support the following: • 7C.5a: Support the efforts of Measure J, the Alternatives to Incarceration and closure of Men's Central Jail and seek increased funding for services and programming through Measure J as well as through redistribution of funding for policing and incarceration. • 7C.5b: Improve systems, strategies and proposals that prevent homelessness, expand affordable housing, as well as prioritize housing opportunities for people living with, affected by, or at risk of transmission of HIV/AIDS, especially LGBTQ people • 7C.5c: Promote family housing and emergency financial assistance as a strategy to maintain housing • 7C.5d: Increase coordination among housing agencies to include intergenerational housing options • 7C.5e: Blend funding to support housing and rental assistance for seniors living with HIV • 7C.5f: Advocate for women's bodily autonomy in all areas of health care services including and not limited to full access to abortions, contraception, fertility/infertility services and family planning • 7C.5g: Eliminate discrimination against or the criminalization of people living with or at risk of HIV/AIDS including those who exchange sex for money (e.g., Commercial Sex Work).
Strategy 7D: Identify root causes and directly call-out systematic racist practices that have adversely affected Black/African American communities.
Activity 7D.1: Standardize the collection of race-based stratified program evaluation data
Activity 7D.2: Disseminate analysis of race-based stratified data via presentations and informational materials
Activity 7D.3: Implement cultural humility training among healthcare providers
Activity 7D.4: Address social and structural barriers with evidence-based interventions
Activity 7D.5: Build the capacity of Black-led organizations (see 5A.1 and 5A.2)
Strategy 7E: Add Quality of Life (Q of L) Indicators for PLWH to the Integrated Plan by 2023
Activity 7E.1: Examine the newly released Q of L Indicators for PLWH included in NHAS 2022-2025 Implementation Plan and decide which ones are applicable to LAC
Activity 7E.2: Identify baseline data for each QoL indicator from local MMP data and determine performance metrics to be added to Integrated Plan

5. GOALS & OBJECTIVES

Key Partners: FQHCs and Community Health Centers, HIV and STD Testing Providers, HIV prevention providers, private providers, academic medical provider training programs including colleges and universities, LAC DHS, LAC DMH, homeless service providers, and City of Long Beach and City of Pasadena Health Departments, LAC SAPC; Act Now Against Meth Coalition (ANAM).

Potential Funding Resources: CDC, HRSA, SAMHSA

Outcomes:

- Increase the number of services and programs available to address meth use disorder
- Increase the availability of mental health services for PLWH and at-risk for HIV
- Reduce the rates of syphilis, gonorrhea, chlamydia and HCV in LA County
- Reduce the rates of syphilis, gonorrhea, chlamydia and HCV among Black/African Americans in LA County
- Increase the number of evidence-based or evidence-informed practices/programs that address SDH

Monitoring Data Source: DHSP HIV Surveillance (eHARS)

Expected Impact on HIV Care Continuum: Increase the number of PLWH who know their HIV status; who are linked to HIV care within 90 days; who are retained in care and who are virally suppressed.

Alignment with NHAS Goals:

- ☒ Prevent New HIV Infections
- ☒ Improve HIV-Related Health Outcomes for PLWH
- ☒ Reduce HIV-Related Disparities & Health Inequities
- ☒ Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic among All Partners & Interested Parties

6. IMPLEMENTATION, MONITORING & FOLLOW-UP

Section VI: 2022-2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up Integrated Planning Approach

a. Implementation: To ensure that the Integrated Plan's goals and objectives are achieved, a detailed implementation plan has been developed which includes performance measures, responsible parties, and a timeline related to each activity (see Appendix 2). In addition to DHSP and the COH there are many key partners that will need to be engaged if the County's ambitious goals are to be reached. These partners include various departments and programs within the LAC system (e.g. DHS, DMH, SAPC, Sheriff's Department, etc.) as well as entities that are external to the LAC system (e.g. HIV service providers, academic institutions, FQHCs, AETC, CBA, HOPWA, etc.). Community members across the County, especially PLWH and people from priority populations also play a key role in the implementation and monitoring of the Integrated Plan. COH and DHSP will work together to coordinate the efforts of these partners by maintaining open lines of communication, information sharing, and closely monitoring progress towards achievement of activities.

The Integrated Plan provides guidance and direction to *all* stakeholders across the County that are invested in ending the HIV epidemic, regardless of the source(s) of funding that supports their work. Thus, the Plan's goals, objectives, strategies and activities can and should be utilized by all stakeholders to coordinate services and programs and align agency-specific plans.

b. Monitoring: The Commission on HIV, in collaboration with DHSP, will be responsible for monitoring progress towards achieving the Plan's goals and objectives. Specifically, the COH's Planning, Priorities and Allocations (PP&A) Committee will take the lead in monitoring progress, trouble-shooting barriers and leading the process for updating the Plan as needed. The COH has a dedicated staff person who will lead these efforts with PP&A. Two PP&A meetings every year will include a formal update on progress towards goals and objectives. In addition, the COH and DHSP will monitor progress yearly using the targets outlined in Table 8. This progress will be used to inform the annual update of the plan.

As noted, the Integrated Plan has been built upon the LAC EHE plan to ensure coordination and no duplication of efforts. DHSP provides regular EHE updates to the COH and also communicates EHE progress and updates through the use of a listserv. To facilitate the monitoring of both the EHE and the Integrated Plan, these activities will continue for the next five years.

c. Evaluation: To evaluate progress on the Integrated Plan's goals and objectives, the COH will carefully monitor each performance measure listed in Table 8 in addition to key data related to the SMART objectives. Analysis of the performance measures will be conducted twice per year by PP&A and findings will be presented to the Commission on HIV and community stakeholders at public meetings twice per year.

6. IMPLEMENTATION, MONITORING & FOLLOW-UP

Table 8: Yearly Performance Measure

GOALS & OBJECTIVES	2022	2023	2024	2025	2026
Diagnose all people with HIV as early as possible					
Increase the percentage of PLWH who are aware of their status to 95% by 2025. 2021 Baseline: 89%	90%	92%	94%	95%	95%
Reduce the number of undiagnosed PLWH from an estimated 6,800 to an estimated 3,067 by 2025. 2021 Baseline: 6,800	5,867	4,934	4,001	3,067	3,067
Decrease the proportion of people newly diagnosed with HIV who are in the late stage of HIV disease at time of diagnosis from 20% to 15% by 2026. 2020 Baseline: 20%	19%	18%	17%	16%	15%
Treat people with HIV rapidly and effectively to reach sustained viral suppression					
Increase the proportion of people diagnosed with HIV who are linked to HIV care w/in 1 month of diagnosis from 76% to 95% by 2025. 2020 Baseline: 76%	83%	87%	91%	95%	95%
Increase the proportion of people diagnosed with HIV who are linked to care within 7 days from 54% (2020) to 65% by 2026. 2020 Baseline: 54%	57%	59%	61%	63%	65%
Increase the proportion of diagnosed PLWH who are virally suppressed from 61% to 95% by 2025. 2021 Baseline: 61%	66%	73%	83%	95%	95%
Prevent new HIV transmissions by using proven interventions, including PrEP and SSPs					
Increase the proportion of persons prescribed PrEP with an indication for PrEP to at least 50% by 2025. 2022 Baseline: 39%	39%	42%	46%	50%	50%
Increase the proportion of Latinx persons prescribed PrEP with an indication for PrEP to at least 50% by 2025. 2022 Baseline of 38%.	39%	42%	46%	50%	50%
Increase the proportion of Black/African American persons prescribed PrEP with an indication for PrEP to at least 50% by 2025. 2022 Baseline of 25%.	30%	35%	40%	45%	50%
Increase the percentage of EOPs and SSPs that provide HIV/STD testing and HCV screening to 80%. 2022 Baseline: 20%	25%	35%	50%	75%	80%
Respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them					
Provide/disseminate at least 5 educational trainings/workshops or educational materials to increase awareness/knowledge related to cluster and outbreak detection and response.	1	1	1	1	1

6. IMPLEMENTATION, MONITORING & FOLLOW-UP

By 2025, increase the total proportion of persons newly diagnosed with HIV who are assigned for Partner Services (PS) to 95%. 2021 Baseline: 73%.	77%	83%	89%	95%	95%
By 2025, increase the total proportion of persons newly diagnosed with HIV who are interviewed for PS to 75%. 2021 Baseline: 46%.	53%	60%	67%	75%	75%
Increase the capacity of the HIV workforce to diagnose and treat PLWH, prevent new HIV infections and reduce HIV-related disparities					
By 2024, conduct a comprehensive assessment of the HIV workforce identifying strengths, needs and potential solutions, including an assessment of the true costs of services and how those services might be financed.			Assessment Completed		
By 2026, implement training, technical assistance and necessary policy changes to increase workforce capacity as outlined in assessment findings.			Activities implemented per assessment		
Integrate systems and services to address the syndemic of HIV, STDs, HCV, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence					
By 2026, the LA County Division of HIV and STD Programs (DHSP) and/or the Commission on HIV (COH) will implement at least three internal efforts to advance system and service integration		1 effort	1 effort	1 effort	
By 2026, DHSP and/or the COH will implement at least three external efforts to advance system and service integration		1 effort	1 effort	1 effort	
Achieve health equity by addressing social determinants of health, stigma, and co-occurring disorders that fuel the HIV epidemic and HIV disparities					
By 2026, increase the number of services and programs available to address meth use disorder by at least 25%	5%	10%	15%	20%	25%
By 2026, increase the availability of mental health services for PLWH and at-risk for HIV by at least 25%	5%	10%	15%	20%	25%
By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV in LA County by at least 25%	5%	10%	15%	20%	25%
By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV among Black/African Americans in LA County by at least 25%	5%	10%	15%	20%	25%
By 2026, increase the number of evidence-based or evidence-informed practices/programs that address SDH by at least 20%	5%	10%	15%	20%	20%

6. IMPLEMENTATION, MONITORING & FOLLOW-UP

d. Improvement: The Integrated Plan is meant to be a working document that is responsive to emerging issues in the field and data that reflect current realities. The COH, in collaboration with DHSP, will use the most current data as they become available to monitor progress and make improvements to the plan as necessary. CDC and HRSA program officers will be informed of any issues that may require revisions and plans to make improvements/adjustments will be vetted by them. In addition, the COH and DHSP will continuously seek feedback from community stakeholders, especially PLWH and those who represent priority populations to guide any proposed revisions.

PP&A will lead the process to update the Plan. Suggestions for revisions will be discussed at the two PP&A meetings dedicated to the Plan's review. The final decisions to update the Plan will be made by the Executive Committee, full COH planning body, and DHSP.

e. Reporting and Dissemination: The Commission on HIV meets monthly, which includes an annual meeting in the fall/winter. As all meetings are open to the public, they will be one of the primary vehicles through which Commissioners and community stakeholders, including PLWH, are updated on the progress of the plan. Formal updates will be scheduled at least two times per year, which will include progress on achieving the goals and SMART objectives outlined in the Integrated Plan, noting any barriers or facilitators to implementing planned activities.

As part of the regular Commission on HIV meetings, there are often presentations from our research partners which are opportunities for additional education for Commissioners. Every year, the Commission on HIV will use a minimum of two research presentations to focus on key aspects of the plan's implementation (e.g., PrEP uptake, street medicine, etc.). Individuals attending the presentations will be asked to complete a presentation evaluation form, which will include at least one question on the information presented regarding the plan. COH staff will collate the responses from these evaluations and present to the PP&A and Executive committees for review. This feedback will inform the annual update of the plan.

In addition to these meetings, the Commission on HIV has a website which will be used for updates on the plan. The COH will post any presentation materials from the updates. They will also maintain a link to the progress report, reflecting progress towards achieving the SMART objectives outlined in the plan. This will be updated as progress is reported, twice per year. Throughout the implementation and monitoring process, the COH and DHSP will work in tandem to coordinate activities with the EHE Steering Committee and the EHE Plan.

Section VII: Letter of Concurrence



LOS ANGELES COUNTY
COMMISSION ON HIV



510 S. Vermont Ave, 14th Floor • Los Angeles, CA 90020 • TEL (213) 738-2816 • FAX (213) 637-4748
HIVCOMM@LACHIV.ORG • <https://hiv.lacounty.gov>

December 1, 2022

Mario J. Pérez, MPH, Director
Division of HIV and STD Programs (DHSP)
Department of Public Health,
County of Los Angeles
600 South Commonwealth Avenue, 10th Floor
Los Angeles, CA 90005

Dear Mr. Pérez:

The Los Angeles County Commission on HIV (Commission), the integrated prevention and care HIV planning council for the Los Angeles County Eligible Metropolitan Area (EMA), concurs with the following submission by the Department of Public Health, Division of HIV and STD Programs (DHSP) in response to the guidance set forth for health departments and HIV planning groups funded by the Centers for Disease Control and Prevention's (CDC's) Division of HIV/AIDS Prevention (DHAP) and Health Resources and Services Administration's (HRSA's) HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, locally referred to as the Comprehensive HIV Plan (CHP).

The Los Angeles County Integrated HIV Prevention and Care Plan, 2022-2026 is Los Angeles County's third integrated HIV services plan. Led by the Los Angeles County Commission on HIV's Priorities, Planning and Allocations (PP&A) Committee, this plan was developed in partnership with DHSP and a vast array of community and organizational partners. The plan is developed in response to the Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022 and as such presents a blueprint for HIV services along the entire spectrum of HIV prevention and care. LA County's Integrated Plan was also developed to align with the California statewide integrated plan, and The National HIV/AIDS Strategy (2022–2025), and Ending the HIV Epidemic Plan for Los Angeles County, 2020-2025 (EHE Plan). The Commission concurs that the Integrated HIV Prevention and Care Plan submission fulfills the requirements described in the CDC/HRSA Integrated HIV Prevention and Care Plan Guidance.

The Commission has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA and affirms that it enumerates the populations most impacted by HIV, describes co-occurring conditions and social determinants that drive the HIV epidemic, and articulates local objectives and activities that align with the overarching goals of the National HIV/AIDS Strategy and the Ending the HIV

Epidemic federal initiative.

To develop the plan, planning steps were integrated into the overall work of the Commission. Integrated planning began in July of 2021 with a presentation at the Commission on HIV monthly meeting. Between July 2021 and November 2022, diverse community stakeholders were engaged in plan development through individual consultations, online surveys, focus groups, and various meetings with Commission subgroups and community coalitions such as the Service Provider Network meetings and the Long Beach HIV Planning Group, to name a few. In addition, the plan underwent a public comment period to harness feedback from the community at large. Moving forward, the tracking and monitoring of the plan will be led by the PP&A Committee, with an annual report developed to highlight successes and challenges.

We appreciate this opportunity to express our concurrence with the local planning efforts and activities and we look forward to continued collaboration to end the HIV epidemic.

Sincerely,

Bridget Gordon

Bridget Gordon, Co-Chair

Danielle Campbell

Danielle Campbell, Co-Chair

Luckie Alexander Fuller

Luckie Alexander Fuller, Co-Chair Elect

Appendix 1: CY 2022 – 2026 CDC DHAP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
Section I: Executive Summary of Integrated Plan and SCSN	<u>Purpose:</u> To provide a description of the Integrated Plan, including the SCSN and the approach the jurisdiction used to prepare and package requirements for submission Tips for meeting this requirement 1. Be sure to write the summary with enough detail to ensure the reader understands how you have met Integrated Plan requirements. 2. If you are using a combination of new and existing materials, be sure to describe how submitted materials relate to each other.		
1. Executive Summary of Integrated Plan and SCSN	Provide an overall description of the Integrated Plan, including the SCSN, and the extent to which previous/other plans/SCSNs inform this plan/SCSN, or provide an overall description of an existing plan/SCSN that meets all requirements and includes the information below.	New material submitted	

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
a. Approach	Describe approach to preparing the Integrated Plan submission (e.g., updated previously submitted plan, integrated sections of existing plans or other documents, developed an entirely new plan, etc.).	New material submitted	
b. Documents submitted to meet requirements	List and describe all documents used to meet submission requirements, including existing materials and newly developed materials used for each requirement.	New material submitted	2
Section II: Community Engagement and Planning Process	<u>Purpose:</u> To describe how the jurisdiction approached the planning process, engaged community members and stakeholders, and fulfilled legislative and programmatic requirements including: 1. SCSN 2. RWHAP Part A and B planning requirements including those requiring feedback from key stakeholders and people with HIV 3. CDC planning requirements Tips for meeting this requirement 1. Review of the HIV National Strategic Plan and the updated HIV strategy, when released. 2. This requirement may include submission of portions of other submitted plans including the EHE plan submitted as a deliverable for PS19-1906. 3. Be sure to provide adequate detail to confirm compliance with legislative and programmatic planning requirements.		

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	4. The community engagement process should reflect the local demographics. 5. The planning process should include key stakeholders and broad-based communities that include but are not limited to: people with HIV, funded-service providers, and stakeholders, especially new stakeholders, from disproportionately affected communities. See <i>Appendix 3</i> for required and suggested examples of stakeholders to be included. 6. Explain how the jurisdiction will build collaborations among systems of prevention and care relevant to HIV in the jurisdictions (e.g., behavioral health and housing services). 7. Include community engagement related to “Respond” and support of cluster detection activities.		
1. Jurisdiction Planning Process	Describe how your jurisdiction approached the planning process. Include in your description the steps used in the planning process, the groups involved in implementing the <u>needs assessment</u> and/or developing planning goals and how the jurisdiction incorporated data sources in the process. Describe how planning included representation from the priority populations. This may include sections from other plans such as the EHE plan. Please be sure to address the items below in your description	New material submitted	2

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
a. Entities involved in process	List and describe the types of entities involved in the planning process. Be sure to include CDC and HRSA-funded programs, new stakeholders (e.g., new partner organizations, people with HIV), as well as other entities such as HOPWA-funded housing service providers or the state Medicaid agency that met as part of the process. See <i>Appendix 3</i> for list of required and suggested stakeholders	New material submitted	6
b. Role of the RWHAP Part A Planning Council/Planning Body (not required for state-only plans)	Describe the role of the RWHAP Part A Planning Council(s)/Planning Body(s) in developing the Integrated Plan.	New material submitted	6
c. Role of Planning Bodies and Other Entities	Describe the role of CDC Prevention Program and RWHAP Part B planning bodies, HIV prevention and care integrated planning body, and any other community members or entities who contributed to developing the Integrated Plan. If the state/territory or jurisdiction has separate prevention and care planning bodies, describe how these planning bodies collaborated to develop the Integrated Plan. Describe how the jurisdiction collaborated with EHE planning bodies. Provide documentation of the type of engagement occurred. EHE planning may be submitted as long as it includes updates that describe ongoing activities.	New material submitted	6

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
d. Collaboration with RWHAP Parts – SCSN requirement	Describe how the jurisdiction incorporated RWHAP Parts A-D providers and Part F recipients across the jurisdiction into the planning process. In the case of a RWHAP Part A or Part B only plan, indicate how the planning body incorporated or aligned with other Integrated Plans in the jurisdiction to avoid duplication and gaps in the service delivery system.	New material submitted	7
e. Engagement of people with HIV – SCSN requirement	Describe how the jurisdiction engaged people with HIV in all stages of the process, including needs assessment, priority setting, and development of goals/objectives. Describe how people with HIV will be included in the implementation, monitoring, evaluation, and improvement process of the Integrated Plan.	New material submitted	7
f. Priorities	List key priorities that arose out of the planning and community engagement process.	New material submitted	7
g. Updates to Other Strategic Plans Used to Meet Requirements	If the jurisdiction is using portions of another local strategic plan to satisfy this requirement, please describe: 1. How the jurisdiction uses annual needs assessment data to adjust priorities. 2. How the jurisdiction incorporates the ongoing feedback of people with HIV and stakeholders. 3. Any changes to the plan as a result of updates assessments and community input. 4. Any changes made to the planning process as a result of evaluating the planning process.	New material submitted	8

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
Section III: Contributing Data Sets and Assessments	<u>Purpose:</u> To analyze the qualitative and quantitative data used by the jurisdiction to describe how HIV impacts the jurisdiction; to determine the services needed by clients to access and maintain HIV prevention, care and treatment services; to identify barriers for clients accessing those services; and to assess gaps in the service delivery system. This section fulfills several legislative requirements including: 1. SCSN 2. RWHAP Part A and B planning requirements including those requiring feedback from key stakeholders and people with HIV 3. CDC planning requirements Tips for meeting this requirement 1. This requirement may include submission of portions of other submitted plans including the EHE plan submitted as a deliverable for PS19-1906. <i>Please ensure that if using a previously developed plan that the data included describes the entire jurisdiction and not just a subsection of the jurisdiction such as an EHE priority county.</i> 2. Be sure to provide adequate detail to confirm compliance with legislative and programmatic planning requirements. 3. Include both narrative and graphic depictions of the HIV-related health disparities in the area including information about HIV outbreaks and clusters.		

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	4. The data used in this section should inform both the situational analysis and the goals established by the jurisdiction. 5. <i>Appendix 4</i> includes suggested data resources to assist with this submission including the Epidemiologic Snapshot.		
1. Data Sharing and Use	Provide an overview of data available to the jurisdiction and how data were used to support planning. Identify with whom the jurisdiction has data sharing agreements and for what purpose.	New material submitted	8
2. Epidemiologic Snapshot	Provide a snapshot summary of the most current epidemiologic profile for the jurisdiction which uses the most current available data (trends for most recent 5 years). The snapshot should highlight key descriptors of people diagnosed with HIV and at-risk for exposure to HIV in the jurisdiction using both narrative and graphic depictions. Provide specifics related to the number of individuals with HIV who do not know their HIV status, as well as the demographic, geographic, socioeconomic, behavioral, and clinical characteristics of persons with newly diagnosed HIV, all people with diagnosed HIV, and persons at-risk for exposure to HIV. This snapshot should also describe any HIV clusters identified and outline key characteristics of clusters and cases	New material submitted	9

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	linked to these clusters. Priority populations for prevention and care should be highlighted and align with those of the HIV National Strategic Plan. Be sure to use the HIV care continuum in your graphic depiction showing burden of HIV in the jurisdiction.	New material submitted	

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
3. HIV Prevention, Care and Treatment Resource Inventory	Create an HIV Prevention, Care and Treatment Resource Inventory. The Inventory may include a table and/or narrative but must address all of the following information in order to be responsive: • Organizations and agencies providing HIV care and prevention services in the jurisdiction. • HRSA (must include all RWHAP parts) and CDC funding sources. • Leveraged public and private funding sources, such as those through HRSA's Community Health Center Program, HUD's HOPWA program, Indian Health Service (IHS) HIV/AIDS Program, Substance Abuse and Mental Health Services Administration programs, and foundation funding. • Describe the jurisdiction's strategy for coordinating the provision of substance use prevention and treatment services (including programs that provide these services) with HIV prevention and care services. • Services and activities provided by these organizations in the jurisdiction and if applicable, which priority population the agency serves. • Describe how services will maximize the quality of health and support services available to people at-risk for or with HIV.	New material submitted	33

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
a. Strengths and Gaps	Please describe strengths and gaps in the HIV prevention, care and treatment inventory for the jurisdictions. This analysis should include areas where the jurisdiction may need to build capacity for service delivery based on health equity, geographic disparities, occurrences of HIV clusters or outbreaks, underuse of new HIV prevention tools such as injectable antiretrovirals, and other environmental impacts.	New material submitted	38
b. Approaches and partnerships	Please describe the approaches the jurisdiction used to complete the HIV prevention, care and treatment inventory. Be sure to include partners, especially new partners, used to assess service capacity in the area.	New material submitted	38

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
4. Needs Assessment	Identify and describe all needs assessment activities or other activities/data/information used to inform goals and objectives in this submission. Include a summary of needs assessment data including: 1. Services people need to access HIV testing, as well as the following status neutral services needed after testing: a. Services people at-risk for HIV need to stay HIV negative (e.g., PrEP, Syringe Services Programs) – Needs b. Services people need to rapidly link to HIV medical care and treatment after receiving an HIV positive diagnosis - Needs 2. Services that people with HIV need to stay in HIV care and treatment and achieve viral suppression – Needs 3. Barriers to accessing existing HIV testing, including State laws and regulations, HIV prevention services, and HIV care and treatment service – Accessibility	New material submitted	46
a. Priorities	List the key priorities arising from the needs assessment process.	New material submitted	68

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
b. Actions Taken	List any key activities undertaken by the jurisdiction to address needs and barriers identified during the needs assessment process.	New material submitted	68
c. Approach	Please describe the approach the jurisdiction used to complete the needs assessment. Be sure to include how the jurisdiction incorporated people with HIV in the process and how the jurisdiction included entities listed in <i>Appendix 3</i> .	New material submitted	69
Section IV: Situational Analysis	<u>Purpose:</u> To provide an overview of strengths, challenges, and identified needs with respect to several key aspects of HIV prevention and care activities. This snapshot should synthesize information from the Community Engagement and Planning Process in Section II and the Contributing Data sets and Assessments detailed in Section III. Tips 1. New or existing material may be used; however, existing material will need to be updated if used. 2. This section not only provides a snapshot of the data and environment for goal-setting but meets the RWHAP legislative requirement for the SCSN. 3. Jurisdictions may submit the Situational Analysis submitted as part of their EHE Plan to fulfill this requirement. <i>However, it must include information for the entire HIV prevention and care system and not just the EHE priority area or service system.</i> If using EHE plans to fulfill this		

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	requirement, be sure to include updates as noted below.		
1. Situational Analysis	Based on the Community Engagement and Planning Process in Section II and the Contributing Data Sets and Assessments detailed in Section III, provide a short overview of strengths, challenges, and identified needs with respect to HIV prevention and care. Include any analysis of structural and systemic issues impacting populations disproportionately affected by HIV and resulting in health disparities. The content of the analysis should lay the groundwork for proposed strategies submitted in the Integrated Plan's goals and objective sections. The situational analysis should include an analysis in each of the following areas: <u>Diagnose</u> all people with HIV as early as possible <u>Treat</u> people with HIV rapidly and effectively to reach sustained viral suppression <u>Prevent</u> new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs) <u>Respond</u> quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them	New material submitted	71

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	<i>Please note jurisdictions may submit other plans to satisfy this requirement, if applicable to the entire HIV prevention and care service system across the jurisdiction.</i>		
a. Priority Populations	Based on the Community Engagement and Planning Process in Section II and the Contributing Data Sets and Assessments detailed in Section III, describe how the goals and objectives address the needs of priority populations for the jurisdiction.	New material submitted	81
Section V: 2022-2026 Goals and Objectives	<u>Purpose:</u> To detail goals and objectives for the next 5 years. Goals and objectives should reflect strategies that ensure a unified, coordinated approach for all HIV prevention and care funding. Tips for meeting this requirement: - Recipients may submit plans (e.g., EHE, Getting to Zero, Cluster and Outbreak Detection and Response plan) for this requirement as long as it sets goals for the entire HIV prevention and care delivery system and geographic area. - Goals and objectives should be in SMART format and structured to include strategies that accomplish the following: - Diagnose all people with HIV as early as possible - Treat people with HIV rapidly and effectively to reach sustained viral suppression - Prevent new HIV transmissions by using proven interventions, including pre-exposure		

Requirement	Requirement Detail	Please indicate whether the jurisdiction created new material and/or the Title/File Name of any existing material attached to meet requirement	Page(s) Where Requirement is Addressed
	prophylaxis (PrEP), post-exposure prophylaxis (PEP) and syringe services programs (SSPs) d. <u>Respond</u> quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them. 4. The plan should include goals that address both HIV prevention and care needs and health equity.		
1. Goals and Objectives Description	List and describe goals and objectives for how the jurisdiction will diagnose, treat, prevent and respond to HIV. Be sure the goals address any barriers or needs identified during the planning process. There should be at least 3 goals and objectives for each of these four areas. See <i>Appendix 2</i> for suggested format for Goals and Objectives. <i>Please note jurisdictions may submit other plans to satisfy this requirement as long as they include goals that cover the entire HIV prevention and care service delivery system and geographic area.</i>	New material submitted	82
a. Updates to Other Strategic Plans Used to Meet Requirements	If the jurisdiction is using portions of another local strategic plan to satisfy this requirement, please describe any changes made as a result of analysis of data.		N/A

Section VI: 2022-2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up	<u>Purpose:</u> To describe the infrastructure, procedures, systems, and/or tools that will be used to support the key phases of integrated planning. In this section jurisdictions will detail how best to ensure the success of Integrated Plan goals and objectives through the following 5 key phases: 1. Implementation 2. Monitoring 3. Evaluation 4. Improvement 5. Reporting and Dissemination Tips for meeting this requirement 1. This requirement may require the recipient to create some new material or expand upon existing materials. 2. Include sufficient descriptive detail for each of the 5 key phases to ensure that all entities understand their roles and responsibilities, and concur with the process. 3. If you are submitting portions of a different jurisdictional plan to meet this requirement, you should include updates that describe steps the jurisdiction has taken to accomplish each of the 5 phases.		
1. 2022-2026 Integrated Planning Implementation Approach	1. Describe the infrastructure, procedures, systems or tools that will be used to support the 5 key phases of integrated planning to ensure goals and objectives are met	New material submitted	97

a. Implementation	2. Describe the process for coordinating partners, including new partners, people with HIV, people at high risk for exposure to HIV, and providers and administrators from different funding streams, to meet the jurisdictions Integrated Plan goals and objectives. Include information about how the plan will influence the way the jurisdiction leverages and coordinates funding streams including but not limited to HAB and CDC funding.	New material submitted	97
b. Monitoring	3. Describe the process to be used for monitoring progress on the Integrated Plan goals and objectives. This should include information about how the jurisdiction will coordinate different stakeholders and different funding streams to implement plan goals. If multiple plans exist in the state (e.g., city-only Integrated Plans, state-only Integrated Plans), include information about how the jurisdiction will collaborate and coordinate monitoring of the different plans within the state to avoid duplication of effort and potential gaps in service provision. Be sure to include details such as specific coordination activities and timelines for coordination. <i>Note: Recipients will be asked to provide updates to both CDC and HRSA as part of routine monitoring of all awards.</i>	New material submitted	97
c. Evaluation	4. Describe the performance measures and methodology the jurisdiction will use to evaluate progress on goals and objectives. Include information about how often the jurisdiction conducts analysis of the performance measures and presents data to the planning group.	New material submitted	97

d. Improvement	5. Describe how the jurisdiction will continue to use data and community input to make revisions and improvements to the plan. Be sure to include how often the jurisdiction will make revisions and how those decisions will be made.	New material submitted	100
e. Reporting and Dissemination	6. Describe the process for informing stakeholders, including people with HIV, about progress on implementation, monitoring, evaluation and improvements made to the plan.	New material submitted	100
f. Updates to Other Strategic Plans Used to Meet Requirements	If the jurisdiction is using portions of another local strategic plan to satisfy this requirement, please describe: 1. Steps the jurisdiction has already taken to implement, monitor, evaluate, improve, and report/disseminate plan activities. 2. Achievements and challenges in implementing the plan. Include how the jurisdiction plans to resolve challenges and replicate successes. 3. Revisions made based on work completed.	New material submitted	100
Section VII: Letters of Concurrence	Provide letters of concurrence or concurrence with reservation. Each letter should specify how the planning body was involved in the Integrated Plan development. Include a letter of concurrence for each planning body in the state/territory or jurisdiction. See <i>Appendix 6</i> for a sample Letter of Concurrence.		101
1. CDC Prevention Program Planning Body Chair(s) or Representative(s)		New material submitted	101
2. RWHAP Part A Planning Council/Planning Body(s) Chair(s) or Representative(s)		New material submitted	101

3. RWHAP Part B Planning Body Chair or Representative		N/A	
4. Integrated Planning Body	If submitting an EHE plan, please ensure that the EHE planning body concurs.	N/A	
5. EHE Planning Body	If submitting an EHE plan, please ensure that the EHE planning body concurs.	N/A	

Appendix 2: Implementation Plan

Pillar I: Diagnose

Goal: Diagnose all people with HIV as early as possible

Objectives:

1. By 2025, increase the percentage of PLWH who are aware of their status to 95%, from a baseline of 89%.
2. By 2025, reduce the number of undiagnosed PLWH from an estimated 6,800 to an estimated 3,067.⁶⁶
3. By 2026, decrease the proportion of people newly diagnosed with HIV who are in the late stage⁶⁷ of HIV disease at time of diagnosis from 20% to 15%.

Strategy 1A: Expand or implement routine opt-out HIV screening in healthcare and other settings (such as emergency departments and community health centers) in high prevalence communities.

Activity	Responsible Party	Performance Measure	Timeframe
1A.1: Assess and monitor the degree that HIV testing is occurring county-wide. Identify infrastructure and healthcare system issues to determine the feasibility of expanding routine opt-out testing.	DHSP	Written report/documentation	By 2023
1A.2: Expand the number of emergency departments and community health centers in high prevalence communities performing routine opt-out HIV screening.	DHSP; EDs; FQHCs	Number of EDs and CHC's performing routine opt-out HIV screening	By 2026
1A.3: Identify additional opportunities in healthcare and non-healthcare settings where HIV testing can be included, such as routine STD screening sites and substance use treatment centers, among others.	DHSP	Written report/documentation	By 2023

Strategy 1B: Develop locally tailored HIV testing programs to reach persons in non-healthcare settings including home/self-testing.

Activity	Responsible Party	Performance Measure	Timeframe
1B.1: Assess and monitor the degree that HIV testing is occurring county-wide (see Strategy 1A). Identify infrastructure and healthcare system issues to determine the feasibility of launching a county-wide rapid HIV self-test program.	DHSP	Written report/documentation	By 2023
1B.2: Develop guidance on HIV self-testing, including linkage to care and prevention services, a quality assurance protocol, and assess readiness of	DHSP	Written guidance	By 2023

⁶⁶ Estimated based on 59,400 PLWH in 2021 and assuming 4,450 new infections and 2,500 deaths by 2025 = $\sim 61,350 \times 5\% = 3,067$ Undiagnosed PLWH in 2025

⁶⁷ Late stage is Stage 3 HIV disease, the criteria being either CD4 < 200 cells/ μ L within 90 days of HIV diagnosis or a diagnosis of an opportunistic illness within 90 days of HIV diagnosis

providers to implement self-testing.			
1B.3: Assess Take Me Home self-testing initiative utilization, barriers & facilitators	DHSP	Written documentation	By 2023
1B.4: Expand use of HIV self-testing among at risk individuals unlikely to receive in-person HIV testing by promoting other types of self-testing (in addition to Take Me Home), as available and appropriate, to ensure equitable access.	DHSP	Report/ documentation	By 2023
Strategy 1C: Increase the rate of annual HIV re-screening among persons at elevated risk for HIV in both healthcare & non-healthcare settings. Implement technology to help providers identify clients due for HIV re-screening & increase ways of maintaining communication with clients.			
Activity	Responsible Party	Performance Measure	Timeframe
1C.1: Develop provider-to-patient communication tools to support providers in identifying at risk clients who are due for HIV re-screening and increase systematic ways of maintaining communication with clients.	DHSP; HIV prevention providers	Number of provider-to-patient communication tools	By 2023
1C.2: Develop a plan for evaluating impact of the provider-to-patient communication tools on client re-screening.	DHSP; HIV prevention providers	Evaluation Plan	By 2023
1C.3: Expand implementation & use of provider-to-patient communication tools among LAC DHSP funded HIV prevention providers.	DHSP; HIV prevention providers	Number of HIV prevention providers using new tools	By 2024
Activity 1C.4: Explore the use of client incentives to maintain re-screening adherence.			
Strategy 1D: Increase the timeliness of HIV diagnoses from point of infection by increasing access to testing and increasing awareness of risk			
Activity	Responsible Party	Performance Measure	Timeframe
1D.1: Increase integration of HIV testing with STD and HCV screening	DHSP	Number of CBOs/clinics that have integrated testing	By 2026
1D.2: Increase the number of STD & HIV express clinics in LA County, especially in Health Districts disproportionately impacted by HIV	DHSP; HIV clinics	Number & location of STD/HIV express clinics	2022-2026
1D.3: Increase community awareness of HIV testing options through advertising and promotional events in multiple languages	DHSP; HIV/STD testing providers	Number & type of advertisements and promotional events by languages	2022-2026
1D.4: Work with SAPC to ensure that all syringe service programs (SSPs) provide integrated testing/screening (HIV, STDs, HCV) and rapid linkage to care	DHSP; SAPC	Number of SSPs that provide integrated testing and LTC rate	2022-2026

1D.5: Explore utilizing a Promotores/Community Health Worker model to increase sexual health literacy and awareness of HIV risk in priority populations	DHSP; COH	Documentation of efforts	By 2023
1D.6: Increase the capacity of Partner Services and Cluster Detection and Response to quickly identify and contact people who may be at risk of HIV/STD/HCV and direct them to testing services (see Respond Pillar activities)	DHSP	Number of people reached through PS and CDR	By 2026

Pillar II: Treat

Goal: Treat people with HIV rapidly and effectively to reach sustained viral suppression

Objectives:

1. By 2025, increase the proportion of people diagnosed with HIV who are linked to HIV care⁶⁸ within one month of diagnosis from 76% to 95%.
2. By 2026, increase the proportion of people diagnosed with HIV who are linked to care within 7 days from 54% (2020) to 65%.
3. By 2025, increase the proportion of PLWDH who are virally suppressed from 61% to 95%.

Strategy 2A: Ensure rapid linkage to HIV care and antiretroviral therapy (ART) initiation for all persons newly diagnosed with HIV.

Activity	Responsible Party	Performance Measure	Timeframe
2A.1: Increase county-wide capacity to provide same-day rapid linkage to care during expanded hours and days for persons newly diagnosed with HIV.	DHSP - Quality Improvement Group	Number of people provided with same-day rapid LTC	By 2026
2A.2: Develop a network of HIV care providers who offer same day appointments with rapid ART disbursement.	DHSP	Established network	By 2023

Strategy 2B: Support re-engagement and retention in HIV care and treatment adherence

Activity	Responsible Party	Performance Measure	Timeframe
2B.1: Expand the use and capacity of peer navigators and/or community health workers for PLWH to increase health literacy, access services and address social determinants of health (housing, food insecurity, etc.)	DHSP; Service Providers	Number of agencies reporting increased use of PNs/CHW	By 2026
2B.2: Increase knowledge & awareness among both providers & community members about long acting injectables and other biomedical advances	AETC; DHSP; Providers	Number of trainings & educational materials	By 2026
2B.3: Create and distribute list of clinical providers of color and LGBTQ culturally competent providers	COH	Documented list	By 2023
2B.4: Create and expand medical and supportive services for cisgender women living with HIV/AIDS. This includes services such as family housing, transportation, mental health, childcare, and substance abuse	DHSP; COH; Providers	Number of services for cisgender women	By 2026

⁶⁸ Linked to HIV care is defined as ≥ 1 CD4/VL/Genotype test reported

2B.5: Create and expand medical and supportive services for transgender persons living with HIV/AIDS	DHSP; COH; Providers	Number of services for trans persons	By 2026
2B.6: Advocate for appropriate allocation and maintenance of funding for the Trans, Gender Nonconforming and Intersex (TGI) Equity Fund created by the passage of AB-2521	COH-Public Policy Committee & Trans Caucus	Meeting minutes	2022-2026
Strategy 2C: Support re-engagement and retention in HIV care and treatment adherence, especially for persons who are not eligible for Ryan White Program-supported services, persons with mental illness, persons with substance use disorders, and unhoused persons.			
Activity	Responsible Party	Performance Measure	Timeframe
2C.1: Comprehensively assess unmet mental health needs of PLWH and identify gaps and areas of improvement in the mental health provider network in LAC.	DHSP; DMH	Report on Unmet Mental Health needs	By 2022
2C.2: Develop partnerships to meet the SUD (particularly meth use disorder) needs of persons at risk for HIV or PLWH and improve the capacity of SUD providers to address the sexual health needs of clients and ensure access to HIV-related services, as needed.	DHSP; SAPC	Number & type of partnerships & capacity-building efforts	2022-2026
2C.3: Develop a report that summarizes critical gaps in the current system and makes recommendations for improvement and investment of County resources, including Ryan White Program funds.	DHSP	Written Report	By 2023
2C.4: Leverage and monitor CalAIM to ensure their programs are appropriate and effective for PLWH	DHSP & COH	Documentation of efforts to leverage and monitor	2022-2026
2C.5: Develop transitional case management service standards that help PLWH transition from RWP into Medi-Cal, Medicare and CalAIM, and develop case management service standards that can monitor if care and support services are meeting the needs of PLWH post-transition.	COH- Aging Caucus	Documented service standards	2022-2026
2C.6: Expand the use of street medicine for unhoused PLWH and those at-risk for HIV	DHSP	Street medicine units of service	2022-2026
Strategy 2D: Expand the promotion of Ryan White Program services to increase awareness, access to, and utilization of available medical care and support services for PLWH			
Activity	Responsible Party	Performance Measure	Timeframe
2D.1: Assess how clients are currently learning about available RWP services. Identify existing and new resources to assist with promotion and educational outreach including, but not limited to, print materials and online resources	DHSP	Documentation of assessment findings	By 2023
Strategy 2E: Develop and fund a housing service portfolio that provides rental subsidies to prevent homelessness among PLWH			
Activity	Responsible Party	Performance Measure	Timeframe

Activity 2E.1: Determine processes and program operations for housing assistance that are aligned with federal funding guidance and restrictions	DHSP	Written findings	By 2023
Activity 2E.2: Identify potential housing partners positioned to serve PLWH and implement an expanded housing program.	DHSP	Number of partners identified	By 2023
Strategy 2F: Explore the impact of conditional financial incentives to increase adherence to treatment for high acuity out-of-care PLWH			
Activity	Responsible Party	Performance Measure	Timeframe
2F.1: Develop processes and program operations for a pilot program that is acceptable to clients and is aligned with federal funding guidance and restrictions	DHSP	Written processes & program operations	By 2023
2F.2: Identify potential clinical sites, train staff on pilot processes, and implement program	DHSP	Documentation of pilot program	By 2023
2F.3: Develop a robust evaluation plan to determine continued use of financial incentives and potential for expansion to other populations	DHSP	Evaluation Plan	By 2023
Strategy 2G: RFP: EHE Priority Populations Interventions			
Activity	Responsible Party	Performance Measure	Timeframe
2G.1: Develop and release RFP to fund 7-10 contracts for identified interventions	DHSP	Number of contracts	By 2023
Strategy 2H: Expand capacity to provide whole-person care to PLWH who are age 50 and older and long-term survivors⁴			
Activity	Responsible Party	Performance Measure	Timeframe
2H.1: Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services ⁴	DHSP; COH Aging Caucus	Written findings	By 2023
2H.2: Identify and implement best practices related to addressing psychosocial and behavioral health needs of older PLWH and long-term survivors including substance use treatment, mental health treatment, and programs to decrease social isolation ⁴	DHSP; research partners; providers	Identification of best practices and efforts to implement	2022-2026
2H.3: Review/update diagnostic screenings to include age-related conditions (i.e. screen for loneliness, ACEs, depression, anxiety, experiences of	Providers; Clinics; COH Aging Caucus	Screening tools developed and utilized	By 2024

⁴ Adapted from the NHAS, 2022-2025

discrimination), using Commission on HIV's Aging Task Force recommendations as a guide			
2H.4: Screen patients for comprehensive benefits analysis and financial screening; and assess access to caregiving support	Providers; Clinics; COH Aging Caucus	Screening tools developed and utilized	By 2024
2H.5: Review Home-Based Case Management service standards for alignment with OT and PT assessments	COH – SBP Committee	Documented review	By 2023

Pillar III: Prevent

Goal: Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs)

Objectives:

1. By 2025, increase the proportion of persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 39%.
2. By 2025, increase the proportion of Black/African American persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 25%.
3. By 2025, increase the proportion of Latinx persons prescribed PrEP with an indication for PrEP to at least 50%, from a 2022 baseline of 38%.
4. By 2026, increase the percentage of EOPs and SSPs that provide HIV/STD testing and HCV screening from 20% to 80%.

Strategy 3A: Accelerate efforts to increase PrEP use (particularly for populations with the highest rates of new HIV diagnoses and low PrEP coverage rates) by adopting new strategies at LAC funded PrEP Centers of Excellence tied to client retention, PrEP navigation, community education, supporting alternatives to daily PrEP, and expanding PrEP support groups; and promoting recent innovations

Activity	Responsible Party	Performance Measure	Timeframe
3A.1: Conduct an in-depth landscape analysis of current PrEP resources and services among primary care providers in high morbidity areas, among providers who serve transgender persons, women's health providers, and SUD providers.	DHSP	Report on landscape analysis	By 2023
3A.2: Implement systematic and innovative strategies at LAC DHSP-funded PrEP Centers of Excellence for enhanced client communication to promote retention in PrEP and sexual health services.	DHSP; PrEP COEs	Documentation of strategies implemented	2022-2026
3A.3: Increase capacity of LAC DPH staff to provide more robust PrEP navigation services to clients served through County STD clinics, Partner Services, and those receiving PrEP/PEP at community pharmacies.	DHSP	Increased capacity	2022-2026
3A.4: Disseminate simple fact-based social marketing PrEP messaging to increase knowledge and awareness of PrEP, alternatives to daily PrEP, how to access PrEP/PEP under SB 159, and help combat misinformation regarding cost, access, and safety.	DHSP; PrEP COEs and providers	Number of SM tools developed and disseminated	2022-2026

3A.5: Work with local stakeholders to identify potential role for PrEP support groups/PrEP ambassadors to support new & continued PrEP use in affected communities.	DHSP; COH; PrEP COEs	Number of PrEP support groups and ambassadors	2022-2026
3A.6: Finalize PrEP campaigns for Black/African American MSM, transwomen and cisgender women, per the Commission on HIV's Black/African American Community Task Force's Recommendations.	DHSP; COH-B/AA TF	Development of PrEP campaigns	By 2023
3A.7: Increase knowledge & awareness among both providers & community members about long acting injectables & other biomedical advances (See 2.B.2)	CBA; DHSP; PrEP providers	Number of trainings, TA; educational materials	2022-2026
3A.8: Help build the capacity of pharmacies to prescribe PrEP/PEP and create a directory of pharmacies that have capacity to prescribe PrEP/PEP under SB159, potentially to be integrated into the GetPrEP website.	DHSP; CBAs	Number pharmacies provided with assistance	2022-2026
3A.9: Develop a public health detailing campaign to expand the number of oral PrEP prescribers in LAC.	DHSP	Number of oral PrEP providers in LAC	2023-2026
Strategy 3B: Increase availability, use, and access to comprehensive syringe services programs (SSPs) and other harm reduction services.			
Activity	Responsible Party	Performance Measure	Timeframe
3B.1: Collaborate with the LAC SAPC Program to identify opportunities to increase the capacity of SSPs, improve the provision or linkage of SSP clients to HIV, STD and HCV prevention and treatment services, and expand the availability of contingency management services to persons with substance use disorder, including meth use.	DHSP; SAPC	Documented efforts to increase capacity of SSPs and expand contingency mngmt.	2022-2026
3B.2: Explore ideas for alternative models of prevention service delivery (e.g., vouchers which can be taken to pharmacies in exchange for clean syringes and HIV self-test kits).	DHSP; COH SAPC	Number of alternative models	2022-2026
3B.3: Distribute information about the efficacy of SSPs to increase the health literacy of HIV providers and community members	DHSP; SAPC; providers	Educational materials developed	2022-2026
3B.4: Destigmatize syringe services/needle exchange and further integrate SSP providers into HIV-related work	DHSP; SAPC; providers	Documented efforts	2022-2026
3B.5: Promote safe consumption/injection sites	DHSP; SAPC; COH; providers	Documented efforts	2022-2026

Pillar IV: Respond**Goal: Respond quickly to potential HIV outbreaks to get vital prevention and treatment services to people who need them****Objectives:**

1. By 2026, provide/disseminate at least 5 educational trainings/workshops or educational materials to increase awareness/knowledge related to cluster and outbreak detection and response
2. By 2025, increase the total proportion of persons newly diagnosed with HIV who are assigned for Partner Services (PS) to 95% from a 2021 baseline of 73%
3. By 2025, increase the total proportion of persons newly diagnosed with HIV who are interviewed for PS to 75% from a 2021 baseline of 46%

Strategy 4A: Refine processes, data systems, and policies for robust, real-time cluster detection, time- space analysis, and response

Activity	Responsible Party	Performance Measure	Timeframe
4A.1: Develop a protocol, training materials, and standard operation plan (SOP).	DHSP	Written protocol, curricula and SOP.	By 2023
4A.2: Continue community engagement regarding the use of HIV molecular surveillance for cluster detection to inform its best use and identify and mitigate any unintended consequences.	DHSP	Number of community engagement efforts	2022-2026
4A.3: Expand routine epidemiological analysis of recent infection by person, place, and time to identify hot-spot locations and sub-populations associated with recent infection to inform rapid investigation and intervention.	DHSP	Expansion of routine epidemiological analysis	2022-2026
4A.4: Educate HIV providers about the use and effectiveness of cluster detection	DHSP	Number of trainings/ educational materials developed	2022-2026

Strategy 4B: Refine current processes to increase capacity of Partner Services to ensure people newly diagnosed are interviewed and close partners are identified and offered services in a timely and effective manner.

Activity	Responsible Party	Performance Measure	Timeframe
4B.1: Increase capacity of LAC DHSP to provide Partner Services to all newly diagnosed persons in LAC	DHSP	Number of PS staff; training of PS staff	2022-2026
4B.2: Implement new STD surveillance system to enhance the identification and assignment of new HIV cases to LAC DPH staff for timely follow-up and Partner Services	DHSP	New STD surveillance system	2023
4B.3: Educate HIV providers about the use and effectiveness of Partner Services	DHSP; CBA	Number of trainings & educational materials	2022-2026

4B.4: Explore increased use of community-embedded Partner Services	DHSP	Documented efforts	2023
Strategy 4C: Data to Care RFP			
Activity	Responsible Party	Performance Measure	Timeframe
4C.1: Develop & release RFP to fund up to 5 contracts for Data to Care activities.	DHSP	Number of contracts	By 2023

Workforce Capacity

Goal: Increase the capacity of the HIV workforce to diagnose and treat PLWH, prevent new HIV infections and reduce HIV-related disparities			
Objectives: 1. By 2024, conduct a comprehensive assessment of the HIV workforce identifying strengths, needs and potential solutions, including an assessment of the true costs of services and how those services might be financed. 2. By 2026, implement training, technical assistance and necessary policy changes to increase workforce capacity as outlined in assessment findings and guided by the strategies below.			
Strategy 5A: Increase the diversity and capacity of the workforce that delivers HIV prevention, care and supportive services to optimally reflect and serve the populations most impacted by HIV.			
Activity	Responsible Party	Performance Measure	Timeframe
5A.1: Conduct an assessment of Black/African American led agencies providing HIV services to identify training/technical assistance (TA) needs	COH-Black/AA Task Force	Assessment report	By 2023
5A.2: Provide TA and/or training for Black/African American led agencies to provide a more equitable playing field to successfully compete for solicitations, based on assessment findings	DHSP, in collaboration w/ Black/AA TF	Number of Black/AA led agencies that receive TA/trainings	By 2023
5A.3: Increase inclusion of peer/paraprofessionals ⁶⁹ in the workforce through training, mentorship, certification, supervision, reimbursement, and team functioning to assist with HIV, STD, HCV, and MH and SUD service provision ⁴	DHSP, AETC, COH-SBP Committee	Increased # of peer/paraprofessionals in the workforce.	By 2026
5A.4: Develop inventory of both formal and informal pipeline programs to prepare workers to work in the HIV/health field	AETC	Report	By 2023
5A.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly	CBOs; AETC; Universities/med. & dental schools	Number of people trained/in training	2022-2026

⁶⁹ Peer/paraprofessionals defined as people who reflect the population(s) being served (e.g. PLWH, people of color, trans persons, etc.) and who may not have formal education/licensure.

from underrepresented populations ⁴			
5A.6: Based on results of workforce capacity assessment, review and revise service standards as necessary	COH-SBP Committee	Revised standards	2022-2026
5A.7: Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV	CBOs; DHSP; COH	Number of PLWH & people from priority pops in leadership positions	2022-2026
Strategy 5B: Ensure that the workforce is adequately prepared to deliver high-quality services in a culturally responsive manner			
Activity	Responsible Party	Performance Measure	Timeframe
5B.1: Include harm reduction principles and the provision of trauma-informed care across provider trainings	DHSP; AETC; CBA; SAPC	Number of curricula that include harm reduction & trauma-informed care	2022-2026
5B.2: Provide gerontology training for Ambulatory Outpatient Medical, Oral Health, Medical Care Coordination and Mental Health service providers to improve awareness and understanding of age-related inequities in care and treatment	DHSP	Number of providers trained on gerontology	By 2025
5B.3: Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work ⁴	DHSP; DHS; AETC; CBA	Number of providers trained on listed topics	2022-2026
5B.4: Identify and make available succession planning and leadership development trainings/programs	AETC; CBA; DHSP; COH	Number of providers trained on topics	2022-2026

System and Service Integration

Goal: Integrate systems and services to address the syndemic of HIV, STDs, HCV, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence⁴

Objectives:

1. By 2026, the LA County Division of HIV and STD Programs (DHSP) and/or the Commission on HIV (COH) will implement at least three internal (within LAC system) efforts to advance system and service integration
2. By 2026, DHSP and/or the COH will implement at least three external efforts to advance system and service integration

Strategy 6A: Increase cross-training and TA opportunities across fields/disciplines

Activity	Responsible Party	Performance Measure	Timeframe
6A.1: Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs ⁴	DHSP; DHS; SAPC	Number of trainings provided	2022-2026
6A.2: Expand opportunities and mechanisms for information sharing and peer-to-peer technical assistance amongst HIV/STD/MH/SUD/Housing providers ⁴	DHSP; COH; SAPC; DMH	Number and type of info sharing/TA	2022-2026
6A.3: Support training for housing service providers on needs of PLWH and LGBTQI persons to improve cultural competencies among staff	HOPWA; COH; DHSP; LAHSA	Number of trainings provided	2022-2026
6A.4: Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services ⁴	Dept. on Aging; COH; SAPC	Number and type of service providers reached	2022-2026
6A.5: Increase the integration of HIV and HCV services including increasing the capacity of FQHCs that provide HIV-related services to screen for and treat HCV	ACDC; DHSP FQHCs	Number of integration mtgs held	2022-2026

Strategy 6B: Leverage the Alliance of Health Integration initiative to integrate services within LA County publicly funded care systems

Activity	Responsible Party	Performance Measure	Timeframe
6B.1: Strive to align strategic planning efforts on HIV, STIs, HCV, substance use disorders, and mental health care across national, state, and local partners ⁴	COH	Number of strategic plans reviewed	2022-2026
6B.2: Optimize RWP, Medicaid, Medicare, and other health systems to ensure they are used in a manner to deliver the highest quality of care for PLWH.	DHS; DHSP	Documentation of efforts	2022-2026

Equity, Social Determinants of Health and Co-Occurring Disorders

Goal: Achieve health equity by addressing social determinants of health, stigma, and co-occurring disorders that fuel the HIV epidemic and HIV disparities

Objectives:

1. By 2026, increase the number of services and programs available to address meth use disorder by at least 25%
2. By 2026, increase the availability of mental health services for PLWH and at-risk for HIV by at least 25%
3. By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV in LA County by at least 25%
4. By 2026, reduce the rates of syphilis, gonorrhea, chlamydia and HCV among Black/African Americans in LA County by at least 25%
5. By 2026, increase the number of evidence-based or evidence-informed practices/programs that address SDH by at least 20%.

Strategy 7A: Advocate for an effective countywide response to SUDs, especially methamphetamine disorder

Activity	Responsible Party	Performance Measure	Timeframe
7A.1: Assess providers' ability to recognize and address meth use disorder	DHSP; SAPC	Assessment completed	By 2023
7A.2: Advocate for improved and additional services and programs associated with methamphetamine use and HIV transmission	COH; CBOs; ANAM	Documentation of efforts taken	2022-2026
7A.3: Expand and enhance mental health services for people living with, affected by, or at risk of contracting HIV/AIDS.	DMH; DHS; DHSP; COH; CBOs	Number of mental health services available	2022-2026
7A.4: Support the building of community-based mental health services.	DMH; COH-Consumer Caucus; CBOs	Number of community-based mental health services	2022-2026

Strategy 7B: Advocate for an effective countywide response to the Sexually Transmitted Disease (STD) epidemic

Activity	Responsible Party	Performance Measure	Timeframe
7B.1: Commission on HIV Public Policy Committee (PPC) will submit a letter to the Board of Supervisors (BOS) that outlines priorities/recommendations to improve the countywide STD response (based on a DPH report previously submitted to the BOS)	COH-PPC	Submitted Letter to BOS	By 2023
7B.2: The PPC will request a formal letter of support from the BOS to support the EHE budget request to the State of California	COH-PPC	Request	By 2023

Strategy 7C: Address social determinants of health and stigma

Activity	Responsible Party	Performance Measure	Timeframe
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7C.1: Create funding opportunities that specifically address social and structural drivers of health as they relate to BIPOC communities	DHSP	Number of funding opportunities that address SDH in BIPOC communities	2022-2026
7C.2: Implement effective, evidence-based and evidence-informed interventions that address stigma and SDHs among PLWH or at risk for HIV	DHSP; HIV service providers	Number of evidence-based /evidence-informed interventions implemented	2022-2026
7C.3: Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors. ⁴	DHPS; Providers	Documented efforts	2022-2026
7C.4: Ensure that the voices/perspectives of PLWH and people at-risk for HIV are represented in pandemic planning and response (e.g., Monkeypox messaging)	DPH	Documented efforts	2022-2026
7C.5: Monitor and advocate for policies that support the following:			
7C.5a: Support the efforts of Measure J, the Alternatives to Incarceration and closure of Men's Central Jail and seek increased funding for services and programming through Measure J as well as through redistribution of funding for policing and incarceration.	COH – Public Policy Committee (PPC)	Documented efforts and PPC meeting minutes	2022-2026
7C.5b: Improve systems, strategies and proposals that prevent homelessness, expand affordable housing, as well as prioritize housing opportunities for people living with, affected by, or at risk of transmission of HIV/AIDS, especially LGBTQ people			
7C.5c: Promote family housing and emergency financial assistance as a strategy to maintain housing			
7C.5d: Increase coordination among housing agencies to include intergenerational housing options			
7C.5e: Blend funding to support housing and rental assistance for seniors living with HIV			
7C.5f: Advocate for women's bodily autonomy in all areas of health care services including and not limited to full access to abortions, contraception, fertility/infertility services and family planning			
7C.5g: Eliminate discrimination against or the criminalization of people living with or at risk of HIV/AIDS including those who exchange sex for money (e.g., Commercial Sex Work).			

Strategy 7D: Identify root causes and directly call-out systematic racist practices that have adversely affected Black/African American communities.			
Activity	Responsible Party	Performance Measure	Timeframe
7D.1: Standardize the collection of race-based stratified program evaluation data	HIV service providers; DHSP	Standardized evaluation measures	2022-2026
7D.2: Disseminate analysis of race-based stratified data via presentations and informational materials	DHSP; Cities of Long Beach, Pasadena, W. Hollywood	Number of presentations/materials that include race-based analysis	2022-2026
7D.3: Implement cultural humility training among healthcare providers	DHSP; AETC	Number of trainings provided	2022-2026
7D.4: Address social and structural barriers with evidence-based interventions	DHSP; Research Partners; CBOs	Number of interventions implemented	2022-2026
7D.5: Build the capacity of Black/African American-led organizations (see 5A.1 and 5A.2)	DHSP	Number of Black/African American led agencies that access training/TA	2022-2026
Strategy 7E: Add Quality of Life (Q of L) Indicators for PLWH to the Integrated Plan by 2023			
Activity	Responsible Party	Performance Measure	Timeframe
7E.1: Examine the newly released Q of L Indicators for PLWH included in NHAS Implementation Plan and decide which ones are applicable to LAC	COH; DHSP	Documented efforts	2023
7E.2: Identify baseline data for each QoL indicator from local MMP data and determine performance metrics to be added to Integrated Plan	COH; DHSP	Performance measures created	2023

Appendix 3: Glossary & Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
AIAN	American Indian and Alaska Native
ART	Antiretroviral therapy
COVID-19	Coronavirus Disease 2019
CDC	Centers for Disease Control and Prevention
DHSP	Division of HIV and STD Programs
EHARS	Enhanced HIV/AIDS Reporting System
EHE	Ending the HIV Epidemic
FQHC	Federally Qualified Health Center
HET	Heterosexuals at increased risk for HIV
HIV	Human Immunodeficiency Virus
HUD	U.S. Department of Housing and Urban Development
IDU	Injection drug use
LAC	Los Angeles County
MHS	Molecular HIV Surveillance
MSM	Men Who Have Sex with Men
NB	Non-Binary
NHPI	Native Hawaiian and Pacific Islander
OMB	Office of Management and Budget
PEP	Post-Exposure Prophylaxis
PLWH	Persons Living with HIV
PLWDH	Persons Living with Diagnosed HIV
PrEP	Pre-Exposure Prophylaxis
PWID	Persons who Inject Drugs
SPA	Service Planning Area
TG	Transgender Persons
US	United States
VL	Viral load

Epidemic – an increase above the usual or expected occurrence of a disease within a population

Prevalence - the total number of cases of disease existing in a population.

Incidence – total number of new infections in a given period of time (usually one year).

Diagnosed Cases – number of cases reported to DHSP or the state. This may contain reports or results that were previously reported.

Number of People Living with HIV in LA County – total number of cases in a given period of time who have HIV and have a Los Angeles County address, and who are not deceased.

Rate – the number of new cases of a disease that occur during a specified period of time in a population at risk for developing the disease. Usually calculated per 100,000 people. Rates take the size of the population into account and are used in order to make comparisons.

of new cases during a specified period of time/# of persons who are at risk for the disease during that same period of time, multiplied by 100,000

95% confidence interval – a lower and upper range of values for a measure/variable of interest which contains the true value of the variable 95% of the time.

EXHIBIT F



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COMMISSION ON HIV



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PLANNING, PRIORITIES & ALLOCATIONS COMMITTEE MEETING

**Tuesday, October 21, 2025
1:00pm – 3:00pm (PST)**

**510 S. Vermont Avenue, 9th Floor, LA 90020
Validated Parking @ 523 Shatto Place, LA 90020**

**As a building security protocol, attendees entering the building must notify parking attendant and/or security personnel that they are attending a Commission on HIV meeting.*

**Agenda and meeting materials will be posted on our website at
<https://hiv.lacounty.gov/planning-priorities-and-allocations-committee>**

Register Here to Join Virtually

<https://lacountyboardofsupervisors.webex.com/web link/register/rb6f8bbf496bca0b9ceb185993c6ec3f4>

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You may provide public comment in person, or alternatively, you may provide written public comment by:

- Emailing hivcomm@lachiv.org
- Submitting electronically at https://www.surveymonkey.com/r/PUBLIC_COMMENTS

** Please indicate your name, the corresponding agenda item, and whether you would like to state your public comment during the meeting. All public comments will be made part of the official record.*

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510 S. Vermont Ave., 14th Floor, Los Angeles CA 90020
MAIN: 213.738.2816 EML: hivcomm@lachiv.org WEBSITE: <https://hiv.lacounty.gov>

AGENDA FOR THE REGULAR MEETING OF THE LOS ANGELES COUNTY COMMISSION ON HIV PLANNING, PRIORITIES, & ALLOCATIONS COMMITTEE

TUESDAY, OCTOBER 21, 2025 | 1:00 PM – 3:00 PM

510 S. Vermont Ave
Terrace Level Conference Room, Los Angeles, CA 90020

Validated Parking: 523 Shatto Place, Los Angeles 90020

MEMBERS OF THE PUBLIC:

To Register + Join by Computer:

<https://lacountyboardofsupervisors.webex.com/weblink/register/rb6f8bbf496bca0b9ceb185993c6ec3f4>

To Join by Telephone: 1-213-306-3065

Password: PLANNING Access Code: 2533 182 7465

Planning, Priorities, and Allocations Committee Members:			
Kevin Donnelly, Co-Chair Carlos Vega-Matos (Alternate)	Daryl Russell Co-Chair	Al Ballesteros, MBA	Rev. Gerald Green (Alternate)
Felipe Gonzalez	Michael Green, PhD	William King, MD, JD (Leave of Absence)	Rob Lester (Committee-only)
Miguel Martinez, MPH, MSW (Committee-only)	Ismael Salamanca	Harold Glenn San Agustin, MD	Dee Saunders
LaShonda Spencer, MD	Lambert Talley (Alternate)	Jonathan Weedman	
QUORUM: 8			

AGENDA POSTED: Oct 16, 2025

PUBLIC COMMENT: Public Comment is an opportunity for members of the public to comment on an agenda item, or any item of interest to the public, before or during the Commission's consideration of the item, that is within the subject matter jurisdiction of the Commission. To submit Public Comment, you may join the virtual meeting via your smart device and post your Public Comment in the Chat box - or- email your Public Comment to mailto:hivcomm@lachiv.org -or- submit your Public Comment electronically [here](#). All Public Comments will be made part of the official record.

ATTENTION: Any person who seeks support or endorsement from the Commission on any official action may be subject to the provisions of Los Angeles County Code, Chapter 2.160 relating to

lobbyists. Violation of the lobbyist ordinance may result in a fine and other penalties. For information, call (213) 974-1093.

ACCOMMODATIONS: Interpretation services for the hearing impaired and translation services for languages other than English are available free of charge with at least 72 hours' notice before the meeting date. To arrange for these services, please contact the Commission Office at (213) 738-2816 or via email at HIVComm@lachiv.org.

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SUPPORTING DOCUMENTATION can be obtained at the Commission on HIV Website at: <http://hiv.lacounty.gov>. The Commission Offices are located at 510 S. Vermont Ave. 14th Floor, Los Angeles, CA 90020. Validated parking is available at 523 Shatto Place, Los Angeles 90020. **Hard copies of materials will not be made available during meetings unless otherwise determined by staff in alignment with the County's green initiative to recycle and reduce waste.*

I. ADMINISTRATIVE MATTERS

- | | | |
|---|------------------|-------------------|
| 1. Call to Order & Meeting Guidelines/Reminders | | 1:00 PM – 1:03 PM |
| 2. Roll Call & Conflict of Interest Statements | | 1:03 PM – 1:05 PM |
| 3. Approval of Agenda | MOTION #1 | 1:05 PM – 1:07 PM |
| 4. Approval of Meeting Minutes | MOTION #2 | 1:07 PM – 1:10 PM |

II. PUBLIC COMMENT

1:10 PM – 1:15 PM

5. Opportunity for members of the public to address the Committee of items of interest that are within the jurisdiction of the Committee. For those who wish to provide public comment may do so in person, electronically by clicking [here](#), or by emailing hivcomm@lachiv.org.

III. COMMITTEE NEW BUSINESS ITEMS

6. Opportunity for Committee members to recommend new business items for the full body or a committee level discussion on non-agendized matters not posted on the agenda, to be discussed and (if requested) placed on the agenda for action at a future meeting, or matters requiring immediate action because of an emergency situation, or where the need to take action arose subsequent to the posting of the agenda.

IV. REPORTS

- | | |
|---|-----------------|
| 7. Commission on HIV (COH) Staff Report | 1:16 PM—1:21PM |
| a. Operational and Commission Updates | |
| 8. Co-chair Report | 1:22 PM—1:30 PM |
| a. November and December Meetings | |

Commission on HIV | Planning, Priorities, and Allocations (PP&A)**October 21, 2025**

9. Division on HIV and STD Programs (DHSP) Report 1:31 PM—2:21 PM
 a. Program Year 34 (PY34) Ryan White Program Utilization Report – Support Services

V. DISCUSSION

2:22 PM—2:54 PM

10. Women’s Caucus Recommendations for Women-Centered Programming
 11. 2026 PP&A Committee Calendar

VI. NEXT STEPS

2:55 PM – 2:57 PM

12. Task/Assignments Recap
 13. Agenda Development for the Next Meeting

VII. ANNOUNCEMENTS

2:58 PM – 3:00 PM

14. Opportunity for members of the public and the committee to make announcements.

VIII. ADJOURNMENT

3:00 PM

15. Adjournment for the meeting of October 21, 2025.

PROPOSED MOTIONS	
MOTION #1	Approve the Agenda Order, as presented or revised.
MOTION #2	Approve the Planning, Priorities and Allocations Committee minutes, as presented or revised.



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(Updated 7.15.24)

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 - Your voice is important and we want to ensure that it is captured accurately on the record. Please be respectful of one another and minimize crosstalk.
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- ☐ Committee members invoking **AB 2449 for "Just Cause" or "Emergency Circumstances"** must communicate their intentions to staff and/or co-chairs no later than the start of the meeting. Members requesting to join pursuant to AB 2449 must have their audio and video on for the entire duration of the meeting and disclose whether there is a person over the age of 18 in the room in order to be counted toward quorum and have voting privileges. For members joining virtually due to "Emergency Circumstances", a vote will be conducted by the Committee/COH for approval.
- ☐ Members will be required to explicitly state their agency's **Ryan White Program Part A and/or CDC prevention conflicts of interest** on the record (versus referring to list in the packet). A list of conflicts can be found in the meeting packet and are recorded on the back of members' name plates, courtesy of staff.

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LOS ANGELES COUNTY COMMISSION ON HIV



Approved by COH
6/8/23

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HIVCOMM@LACHIV.ORG • <http://hiv.lacounty.gov>

CODE OF CONDUCT

The Commission on HIV welcomes commissioners, guests, and the public into a space where people of all opinions and backgrounds are able to contribute. In this space, we challenge ourselves to be self-reflective and committed to an ongoing understanding of each other and the complex intersectionality of the lives we live. We create a safe environment where we celebrate differences while striving for consensus in the fights against our common enemies: HIV and STDs. We build trust in each other by having honest, respectful, and productive conversations. As a result, the Commission has adopted and is consistently committed to implementing the following guidelines for Commission, committee, and associated meetings.

All participants and stakeholders should adhere to the following:

- 1) We approach all our interactions with compassion, respect, and transparency.**
- 2) We respect others' time by starting and ending meetings on time, being punctual, and staying present.**
- 3) We listen with intent, avoid interrupting others, and elevate each other's voices.**
- 4) We encourage all to bring forth ideas for discussion, community planning, and consensus.**
- 5) We focus on the issue, not the person raising the issue.**
- 6) Be flexible, open-minded, and solution-focused.**
- 7) We give and accept respectful and constructive feedback.**
- 8) We keep all issues on the table (no "hidden agendas"), avoid monopolizing discussions and minimize side conversations.**
- 9) We have no place in our deliberations for racist, sexist, homophobic, transphobic, and other discriminatory statements, and "-isms" including misogyny, ableism, and ageism.**
- 10) We give ourselves permission to learn from our mistakes.**

In response to violation of the Code of Conduct which results in meeting disruption, Include provisions of SB 1100 which states in part, "... authorize the presiding member of the legislative body conducting a meeting or their designee to remove, or cause the removal of, an individual for disrupting the meeting Removal to be preceded by a warning to the individual by the presiding member of the legislative body or their designee that the individual's behavior is disrupting the meeting and that the individual's failure to cease their behavior may result in their removal." Complaints related to internal Commission matters such as alleged violation of the Code of Conduct or other disputes among members are addressed and resolved in adherence to Policy/Procedure #08.3302." (Commission Bylaws, Article VII, Section 4.)

APPROVED BY OPERATIONS COMMITTEE ON 05/25/23; COH 06/08/23

Approved (11/12/1998); Revised (2/10/2005; 9/6/2005); Revised (4/11/19; 3/3/22, 3/23/23; 5/30/23)

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LOS ANGELES COUNTY
COMMISSION ON HIV



COMMISSION MEMBER "CONFLICTS-OF-INTEREST"

Updated 9/2/25

In accordance with the Ryan White Program (RWP), conflict of interest is defined as any financial interest in, board membership, current or past employment, or contractual agreement with an organization, partnership, or any other entity, whether public or private, that receives funds from the Ryan White Part A program. These provisions also extend to direct ascendants and descendants, siblings, spouses, and domestic partners of Commission members and non-Commission Committee-only members. Based on the RWP legislation, HRSA guidance, and Commission policy, it is mandatory for Commission members to state all conflicts of interest regarding their RWP Part A/B and/or CDC HIV prevention-funded service contracts prior to discussions involving priority-setting, allocation, and other fiscal matters related to the local HIV continuum. Furthermore, Commission members must recuse themselves from voting on any specific RWP Part A service category(ies) for which their organization hold contracts. ***An asterisk next to member's name denotes affiliation with a County subcontracted agency listed on the addendum.**

COMMISSION MEMBERS		ORGANIZATION	SERVICE CATEGORIES
ALE-FERLITO	Dahlia	City of Los Angeles AIDS Coordinator	No Ryan White or prevention contracts
ALVAREZ	Miguel	No Affiliation	No Ryan White or prevention contracts
ARRINGTON	Jayda	Unaffiliated representative	No Ryan White or prevention contracts
BALLESTEROS	AI	JWCH, INC.	Benefits Specialty
			Core HIV Medical Services - AOM; MCC & PSS
			Mental Health
			Oral Health
			STD Testing and STD Screening, Diagnosis & Treatment Services (STD-SDTS)
			HTS - Storefront
			HTS - Syphilis, DX Link TX - CSV
			Biomedical HIV Prevention
			Data to Care Services
			Medical Transportation Services
BLEA	Leroy	California Department of Public Health, Office of AIDS	Part B Grantee
BURTON	Alasdair	No Affiliation	No Ryan White or prevention contracts
CAMPBELL	Danielle	T.H.E. Clinic, Inc.	Core HIV Medical Services - AOM; MCC & PSS
			Medical Transportation Services
CIELO	Mikhaela	Los Angeles General Hospital	No Ryan White or prevention contracts
CUEVAS	Sandra	Pacific AIDS Education and Training - Los Angeles	No Ryan White or prevention contracts
CUMMINGS	Mary	Bartz-Altadonna Community Health Center	No Ryan White or prevention contracts

COMMISSION MEMBERS		ORGANIZATION	SERVICE CATEGORIES
DAVIES	Erika	City of Pasadena	No Ryan White or prevention contracts
DAVIS (PPC Member)	OM	Aviva Pharmacy	No Ryan White or prevention contracts
DOLAN (SBP Member)	Caitlyn	Men's Health Foundation	Core HIV Medical Services - AOM; MCC & PSS
			Biomedical HIV Prevention Services
			Vulnerable Populations (YMSM)
			Sexual Health Express Clinics (SHEX-C)
			Data to Care Services
			Medical Transportation Services
DONNELLY	Kevin	Unaffiliated representative	No Ryan White or prevention contracts
FERGUSON	Kerry	No Affiliation	No Ryan White or prevention contracts
FINLEY	Jet	Unaffiliated representative	No Ryan White or prevention contracts
FRAMES	Arlene	Unaffiliated representative	No Ryan White or prevention contracts
FRANKLIN*	Arburtha	Translatin@ Coalition	Vulnerable Populations (Trans)
GERSH (SBP Member)	Lauren	APLA Health & Wellness	Benefits Specialty
			Core HIV Medical Services - AOM; MCC & PSS
			Intensive Case Management Services
			Nutrition Support (Food Bank/Pantry Service)
			Oral Health
			STD-Ex.C
			HERR
			Biomedical HIV Prevention Services
			Medical Transportation Services
			Data to Care Services
			Residential Facility For the Chronically Ill (RCFCI)
GONZALEZ	Felipe	Unaffiliated representative	No Ryan White or Prevention Contracts
GREEN	Gerald	Minority AIDS Project	Benefits Specialty
GREEN	Joseph	Unaffiliated representative	No Ryan White or prevention contracts

COMMISSION MEMBERS		ORGANIZATION	SERVICE CATEGORIES
GUTIERREZ	Joaquin	Unaffiliated representative	No Ryan White or prevention contracts
HARDY	David	University of Southern California	No Ryan White or prevention contracts
HERRERA	Ismael "Ish"	Unaffiliated representative	No Ryan White or prevention contracts
JONES	Terrance	Unaffiliated representative	No Ryan White or prevention contracts
KOCHEMS	Lee	Unaffiliated representative	No Ryan White or prevention contracts
KING	William	W. King Health Care Group	No Ryan White or prevention contracts
LESTER (PP&A Member)	Rob	Men's Health Foundation	Core HIV Medical Services - AOM; MCC & PSS
			Biomedical HIV Prevention Services
			Vulnerable Populations (YMSM)
			Sexual Health Express Clinics (SHEX-C)
			Data to Care Services
			Medical Transportation Services
MARTINEZ (PP&A Member)	Miguel	Children's Hospital Los Angeles	Core HIV Medical Services - AOM; MCC & PSS
			STD Testing and STD Screening, Diagnosis & Treatment Services (STD-SDTS)
			HTS - Storefront
			Biomedical HIV Prevention Services
MARTINEZ-REAL	Leonardo	Unaffiliated representative	Medical Transportation Services
			No Ryan White or prevention contracts
MAULTSBY	Leon	In the Meantime Men's Group	Promoting Healthcare Engagement Among Vulnerable Populations
MENDOZA	Vilma	Unaffiliated representative	No Ryan White or prevention contracts
MINTLINE (SBP Member)	Mark	Western University of Health Sciences	No Ryan White or prevention contracts
NASH	Paul	University of Southern California	No Ryan White or prevention contracts

COMMISSION MEMBERS		ORGANIZATION	SERVICE CATEGORIES
NELSON	Katja	APLA Health & Wellness	Benefits Specialty
			Core HIV Medical Services - AOM; MCC & PSS
			Intensive Case Management Services
			Nutrition Support (Food Bank/Pantry Service)
			Oral Health
			STD-Ex.C
			HERR
			Biomedical HIV Prevention Services
			Medical Transportation Services
			Data to Care Services
			Residential Facility For the Chronically Ill (RCFCI)
PATEL	Byron	Los Angeles LGBT Center	Core HIV Medical Services - AOM; MCC & PSS
			Vulnerable Populations (YMSM)
			Vulnerable Populations (Trans)
			STD Testing and STD Screening, Diagnosis & Treatment Services (STD-SDTS)
			HTS - Storefront
			HTS - Social and Sexual Networks
			Biomedical HIV Prevention Services
			Medical Transportation Services
PERÉZ	Mario	Los Angeles County, Department of Public Health, Division of HIV and STD Programs	Ryan White/CDC Grantee
RICHARDSON	Dechelle	No Affiliation	No Ryan White or prevention contracts
RUSSEL	Daryl	Unaffiliated representative	No Ryan White or prevention contracts
SALAMANCA	Ismael	City of Long Beach	Benefits Specialty
			Core HIV Medical Services - AOM; MCC & PSS
			Biomedical HIV Prevention Services
			HTS - Social and Sexual Networks
			Medical Transportation Services

COMMISSION MEMBERS		ORGANIZATION	SERVICE CATEGORIES
SAMONE-LORECA	Sabel	Minority AIDS Project	Benefits Specialty
SATTAH	Martin	Rand Schrader Clinic LA County Department of Health Services	No Ryan White or prevention contracts
SAN AGUSTIN	Harold	JWCH, INC.	Benefits Specialty
			Core HIV Medical Services - AOM; MCC & PSS
			Mental Health
			Oral Health
			STD Testing and STD Screening, Diagnosis & Treatment Services (STD-SDTS)
			HTS - Storefront
			HTS - Syphilis, DX Link TX - CSV
			Biomedical HIV Prevention Services
			Data to Care Services
			Medical Transportation Services
SAUNDERS	Dee	City of West Hollywood	No Ryan White or prevention contracts
SPENCER	LaShonda	Oasis Clinic (Charles R. Drew University/Drew CARES)	Core HIV Medical Services - PSS
			HTS - Storefront
			HTS - Social and Sexual Networks
TALLEY	Lambert	Grace Center for Health & Healing	No Ryan White or prevention contracts
VEGA-MATOS	Carlos	Men's Health Foundation	Core HIV Medical Services - AOM; MCC & PSS
			Biomedical HIV Prevention Services
			Vulnerable Populations (YMSM)
			Sexual Health Express Clinics (SHEX-C)
			Data to Care Services
			Medical Transportation Services
WEEDMAN	Jonathan	ViaCare Community Health	Biomedical HIV Prevention
			Core HIV Medical Services - AOM & MCC
YBARRA	Russell	Capitol Drugs	No Ryan White or prevention contracts



LOS ANGELES COUNTY
COMMISSION ON HIV



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**PLANNING, PRIORITIES, AND ALLOCATIONS (PP&A)
 COMMITTEE MEETING MINUTES
 August 19, 2025**

COMMITTEE MEMBERS			
P = Present P* = Present as member of the public; does not meet AB 2449 requirements A = Absent EA = Excused Absence			
Kevin Donnelly, Co-Chair	P	Miguel Martinez, MPH, MSW	P
Daryl Russell, Co-Chair	EA	Ismael Salamanca	P
Al Ballesteros, MBA	P	Harold Glenn San Agustin, MD	P
Felipe Gonzalez	P	Dee Saunders	P
Reverend Gerald Green	A	LaShonda Spencer, MD	P
Michael Green, PhD, MHSA	EA	Lambert Talley	EA
William King, MD, JD	P	Carlos Vega-Matos	P
Rob Lester	P	Jonathan Weedman	EA
COMMISSION STAFF AND CONSULTANTS			
Cheryl Barrit, Dawn McClendon, Lizette Martinez			
DHSP STAFF			
Paulina Zamudio, Victor Scott, Pamela Ogata			

*Some participants may not have been captured electronically. Attendance can be corrected by emailing the Commission.

*Members of the public may confirm their attendance by contacting Commission staff at hivcomm@lachiv.org.

*Meeting minutes may be corrected up to one year from the date of approval.

Meeting agenda and materials can be found on the Commission's website. Click [HERE](#).

I. ADMINISTRATIVE MATTERS

1. CALL TO ORDER AND MEETING GUIDELINES/REMINDERS

K. Donnelly, Planning, Priorities and Allocations (PP&A) co-chair, called the meeting to order at approximately 1:08pm.

2. ROLL CALL & CONFLICT OF INTEREST STATEMENTS

C. Barrit, Executive Director, conducted roll call and committee members were reminded to state their conflicts.

ROLL CALL (PRESENT): A. Ballesteros, K. Donnelly, F. Gonzalez, W. King, R. Lester, M. Martinez, I. Salamanca, H. San Agustin, S. Saunders, L. Spencer, C. Vega-Matos

Planning, Priorities and Allocations Committee

August 19, 2025

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3. Approval of Agenda

MOTION #1: Approve the Agenda Order (✓Passed by Consensus)

4. Approval of Meeting Minutes

MOTION #2: Approval of Meeting Minutes (✓Passed by Consensus)

II. PUBLIC COMMENT

5. Opportunity for members of the public to address the Committee on items of interest that is within the jurisdiction of the Committee.

Robert Boller of Project Angel Food made the following statement:

I just want to thank the PP&A committee. You guys have our back, and I was very happy to see that you supported Nutrition Support services. It's very important and it's an evidence-based program that saves money, reduces the healthcare costs, proves health outcomes and client satisfaction - the three aims of healthcare reform. But I also know that the Commission, as a whole, voted to do deeper cuts to nutrition support. So, I just wanted to remind everyone that in the 1st May meeting, there's a letter that we submitted that kind of goes into details of the evidence-based nutrition support, and I hope the commission and the public at large can meet that and again thank you very much. I also want to reiterate our commitment to people living with HIV/AIDS as well as the community at large. We are actually in talks with APLA to help them with their delivery of NOLP groceries. It's something we've been wanting to get into and we're seeing this as an opportunity to help. Thank you very much.

J. Green announced that the Executive Committee will be reviewing the proposed bylaws changes including the 49 public comments that were received at their meeting next week on August 28 from 1pm-3pm at the Vermont Corridor. He noted that there are several important comments that need to be discussed and one of them is the recommendation from DHSP to unintegrate the Commission (to remove prevention and focus solely on Ryan White Care).

III. COMMITTEE NEW BUSINESS

6. Opportunity for Committee members to recommend new business items for the full body or a committee-level discussion on non-agendized matters not posted on the agenda, to be discussed and (if requested) placed on the agenda for action at a future meeting, or matters requiring immediate action because of an emergency situation, or where the need to take action arose subsequent to the posting of the agenda.

There was no committee new business.

IV. REPORTS

7. Executive Director/Staff Report

- C. Barrit, reiterated that the Executive Committee will be reviewing the proposed changes to the Commission on HIV (COH) bylaws and public comment to the proposed changes at their

Planning, Priorities and Allocations Committee
 August 19, 2025
 Page 3 of 5

next meeting on August 28 from 1pm-3pm at the Vermont Corridor. See Executive Committee [meeting page](#) on the COH website for meeting agenda and additional details.

- C. Barrit reminded the group that the Commission is going through staff changes and transitions with her retirement at the end of the month and asked the group to work with each other to assess staff capacity around Commission activities and goals. She noted that the COH is still waiting for approval and feedback from DHSP regarding the COH's proposed budget for the year. The COH did cut over 30% which is in alignment with the directive for all DHSP funded contractors to adjust budgets at a 30 % reduction. She noted there is a smaller pool of money for operational costs, but staff are prepared to ensure the duties of the COH are fulfilled.

8. Co-chair Report

- K. Donnelly reminded the committee that the public comment period for the Patient Support Services service standards is open and the deadline to submit any feedback or questions is September 30, 2025. Proposed service standards and instructions for submitting public comment can be found [here](#). The Standards and Best Practices Committee will review public comments at their next meeting on October 7, 2025 meeting.

9. Division of HIV and STD Programs Report

a. Program Year 34 (PY34) Ryan White Program Utilization Report

- DHSP staff, S. Oksuzyan, provided a PY34 Ryan White Program Utilization Report to the committee; see [meeting packet](#) for presentation slides.
- The report showed that the Ryan White Program (RWP) is reaching and serving LAC priority populations. The highest expenditures per client were attributed to the Linkage and Re-Engagement Program, followed by Housing and Home-Based Case Management services. The lowest expenditures per client were seen in Benefit Specialty, Mental Health and Nutrition Support services.
- Engagement, retention in care and viral suppression percentages were higher in RWP clients when compared to people living with HIV (PLWH) in Los Angeles County for PY34.

b. 2027-2031 Integrated HIV Plan Updates

- P. Ogata reported that DHSP has been in conversations with the California Department of Public Health's Office of AIDS (OA) around planning for the 2027-2031 Integrated HIV Plan. DHSP has decided to align with the California OA plan and the state plan will include a section specific to Los Angeles County. Commission staff will work with DHSP to determine COH contributions to the plan.

c. Program Years 35 (March 1, 2025-February 28, 2026) Reallocations

- P. Ogata provided a report on current DHSP funding and outlined recommended

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reallocations based on funding and need. She reported that DHSP received their final notice of award for Ryan White Part A and Minority AIDS Initiative (MAI) funding for Program Year 35 (PY35) from the Health Services and Resources Administration (HRSA) as well as final award for HRSA Ending the HIV Epidemic (EHE) funding and final award for Centers for Disease Control and Prevention (CDC) PCHD grant. To date, DHSP has received all funding from the federal government for PY35.

- The final Ryan White Part A funding totaled approximately \$42.5 million and MAI award of approximately \$3.7 million with a final notice of award of approximately \$46.295 million for PY35. There was a reduction of approximately 0.08% in funding from PY34. The total award amount for direct services is \$37.6 million from Part A and \$3.3 million from MAI. Ten percent of the full award amount was reserved for administrative fees as well as approximately \$750,000 for legislatively mandated clinical quality management (CQM) activities. See [meeting packet](#) for more details.
- P. Ogata reviewed the key action items DHSP took as the program worked to plan around uncertain funding including the layoff or reassignment of 78 DHSP staff, numerous meeting the stakeholders and contracted providers and aligning contract obligations with projected federal funding/revenue for the fiscal year resulting in a 30% reduction of all HIV care and treatment contracts. See [meeting packet](#) for more details.
- D. Russell requested clarity on DHSP staff cuts that were impacted by HRSA Ryan White Program (RWP) funding. He also commented that some RWP clients have noted that under nutrition services, food delivery services were no longer available. P. Zamudio noted that this is a specific add-on services that was implemented by one provider using a DoorDash food delivery model for clients. The service is not required but due to the 30% reduction in funding contracts it is no longer being implemented by that particular agency that was utilizing the DoorDash food delivery service. Clients can still access foodbank services.
- Lingering uncertainties were outlined including the portion of the \$65 million dollars from the California Department of Public Health's Office of AIDS (OA) that was earmarked to help various counties deal with HIV related funding gaps for 2025-2026. DHSP continues to meet with the OA monthly. There is additional uncertainty around the County budget and available funding as the County continues to see loss in revenue due to Executive Orders and the federal budget. See [meeting packet](#) for more details.
- DHSP noted a reallocation was needed for PY35 to allocate funds to a new service – Patient Support Services – that was under solicitation when the committee originally completed their priority setting and allocation for PY35 in September 2024. To maximize funding, DHSP also recommended allocating Part A funds for Residential Care for the Chronically Ill (RCFCI) housing which has been historically supported by HRSA Part B funds and transfer Transitional Residential Care Facility (TRCF) housing to Part B funds. There was an additional recommendation to support home delivered meals within Nutritional Support services with Part A funds. Last year, home delivered meals was supported with EHE funds, but this service has been typically funded under Part A. See [meeting packet](#) for proposed reallocations and more details.

Planning, Priorities and Allocations Committee

August 19, 2025

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- K. Nelson, member of the public, asked if the reallocation for an annual RWP Part A application and if the reallocation will have an impact of the 30% cuts to contracted providers. P. Ogata noted the reallocation is not for an application but rather a Program Terms Report that is due to HRSA in early October and that the reallocation aligns with the 30% funding cut in contracts and contract obligations.
- M. Martinez asked why Early Intervention Services is only funded through June. P. Zamudio mentioned that some of the Public Health Clinics may close due to lack of funding, in general, so there is uncertainty if testing services will continue to be offered.

MOTION #3 - Approve the Ryan White Program Year 35 (PY35) Allocations, as presented or revised and provide DHSP the authority to make adjustments of 10% greater or lesser than the approved allocations amount, as expenditure categories dictate, without returning to this body.

A. Ballesteros – Y, K. Donnelly - Y, F. Gonzalez - Y, W. King - Y, R. Lester - Y, M. Martinez - Y, I. Salamanca - Y, H. San Agustin - Y, S. Saunders - Y, L. Spencer - Y

V. NEXT STEPS

10. Task/Assignments Recap

- a. Commission staff will work with co-chairs to develop the agenda for the September PP&A Committee meeting.
- b. Allocations will move forward to the Executive Committee for review and approval.

11. Agenda Development for the Next Meeting

- a. DHSP to provide a report on PY34 RWP core services utilization.

VII. ANNOUNCEMENTS

12. Opportunity for Members of the Public and the Committee to Make Announcements

There were no announcements.

VIII. ADJOURNMENT

13. Adjournment for the Regular Meeting of August 19, 2025.

The meeting was adjourned by K. Donnelly at 2:56pm.



LOS ANGELES COUNTY
COMMISSION ON HIV

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**PLANNING, PRIORITIES, AND ALLOCATIONS (PP&A)
COMMITTEE MEETING MINUTES
September 16, 2025**

COMMITTEE MEMBERS			
P = Present P* = Present as member of the public; does not meet AB 2449 requirements A = Absent EA = Excused Absence			
Kevin Donnelly, Co-Chair	P	Miguel Martinez, MPH, MSW	P*
Daryl Russell, Co-Chair	AB2449	Ismael Salamanca	EA
Al Ballesteros, MBA	A	Harold Glenn San Agustin, MD	P
Felipe Gonzalez	P	Dee Saunders	EA
Reverend Gerald Green	A	LaShonda Spencer, MD	P
Michael Green, PhD, MHSA	EA	Lambert Talley	P
William King, MD, JD	EA	Carlos Vega-Matos	P
Rob Lester	P	Jonathan Weedman	A
COMMISSION STAFF AND CONSULTANTS			
Jose Garibay, Lizette Martinez			
DHSP STAFF			
Paulina Zamudio, Pamela Ogata, Sona Oksuzyan, Amanda Wahnich			

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*Members of the public may confirm their attendance by contacting Commission staff at hivcomm@lachiv.org.

*Meeting minutes may be corrected up to one year from the date of approval.

Meeting agenda and materials can be found on the Commission's website. Click [HERE](#).

I. ADMINISTRATIVE MATTERS

1. CALL TO ORDER AND MEETING GUIDELINES/REMINDERS

K. Donnelly, Planning, Priorities and Allocations (PP&A) co-chair, called the meeting to order at approximately 1:05pm.

2. ROLL CALL & CONFLICT OF INTEREST STATEMENTS

L. Martinez, Commission staff, conducted roll call and committee members were reminded to state their conflicts.

ROLL CALL (PRESENT): K. Donnelly, F. Gonzalez, R. Lester, H. San Agustin, D. Russell, L. Spencer, L. Talley, C. Vega-Matos

3. Approval of Agenda

MOTION #1: Approve the Agenda Order **(No vote held; quorum was not reached.)**

Planning, Priorities and Allocations Committee
September 16, 2025
Page 2 of 4

4. Approval of Meeting Minutes

MOTION #2: Approval of Meeting Minutes **(No vote held; quorum was not reached.)**

II. PUBLIC COMMENT

5. Opportunity for members of the public to address the Committee on items of interest that is within the jurisdiction of the Committee.

There was no public comment.

III. COMMITTEE NEW BUSINESS

6. Opportunity for Committee members to recommend new business items for the full body or a committee-level discussion on non-agendized matters not posted on the agenda, to be discussed and (if requested) placed on the agenda for action at a future meeting, or matters requiring immediate action because of an emergency situation, or where the need to take action arose subsequent to the posting of the agenda.

There was no committee new business.

IV. REPORTS

7. Commission on HIV Staff Report

- L. Martinez reported that the Executive Committee will be continuing their review of public comment to the proposed changes to the Commission on HIV (COH) bylaws and at their September 25th meeting from 1pm-3pm at the Vermont Corridor. All interested parties are invited to attend and provided additional public comment, if applicable. See Executive Committee [meeting page](#) on the COH website for meeting agenda and additional details.
- L. Martinez reminded the group that the next COH will be held on October 9, 2025 at 9am at Jessie Owens Park Auditorium. Meeting details will be forthcoming. She noted that the proposed final recommendations for the restructuring of the COH will be presented at the October meeting.

8. Co-chair Report

a. September 18th Executive Committee Special Meeting

- K. Donnelly reported that the Executive Committee will be having a special meeting on Thursday, September 18 from 1pm-3pm at the Vermont Corridor. The focus of the meeting is to discuss the Commission's role in prevention planning as an integrated HIV planning body and shared strategies on how to improve prevention planning efforts and strengthen partnerships as the COH transitions into a new structure. See [meeting packet](#) for more details,

b. September 19th Power of Aging Event

- K. Donnelly announced that the Aging Caucus will be hosting the Power of Aging Event on

Planning, Priorities and Allocations Committee
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Friday, Sept. 19th in recognition of National Aging and HIV Awareness Day. The event will take place at the Vermont Corridor from 9am to 3pm and will focus on navigating services in times of uncertainty. See [event flyer](#) for more details.

c. September 26th California HIV/HCV/STI Strategic Plan's Implementation Blueprint Webinar

- K. Donnelly announced that the California Department of Public Health, Office of AIDS (CDPH-OA) will be hosting an informational webinar on the California HIV/HCV/STI Strategic Plan's Implementation Blueprint on September 26th, 2025, at 10:30 AM. This webinar will review the syndemic approach taken in California's Strategic Plan Implementation Blueprint, provide a refresher on the background and content, and help participants gain understanding of why this is important now. See [webinar registration](#) to register.

9. Division of HIV and STD Programs Report

a. Program Year 34 (PY34) Ryan White Program Utilization Report – Core Services

- DHSP staff, S. Oksuzyan, provided a PY34 Ryan White Program Utilization Report to the committee focusing on core Ryan White Program services; see [meeting packet](#) for presentation slides.
- The report showed a decreased utilization in Ambulatory/Outpatient Medical (AOM) services, Home-Based Case Management services and Mental Health services and an increased utilization in Medical Care Coordination services and Oral Health services. The highest expenditures per client were attributed to Housing and Home-Based Case Management services. The lowest expenditures per client were seen in Mental Health services and AOM services.
- Engagement, retention in care and viral suppression percentages were higher in RWP clients using Oral Health services, Home-Based Case Management services and Mental Health services.

10. Ryan White Program Year 36 (PY36) Reallocations

- DHSP staff requested the Committee review their PY36 allocations and reallocate percentages to include the new Partner Support Services within Non-Medical Case Management Services. Initial PY36 allocations did not include funding for this new service because it was under the solicitation process at the time of allocation.
- The Committee recommended aligning PY36 reallocations with PY35 allocations with the intent to revisit the allocations at a later date once more data and expenditure reports are available.

MOTION #3 - Approve the Ryan White Program Year 35 (PY35) Allocations, as presented or revised and provide DHSP the authority to make adjustments of 10% greater or lesser than the approved allocations amount, as expenditure categories dictate, without returning to this body. (No vote was held; quorum was not reached.)

V. NEXT STEPS

11. Task/Assignments Recap

Planning, Priorities and Allocations Committee

September 16, 2025

Page 4 of 4

- a. Commission staff will work with co-chairs to develop the agenda for the October PP&A Committee meeting.
- b. PY36 Allocations will move forward to the Executive Committee for review and approval.

12. Agenda Development for the Next Meeting

- a. DHSP to provide a report on PY34 RWP support services utilization.
- b. Review recommendations from the Women's Caucus.
- c. DHSP to provide a response to the proposed PY35-37 Directives.

VII. ANNOUNCEMENTS

13. Opportunity for Members of the Public and the Committee to Make Announcements

There were no announcements.

VIII. ADJOURNMENT

14. Adjournment for the Regular Meeting of September 16, 2025.

The meeting was adjourned by K. Donnelly at 2:27pm.



Ryan White Program Utilization Summary Year 34: Support Services (March 1, 2024-February 28, 2025)



Sona Oksuzyan, Supervising Epidemiologist

Amanda Wahnich, Supervising Epidemiologist

Monitoring and Evaluation Unit

Division of HIV and STD Programs

October 21, 2025

Agenda

- Support Services Overview
- Support Services Deep Dive Framework
- Support Services Expenditures
- Key Takeaways



Overview of Support Services



Emergency Financial Assistance (EFA)

2 contracted agencies (DHS, APLA)

Provides **limited one-time or short-term payments to assist RWP clients with an urgent need for rent.**
Annual cap was \$5,000.



Housing Service (HS)

4 contracted sites (APLA, DHS, Project New Hope, Salvation Army Alegria)

Provides **temporary or permanent housing with supportive services** for RWP clients



Benefit Specialty Services (BSS)

12 contracted sites

Provide **coordination, guidance and assistance in accessing multiple services** (medical, social, community, legal, financial, employment, vocational, and/or other needed services) and additional public and private programs (if eligible)



Nutrition Support (NS)

3 contracted sites (APLA, Bienestar, and Project Angel Food)

Provides **food to RWP clients**, improving and sustaining nutrition, food security and quality of life



Substance Use Residential (SUR)

1 contracted site (Tarzana Treatment Center)

Provides **outpatient treatment services for substance use disorders**



Linkage and Re-engagement Program (LRP)

DHSP: DCS Health Navigators

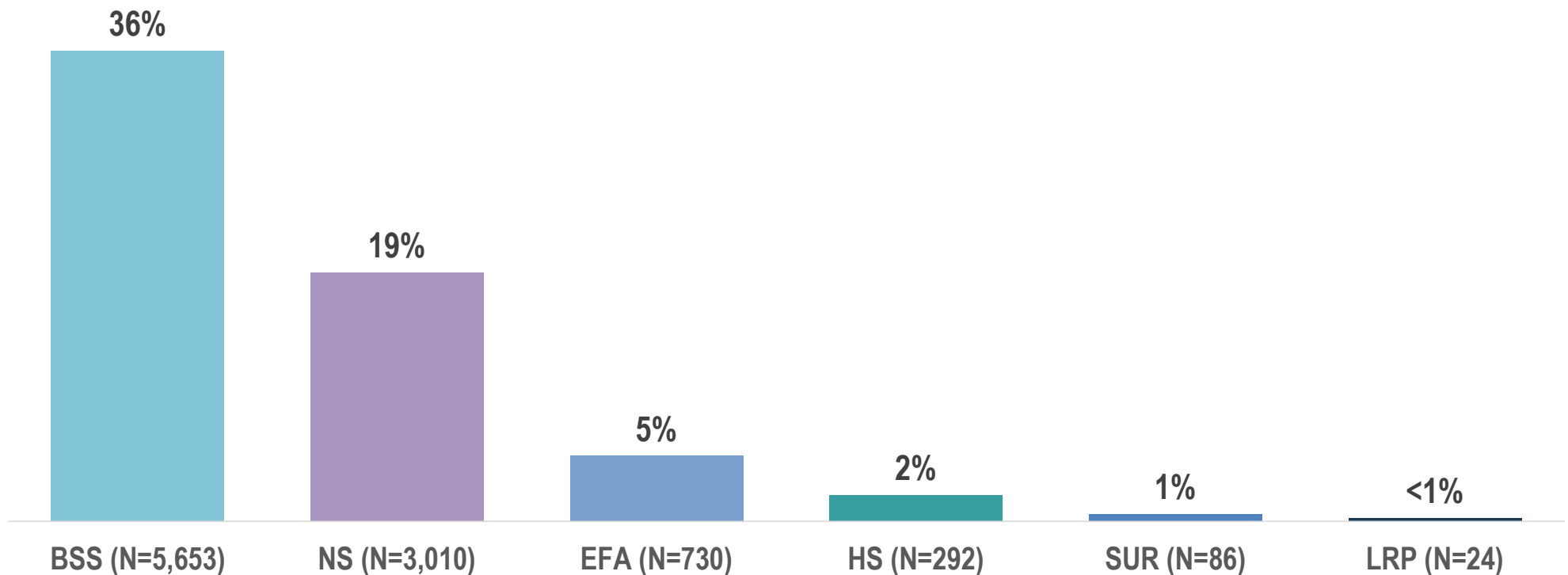
Assists **people newly diagnosed or living with HIV who are lost or returning to treatment to re-engage in care** (medical and psychosocial services).

In Year 34, Benefits Specialty Services (BSS) and Nutrition Services (NS) were the most highly utilized support services.



COUNTY OF LOS ANGELES
Public Health

Utilization of RWP Support Services, Year 34
(Total RWP clients N=15,843)



Support Service Category Deep Dive Framework



Overall Service Utilization and Expenditure Summary

- Client Served
- Service Units (Total and Per Client)
- Expenditures (Total and Per Client)

Client Demographics

- Gender
- Race
- Age

Priority Population Engagement

- Latinx MSM
- Black/AA MSM
- Age $\geq$ 50 years
- Women of color
- Transgender Clients
- Age 13-29 clients
- People who inject drugs (PWID)
- Unhoused < 12 months

Health Determinants

- Primary language
- Income
- Primary insurance
- Housing Status
- Incarceration history

HIV Care Continuum Outcomes

- Engaged in Care
- Retained in Care
- Suppressed Viral Load

Emergency Financial Assistance (EFA)

↑ 18% increase in service utilization in Year 34 compared to Year 33

↑ 14% increase in expenditures in Year 34 compared to Year 33



COUNTY OF LOS ANGELES
Public Health

- A total of **730 unique clients** received EFA services, representing **4% of RWP clients**
- There was an **overall increase in EFA utilization and expenditures** over the last four years

EFA Clients

EFA Expenditures



EFA Service Utilization & Expenditures Summary, Year 34



Service Category	Unique Clients Served	Service Unit(s)	Total Service Units	Units per client	Expenditures	Expenditures per client
EFA	730	Dollars	2,873,110	3,936	\$2,975,974	\$4,077

Funding Source:

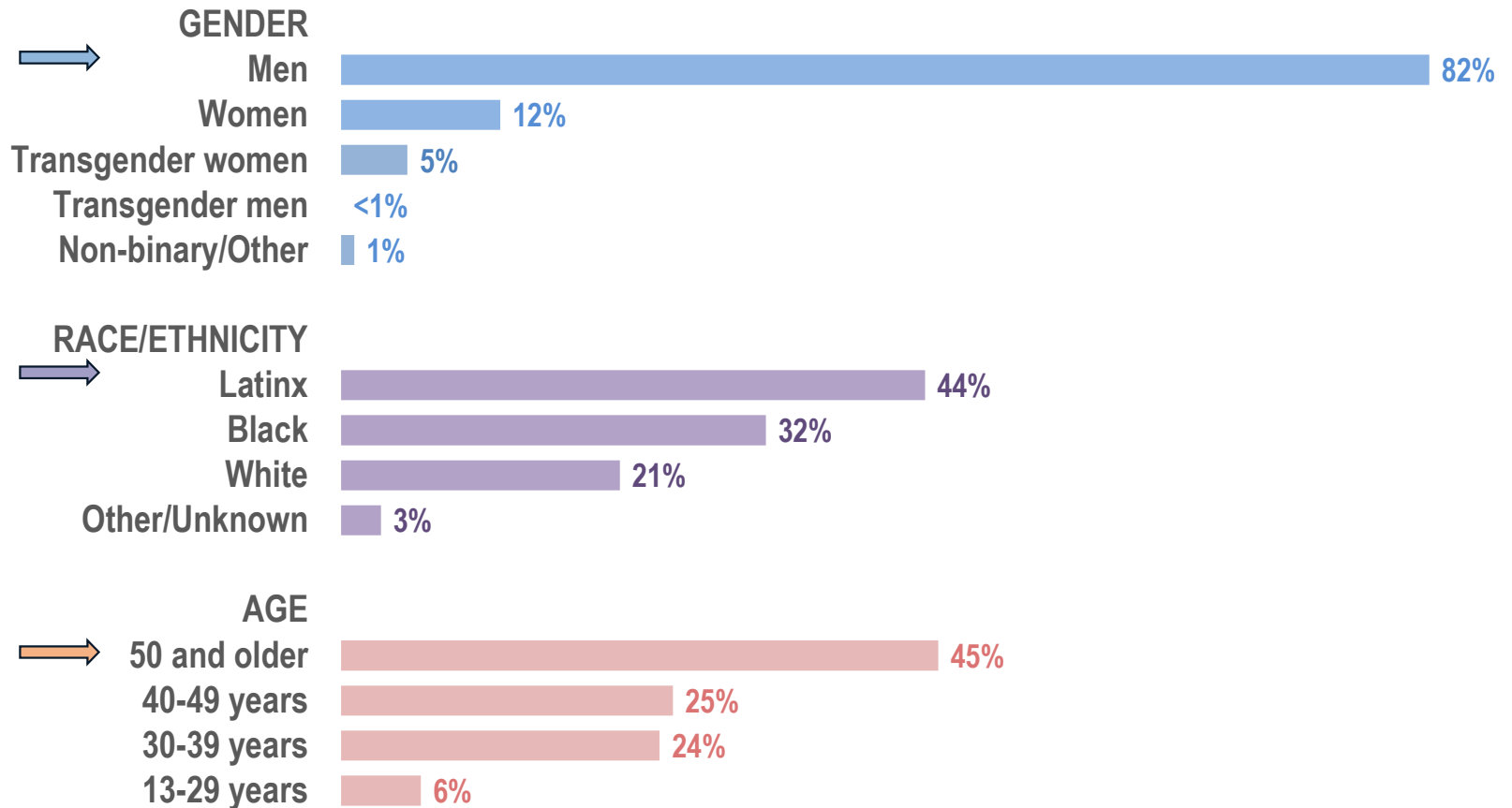
- Part A - \$1,539,288
- HRSA EHE - \$765,693
- HIV NCC - \$670,993

EFA clients were predominantly men, Latinx, and RWP clients aged 50 and older



COUNTY OF LOS ANGELES
Public Health

EFA Client Demographics, Year 34, N=730

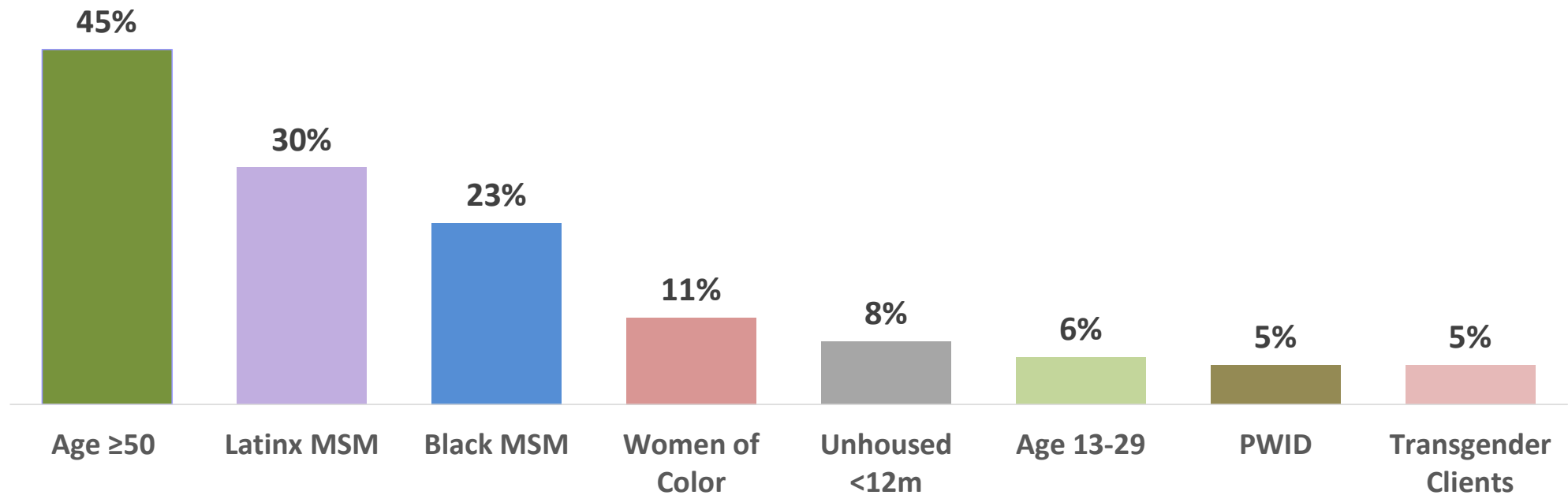


LAC Priority Populations* Accessing EFA, Year 34



COUNTY OF LOS ANGELES
Public Health

- Over half of EFA clients were **aged 50 and older**, representing the largest group
- **Latinx MSM** represented almost a third of EFA clients
- **Black MSM** represented about a quarter of EFA clients



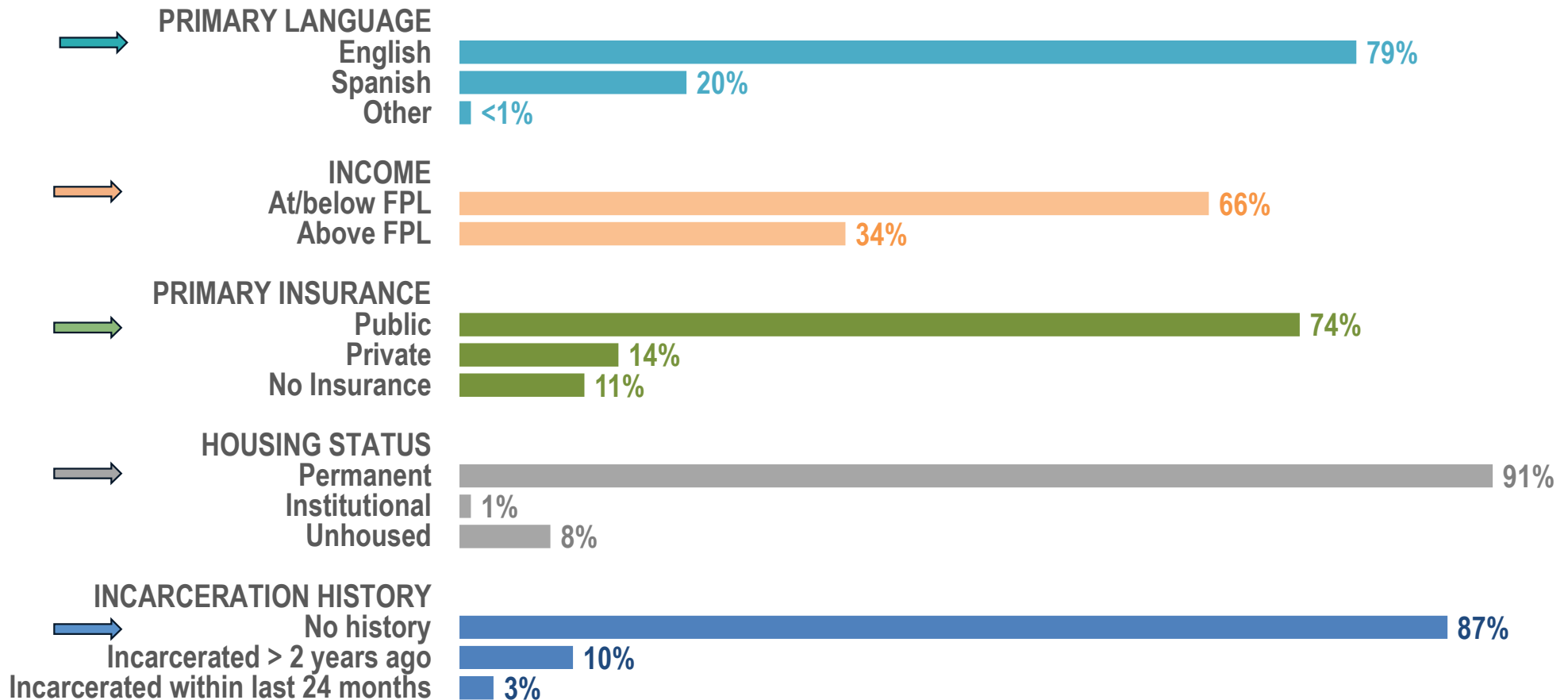
*Priority population groups are not mutually exclusive, they may overlap

Most EFA clients were English speakers, living ≤ FPL, had private insurance, were permanently housed, and had no incarceration history



COUNTY OF LOS ANGELES
Public Health

EFA Client Health Determinants, Year 34, N=730

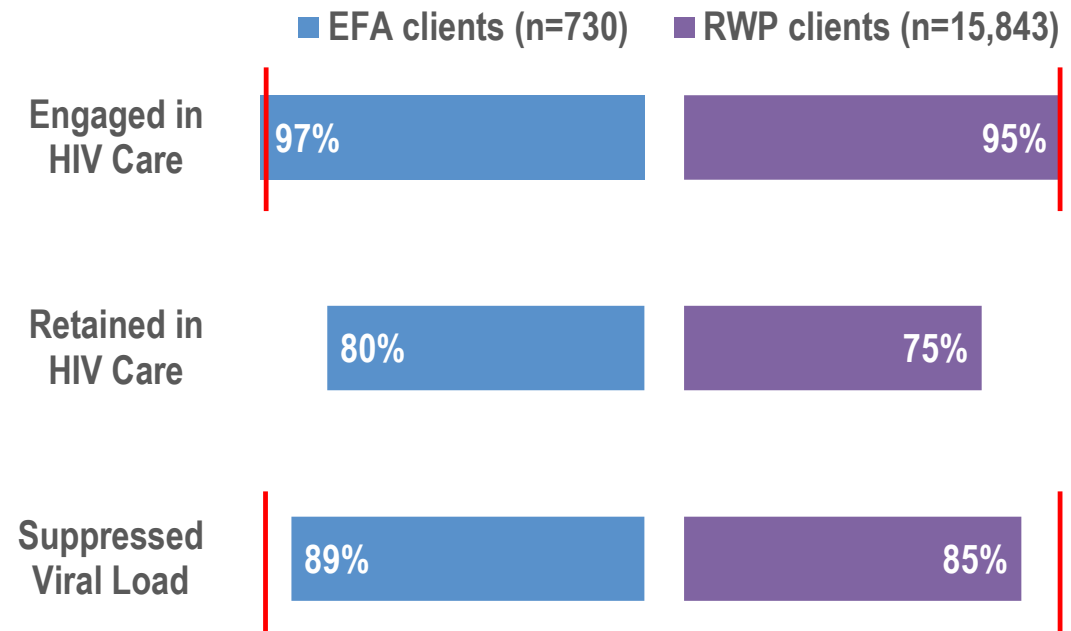


HIV Care Continuum in EFA clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a, retention in care^b, and viral load suppression^c percentages were higher for EFA clients compared to RWP clients overall, Year 34
- EFA clients did not meet the EHE target of 95% for viral suppression. However, they met the local target of 95% for engagement in care.



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

— 95% Target

Data source: HIV Casewatch as of 5/1/2025

Housing Services (HS)

↑ 18% increase in service utilization in Year 34 compared to Year 33

↑ 26% increase in expenditures in Year 34 compared to Year 33



COUNTY OF LOS ANGELES
Public Health

- A total of **292 unique clients** received HS, representing **2% of RWP clients** in Year 34
 - Permanent Supportive Housing (H4H): **193** clients
 - Residential Care Facilities for the Chronically Ill: **68** clients
 - Transitional Residential Care Facilities: **39** clients
- HS utilization and expenditures **increased** in the last 4 years.

HS Clients

237 292

YR31 YR32 YR33 YR34

HS Expenditures

\$5,374,397 \$10,412,224

YR31 YR32 YR33 YR34

HS Service Utilization & Expenditures Summary, Year 34



Service Category	Unique Clients Served	Service Unit(s)	Total Service Units	Units per client	Expenditures	Expenditures per client
HS	292	Days	61,766	280	\$10,412,224	\$35,658
Permanent Supportive Housing (H4H)	193	Days	61,525	319	\$5,530,755	\$28,657
Residential Care Facilities for the Chronically Ill	68	Days	14,049	207	\$4,033,827	\$59,321
Transitional Residential Care Facilities	39	Days	6,192	159	\$847,642	\$21,734

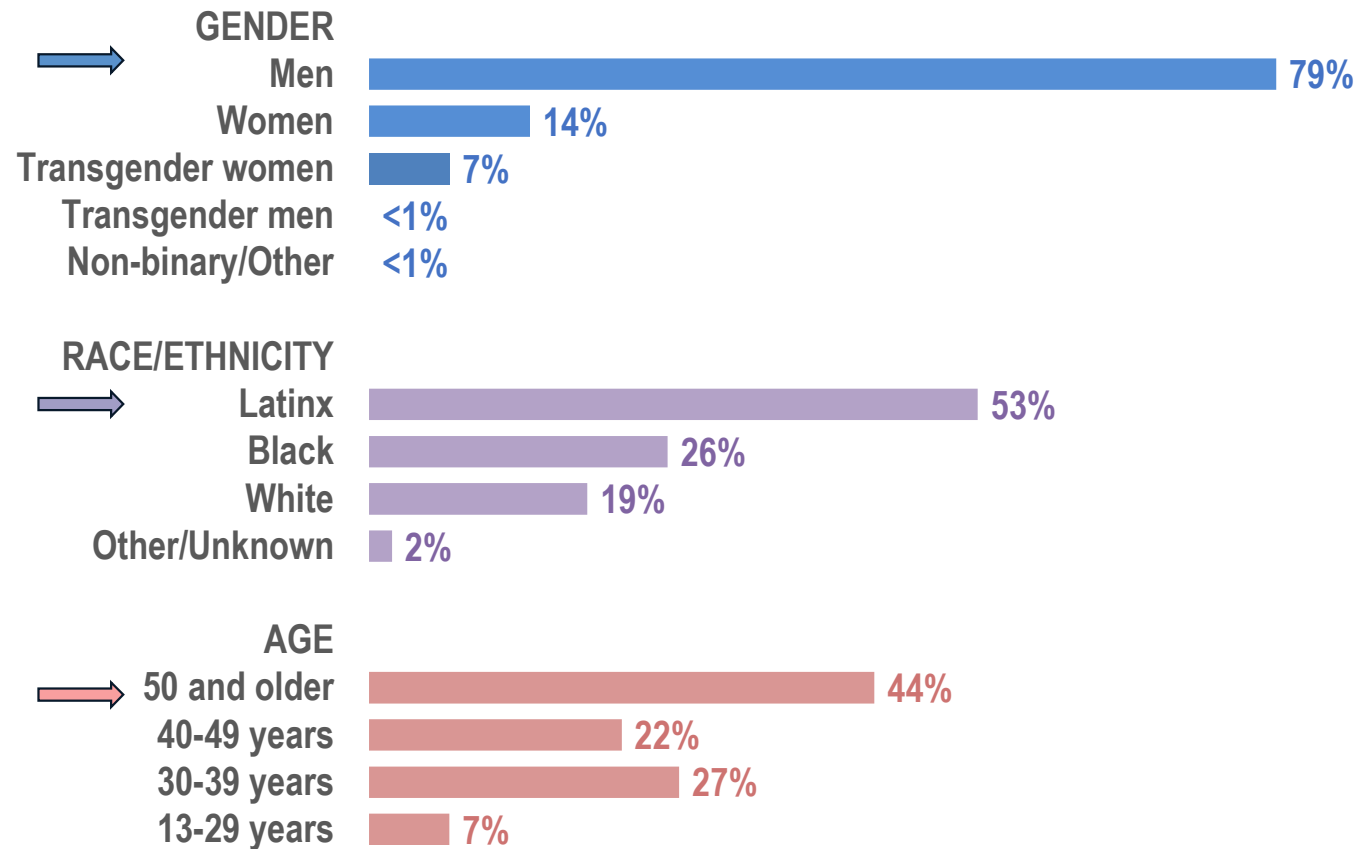
Funding Source:

- Part A - \$484,771
- MAI - \$3,305,635
- Part B – \$4,396,698
- HIV NCC - \$2,225,120



HS clients were predominantly men, Latinx, and were aged 50 and older

HS Client Demographics, Year 34, N=292

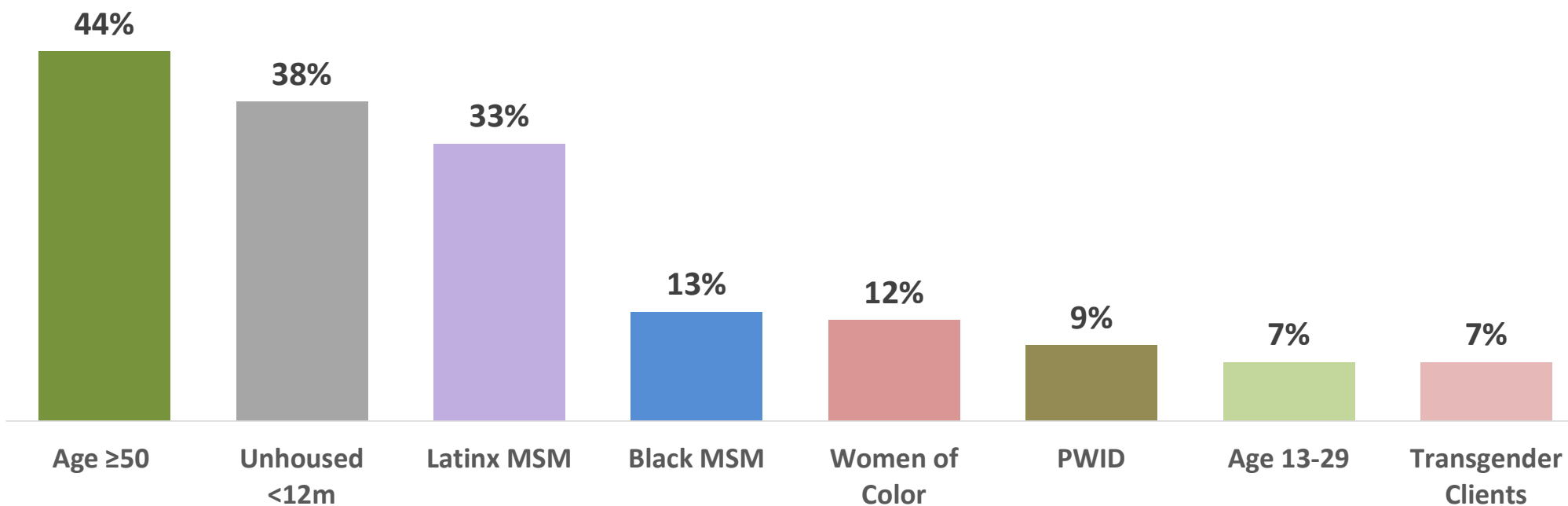


LAC Priority Populations* Accessing HS, Year 34



COUNTY OF LOS ANGELES
Public Health

- RWP clients **aged 50 and older** represented 44% of HS clients, the largest priority populations
- **Unhoused** at some point during Year 34 people represented about 38% of HS clients
- **Latinx MSM** represented a third of HS clients



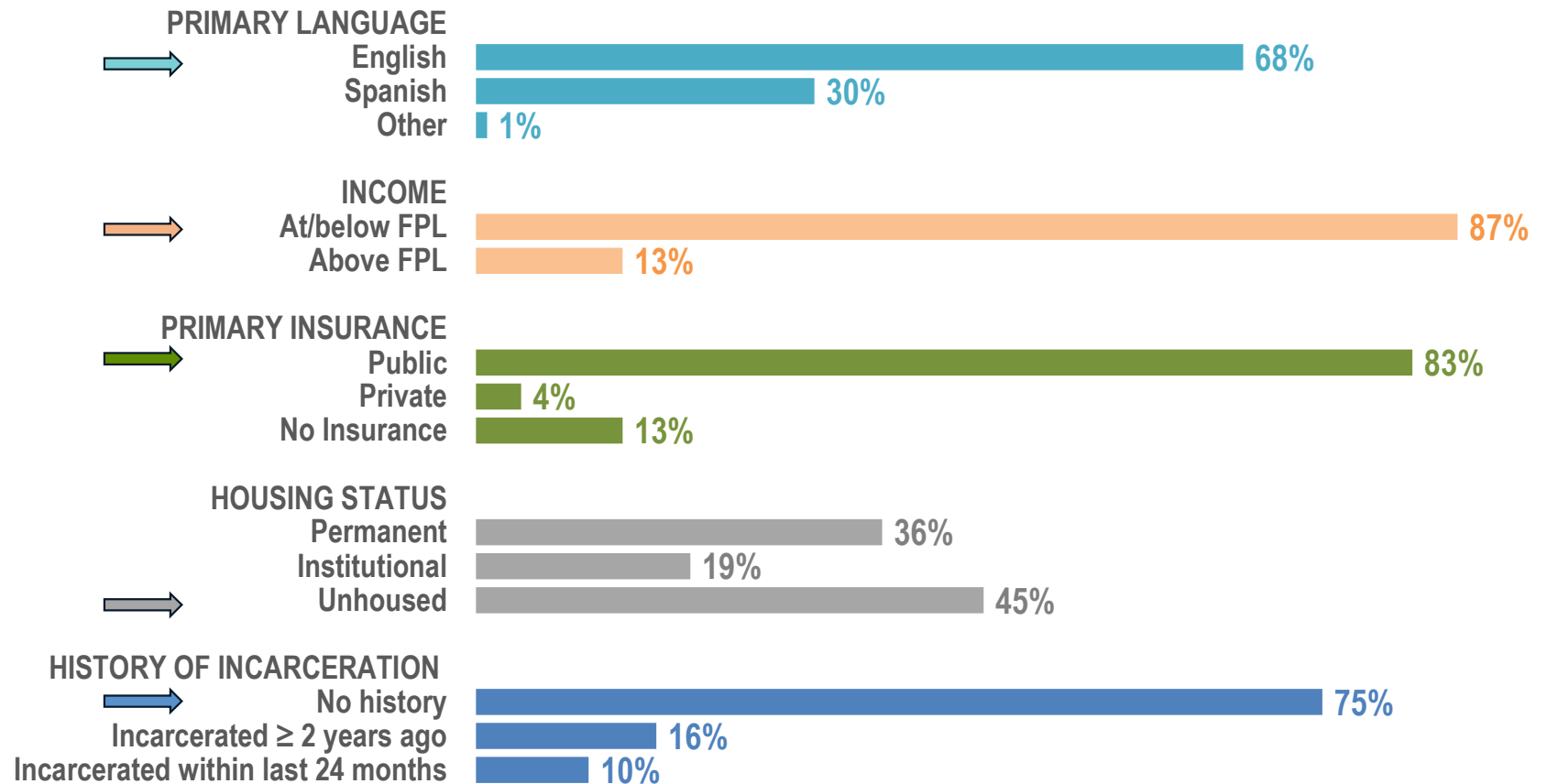
*Priority population groups are not mutually exclusive, they may overlap

Most HS clients were English-speakers, living ≤ FPL, had public insurance, were unhoused, and had no history of incarceration



COUNTY OF LOS ANGELES
Public Health

HS Client Health Determinants, Year 34, N=292



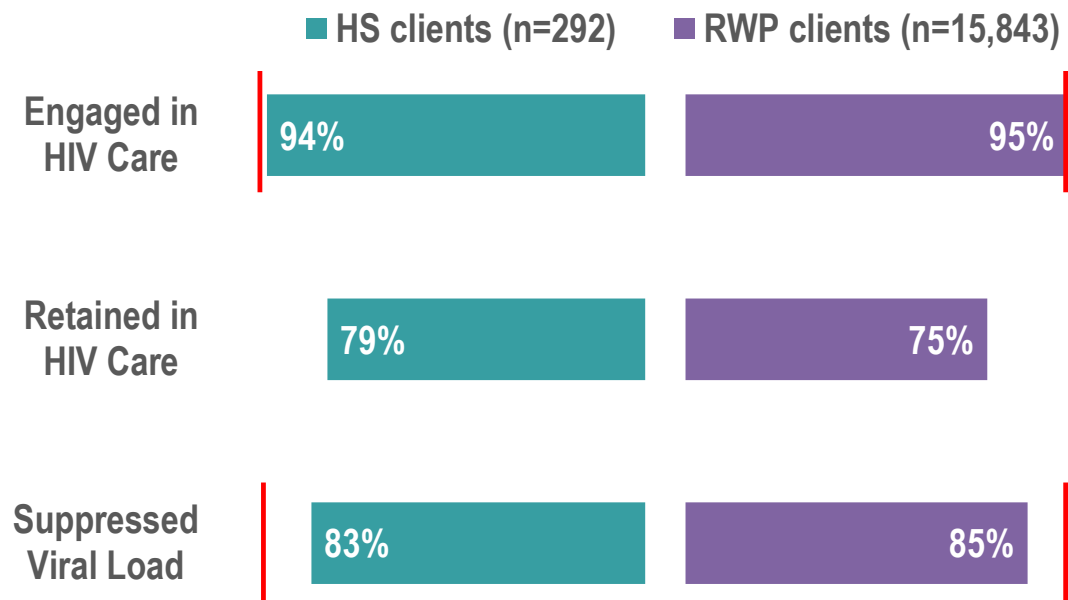
HIV Care Continuum in HS Clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a and viral load suppression^c percentages were lower for HS clients compared to RWP clients overall, Year 34 Retention in care^b was higher among housing clients than RWP clients overall

- HS clients did not meet the EHE targets



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

— 95% Target

Data source: HIV Casewatch as of 5/1/2025

Benefit Specialty Services (BSS)

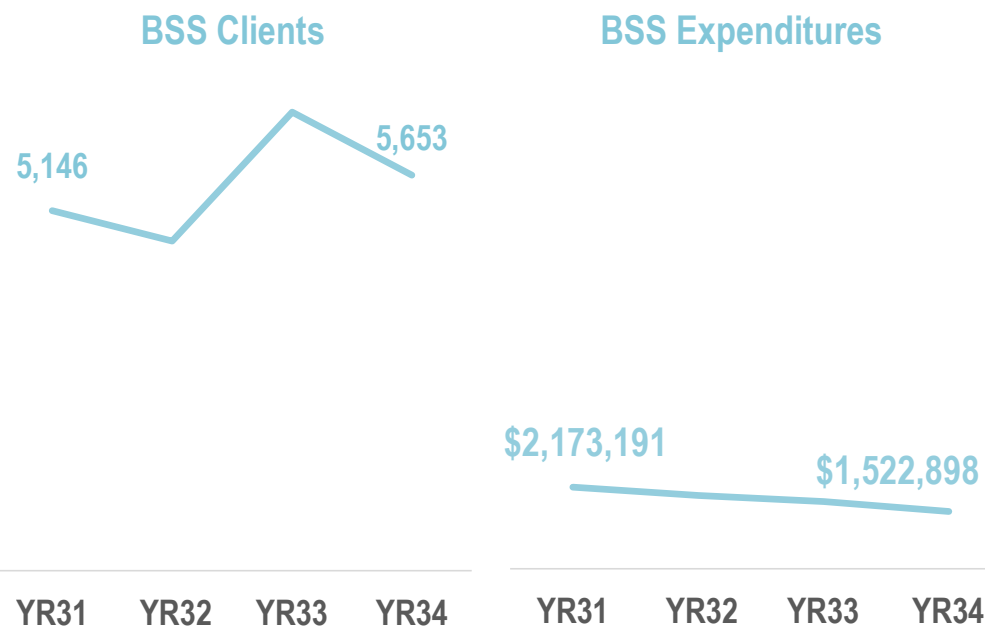
↓ 14% decrease in service utilization in Year 34 compared to Year 33

↓ 15% decrease in expenditures in Year 34 compared to Year 33



COUNTY OF LOS ANGELES
Public Health

- A total of **5,653 unique clients** received **BSS**, representing **36% of RWP clients**
- While **BSS utilization** varied in the past 4 years, expenditures have **decreased**.



BSS Service Utilization & Expenditures Summary, Year 34



COUNTY OF LOS ANGELES
Public Health

Service Category	Unique Clients Served	Service Unit(s)	Total Service Units	Units <u>per client</u>	Expenditures	Expenditures <u>per client</u>
BSS	5,653	23,541	Hours	4	\$1,522,898	\$269

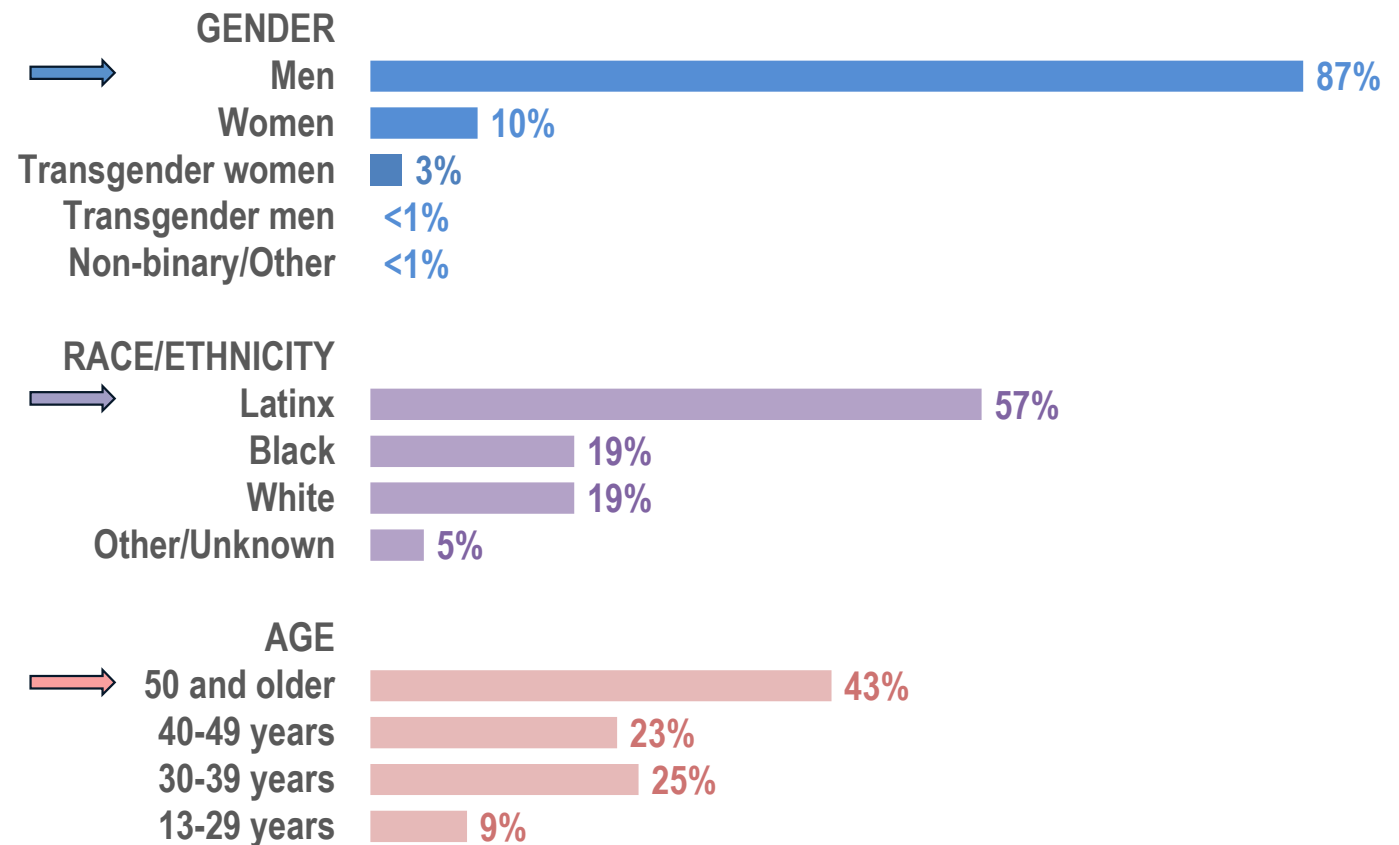
Funding Source:

- Part A - \$1,522,898



Most BSS clients were men, Latinx, and were aged 50 and older

BSS Client Demographics, Year 34, N=5,653

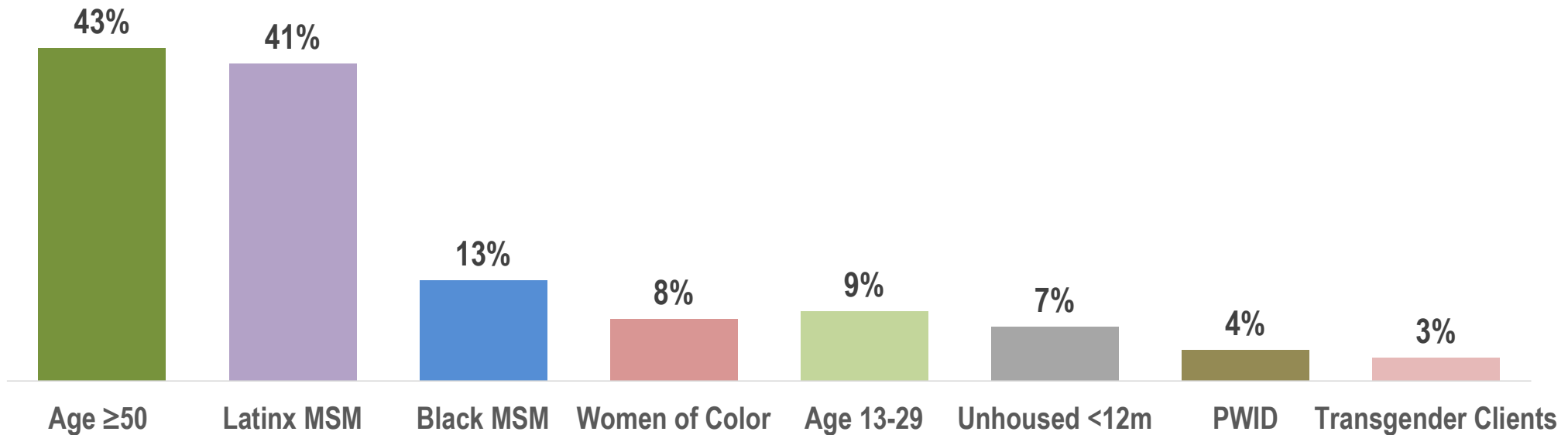


LAC Priority Populations* Accessing BSS, Year 34



COUNTY OF LOS ANGELES
Public Health

- **Clients age ≥ 50** represented the **largest percentage of BSS clients**
- **Latinx MSM** clients were the second highest priority population served by BSS



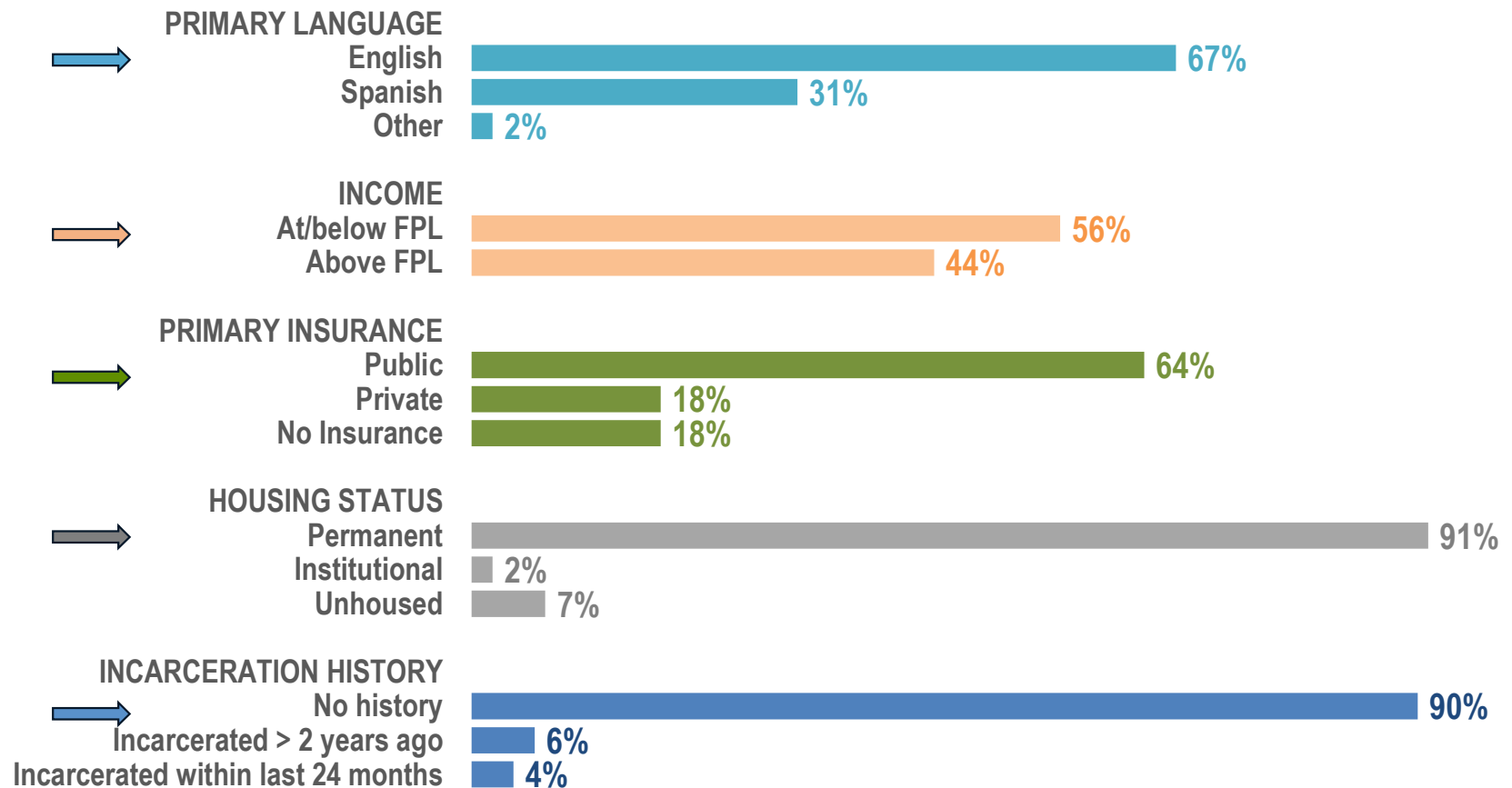
*Priority population groups are not mutually exclusive, they may overlap

Most BSS clients were English-speakers, were living $\leq$ FPL, had public insurance, were permanently housed, and had no history of incarceration



COUNTY OF LOS ANGELES
Public Health

BSS Client Health Determinants, Year 34, N=5,653

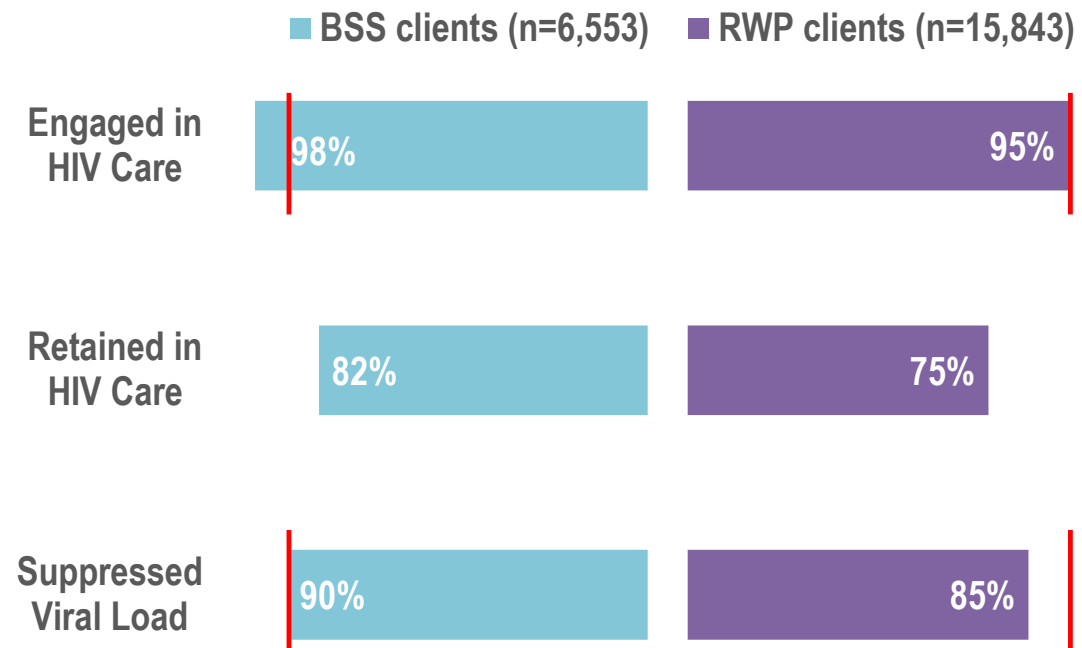


HIV Care Continuum in BSS clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a, retention^b, and viral load suppression^c percentages were higher for BSS clients compared to RWP clients overall, Year 34
- BSS clients did not meet the EHE target of 95% for viral suppression. However, they met the local target of 95% for engagement in care.



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

95% Target

Data source: HIV Casewatch as of 5/1/2025

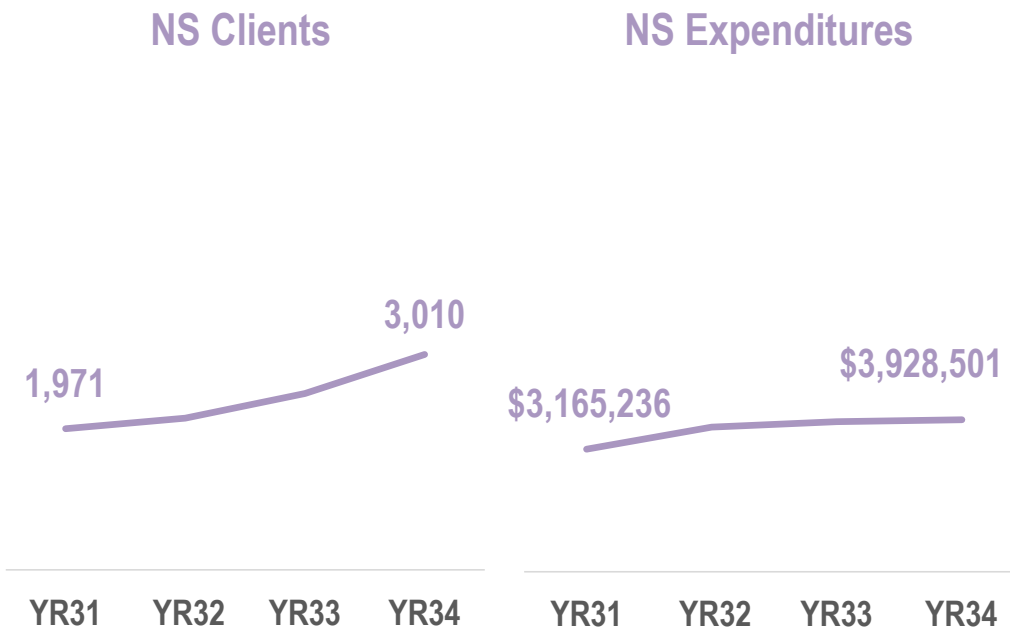
Nutrition Support Services (NS)

↑ 22% increase in service utilization in Year 34 compared to Year 33

↑ 1% increase in expenditures in Year 34 compared to Year 33



- A total of **3,010 unique clients** received NS, representing **19% of RWP clients**
 - Delivered Meals* – 457 clients
 - Food Bank* – 2,700 clients
- NS utilization and expenditures increased** in the last four years



NS Service Utilization & Expenditures Summary, Year 34



Service Category	Unique Clients Served	Service Unit(s)	Total Service Units	Units per client	Expenditures	Expenditures per client
NS	3,010	Various	507,949	169	\$3,928,501	\$1,305
Delivered Meals	457	Meals	270,390	592	\$2,597,212	\$5,683
Food Bank	2,700	Bags of groceries	237,559	88	\$1,331,289	\$493

Funding Source:

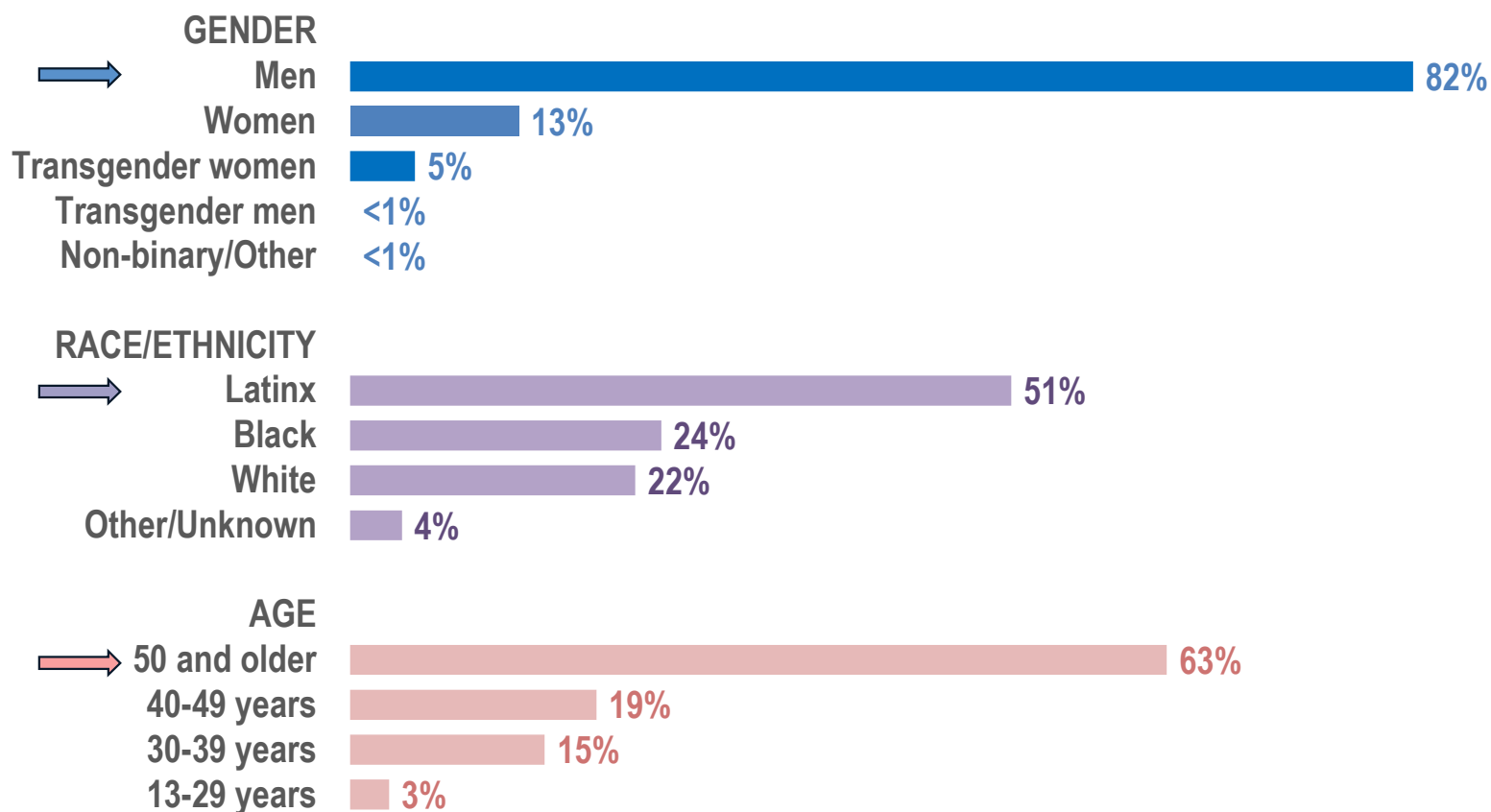
- Part A - \$2,597,212
- HRSA EHE - \$1,000,000
- HIV NCC - \$331,289

Most NS clients were men, Latinx and were aged 50 and older



COUNTY OF LOS ANGELES
Public Health

NS Client Demographics Year 34, N=3,010

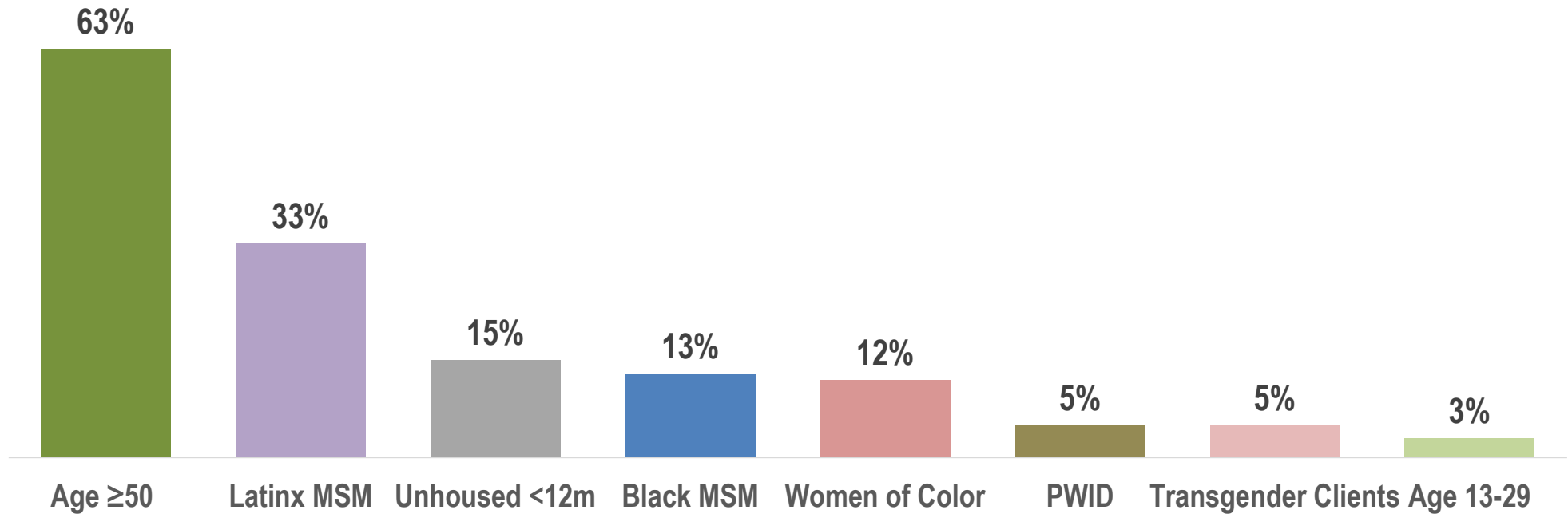


LAC Priority Populations* Accessing NS, Year 34



COUNTY OF LOS ANGELES
Public Health

- **Clients age ≥ 50** represented most NS utilization clients (including subservices)
- **Latinx MSM** clients were the second highest NS utilization clients (including subservices)



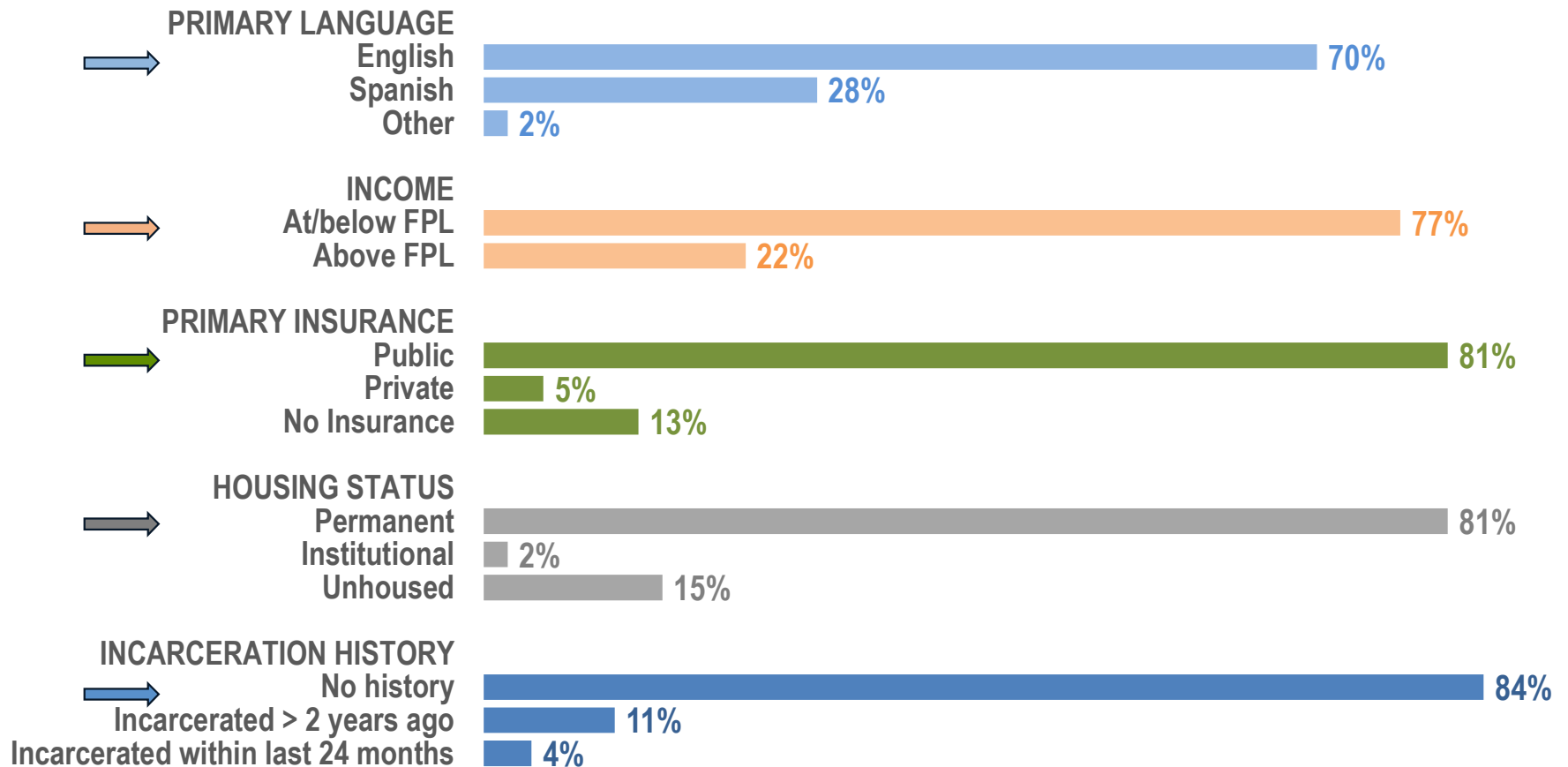
*Priority population groups are not mutually exclusive, they may overlap

Most of NS clients were English-speakers, lived ≤ FPL, had public insurance, were permanently housed, and had no history of incarceration



COUNTY OF LOS ANGELES
Public Health

NS Client Health Determinants, Year 34, N=3,010



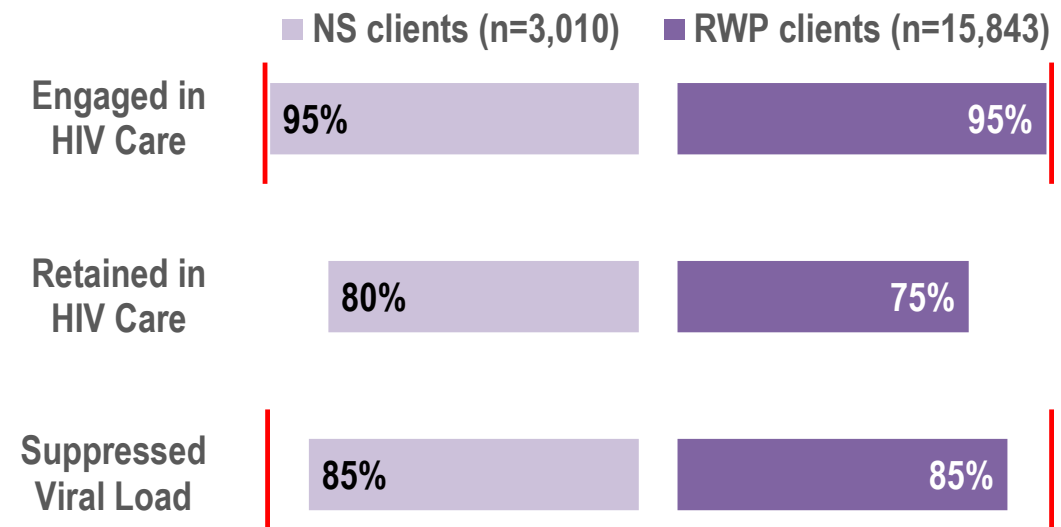
HIV Care Continuum in NS Clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a and viral load suppression^c percentages were similar for NS service clients compared to RWP clients in Year 34. Retention in care^b was higher among NS clients than RWP clients overall

- NS service clients did not meet EHE or local targets



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

95% Target

Data source: HIV Casewatch as of 5/1/2025

Substance Use Residential (SUR) Services

➡ No significant changes in the number of clients served.

⬆ 34% increase in expenditures in Year 34 compared to Year 33



COUNTY OF LOS ANGELES
Public Health

- A total of **86 unique clients** received **SUR** services, represented **<1% of RWP clients**.
- While **utilization of SUR services** had no significant changes over four years, **expenditures increased** considerably.

SUR Clients

SUR Expenditures



SUR Service Utilization & Expenditures Summary, Year 34



COUNTY OF LOS ANGELES
Public Health

Service Category	Unique Clients Served	Service Unit(s)	Total Service Units	Units <u>per client</u>	Expenditures	Expenditures <u>per client</u>
SUR	86	Days	12,975	151	\$973,125	\$11,315

Funding Source:

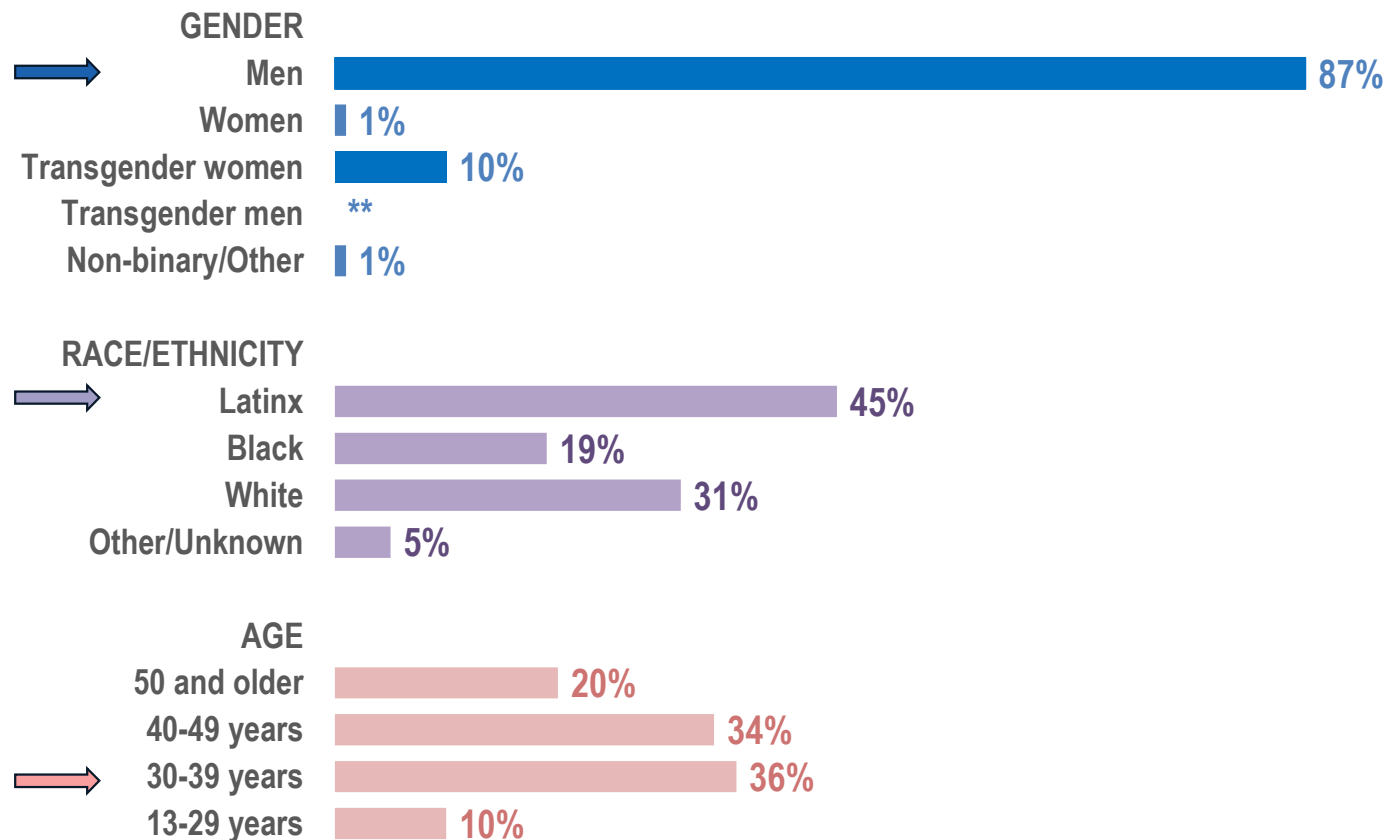
- *Part B - \$891,175*
- *SAPC Non-DMC - \$55,000*
- *HIV NCC - \$ 6,950*

SUR clients were predominantly men, Latinx, and aged 30-39 years old



COUNTY OF LOS ANGELES
Public Health

SUR Client Demographics, Year 34, N=86

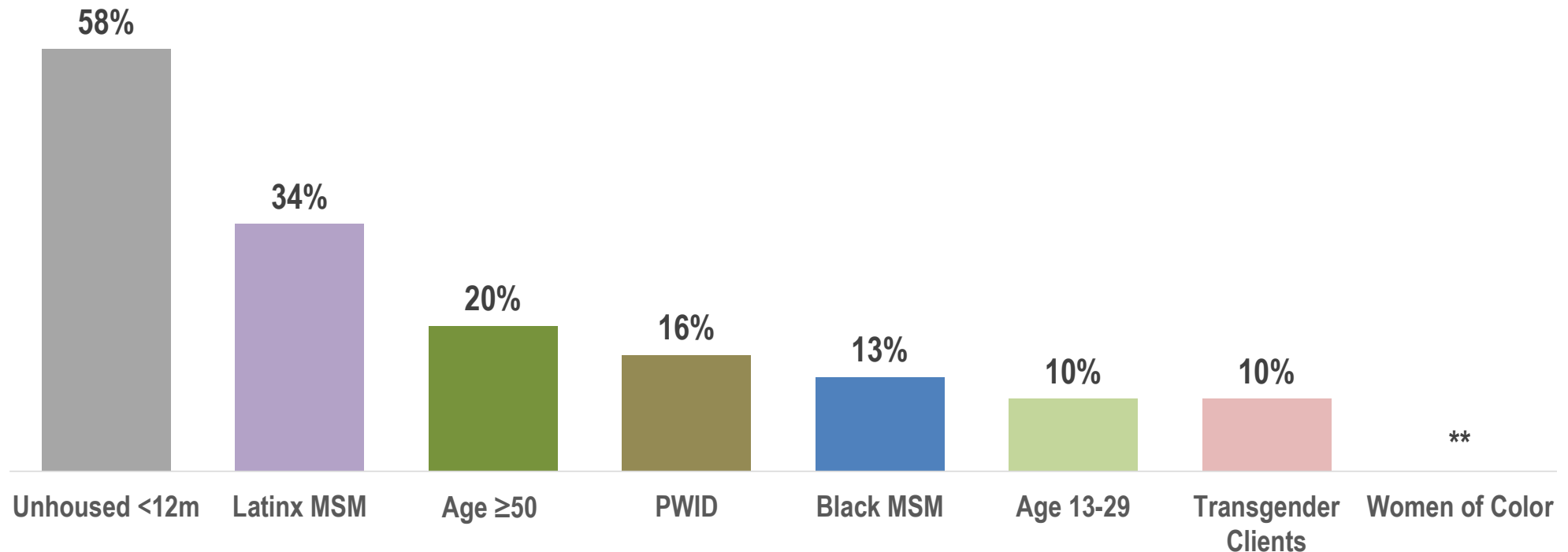


LAC Priority Populations* Accessing SUR, Year 34



COUNTY OF LOS ANGELES
Public Health

- **Unhoused** at some point during Year 34 clients represented the majority of SUR clients
- **Latinx MSM** were the next highest served by SUR followed by people aged 50 and older



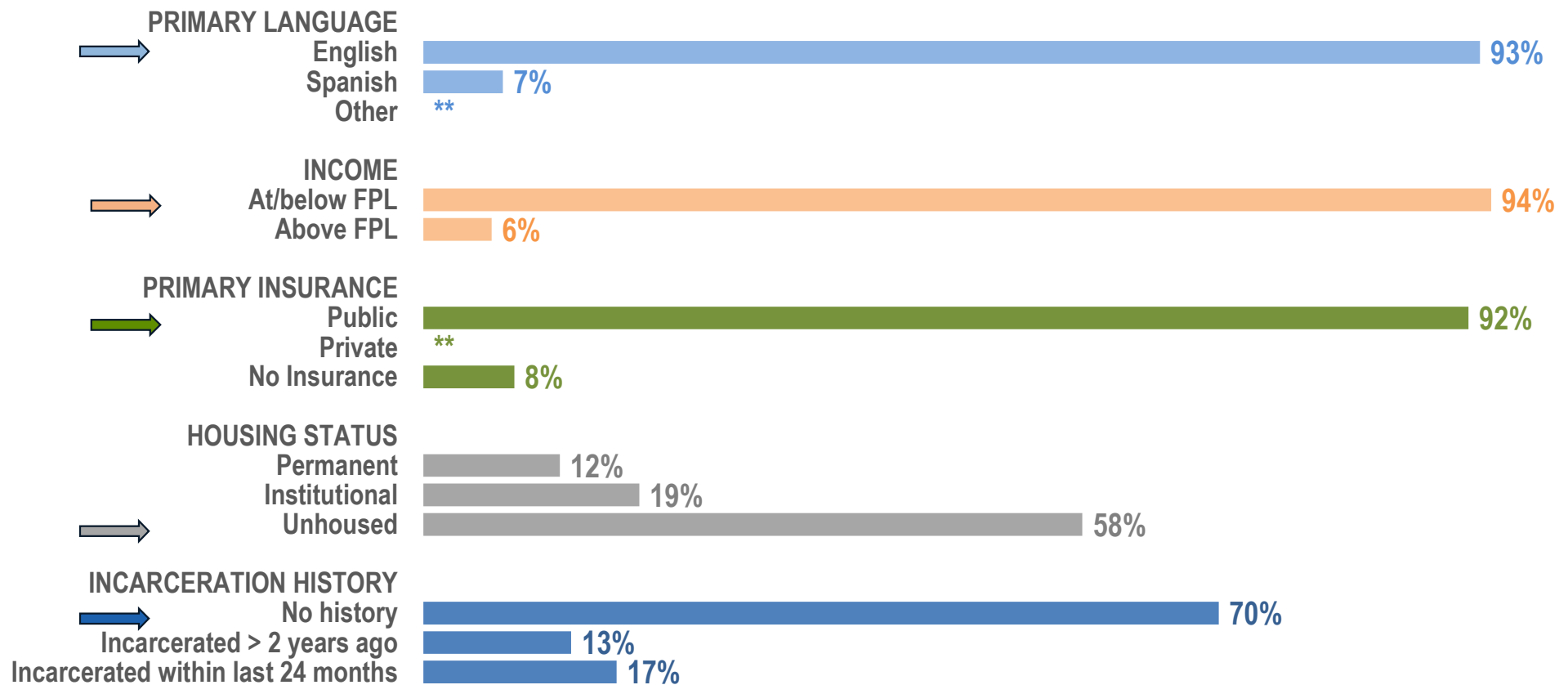
*Priority population groups are not mutually exclusive, they may overlap

SUR clients were predominantly English-speakers, living $\leq$ FPL, had public insurance, were unhoused, and had no incarceration history.



COUNTY OF LOS ANGELES
Public Health

SUR Client Health Determinants, Year 34, N=86

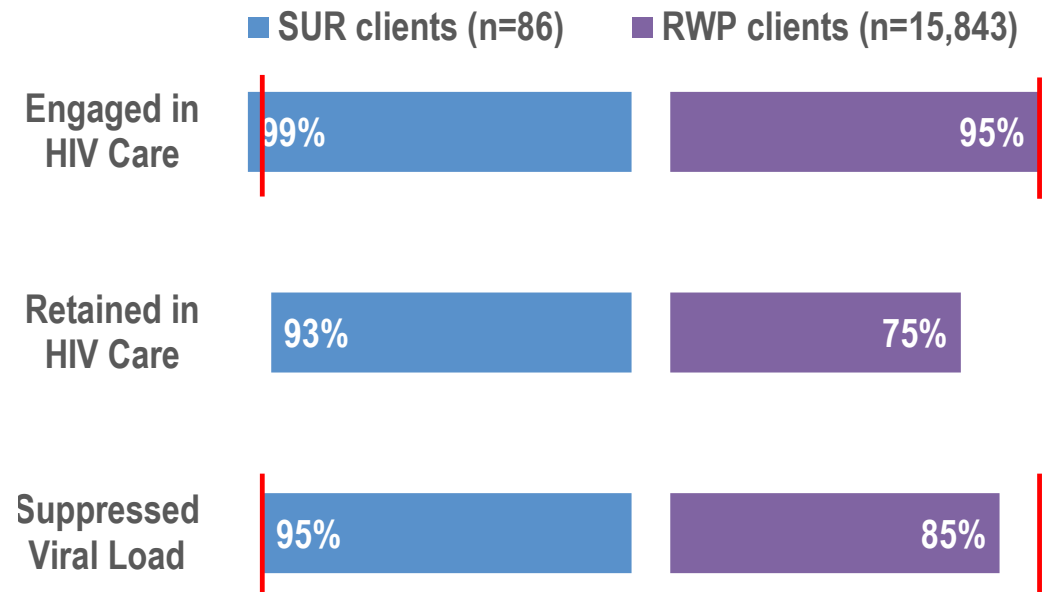


HIV Care Continuum in SUR Clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a, retention^b, and viral load suppression^c percentages were higher for SUR clients compared to RWP clients overall, Year 34
- SUR clients met the EHE target of 95% for viral suppression and the local target of 95% for engagement in care



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

— 95% Target

Data source: HIV Casewatch as of 5/1/2025

Linkage and Re-engagement Program (LRP)

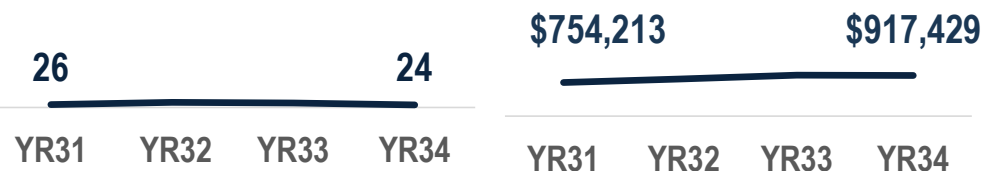
↓ 40% decrease in service utilization in Year 34 compared to Year 33

→ No significant decrease in expenditures in Year 34 compared to Year 33

- A total of **24 unique clients** received **LRP** services, representing **<1% of RWP clients**
- While **utilization of LRP service decreased** in the past 4 years, **expenditures increased**

LRP clients

LRP expenditures



COUNTY OF LOS ANGELES
Public Health

LRP Service Utilization & Expenditures Summary, Year 34



Service Category	Unique Clients Served*	Service Unit(s)	Total Service Units	Units per client	Expenditures	Expenditures per client
LRP	24	Hours	479	20	\$917,429	\$38,226

Funding Source:

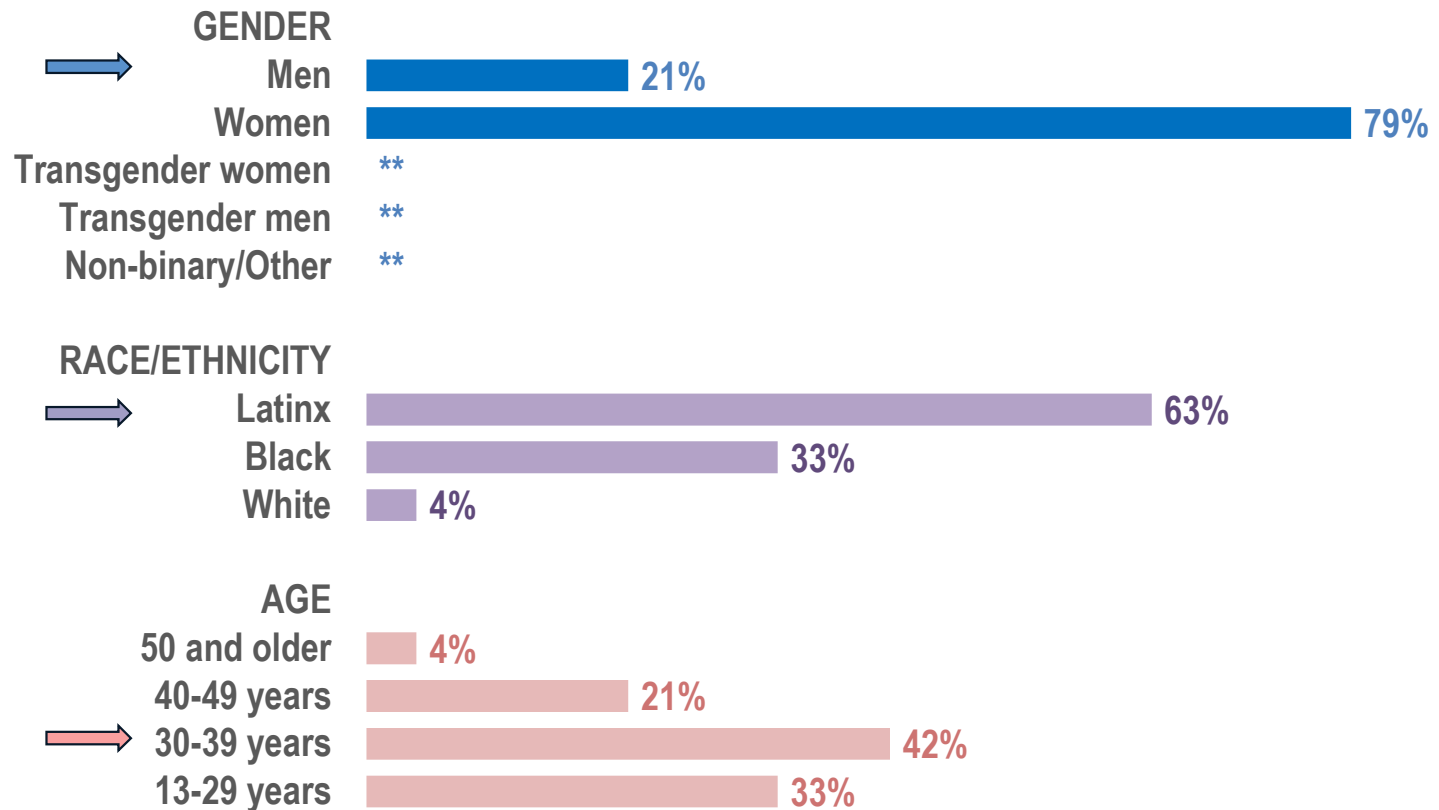
- HRSA EHE- \$697,379
- HIV NCC- \$220,050

*244 referrals for LRP, 196 accepted referrals; 24 served by LRP entered in CaseWatch

Most LRP clients were women, Latinx, and aged 39 years and below



LRP Client Demographics, Year 34, N=24

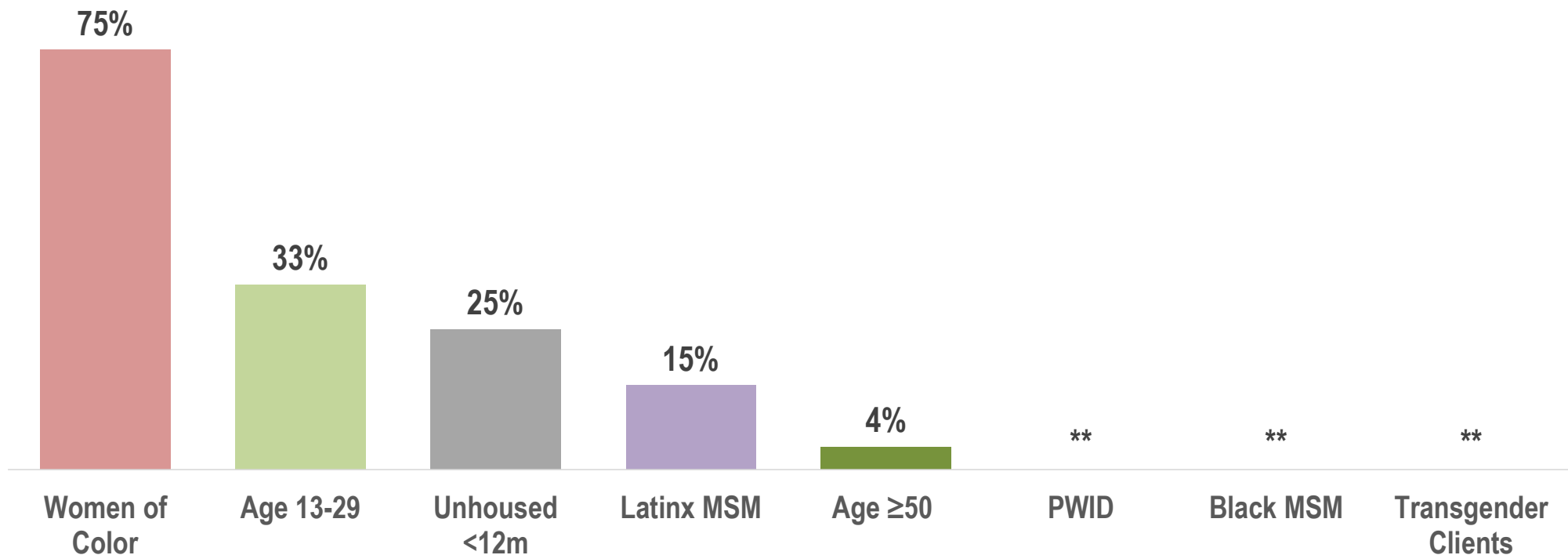


LAC Priority Populations* Accessing LRP, Year 34



COUNTY OF LOS ANGELES
Public Health

- **Women of color** represented the majority of LRP clients
- LRP clients **aged 13-29** and recently **unhoused** were the second highest priority population



*Priority population groups are not mutually exclusive, they may overlap

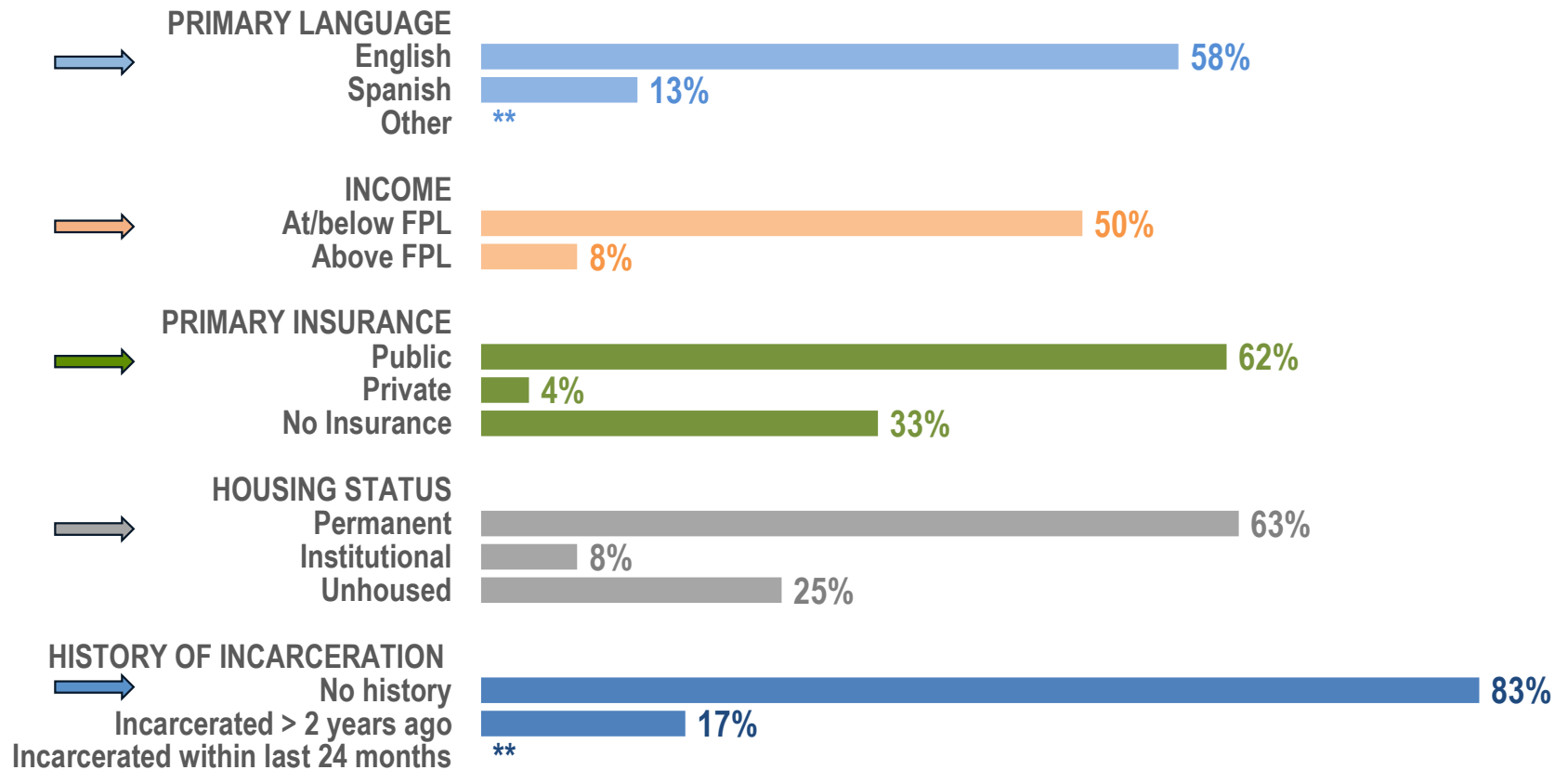
Most of LRP clients were English-speakers, living ≤ FPL, insured, permanently housed, and had incarceration history

SC0



COUNTY OF LOS ANGELES
Public Health

LRP Client Health Determinants, Year 34, N=24



Totals may not sum to 100% due to incomplete reporting

Slide 40

SC0

Made slight change to title

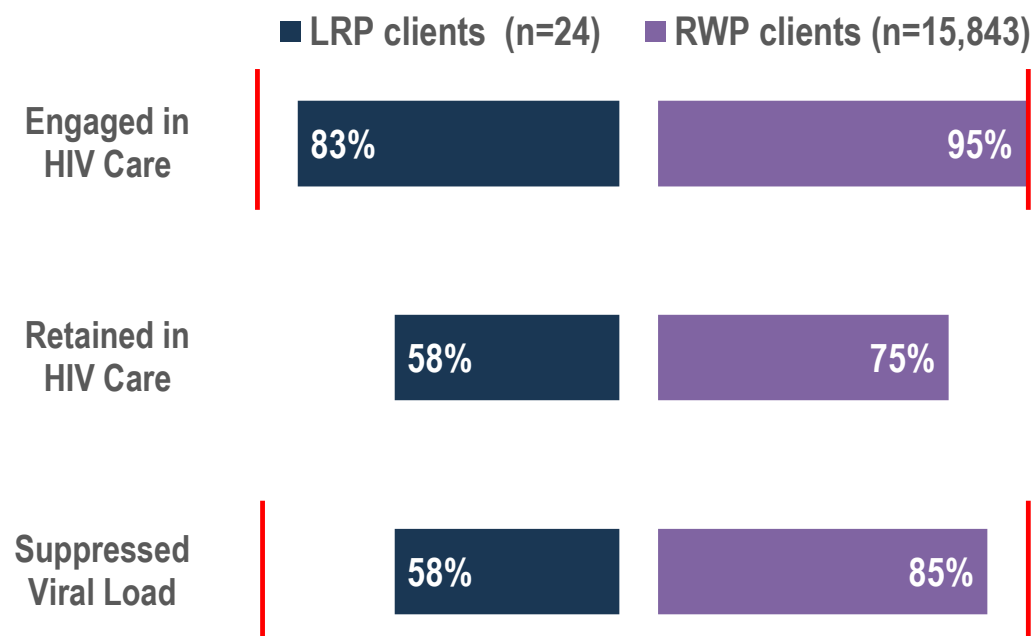
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HIV Care Continuum in LRP clients, Year 34



COUNTY OF LOS ANGELES
Public Health

- Engagement^a, retention in care^b, and viral suppression^c was lower for LRP clients compared to RWP clients overall, Year 34
- LRP clients did not meet the EHE target of 95% for viral suppression; neither they met the local target of 95% for engagement in care



^a**Engagement in Care** defined as 1 ≥ viral load, CD4 or genotype test reported in the 12-month period based on HIV laboratory data as of 5/5/2025

^b**Retention in care** defined as 2 ≥ viral load, CD4 or genotype test reported >30 days apart in the 12-month period based on HIV laboratory data as of 5/5/2025

^c**Viral suppression** defined as most recent viral load test <200 copies/mL in the 12-month period based on HIV laboratory data as of 5/5/2025

— 95% Target

Data source: HIV Casewatch as of 5/1/2025

Expenditures for Support RWP Services, Year 34



EFA	<i>\$2,975,974</i>
HS	<i>\$10,412,224</i>
BSS	<i>\$1,522,898</i>
NS	<i>\$3,928,501</i>
SUR	<i>\$973,125</i>
LRP	<i>\$917,429</i>

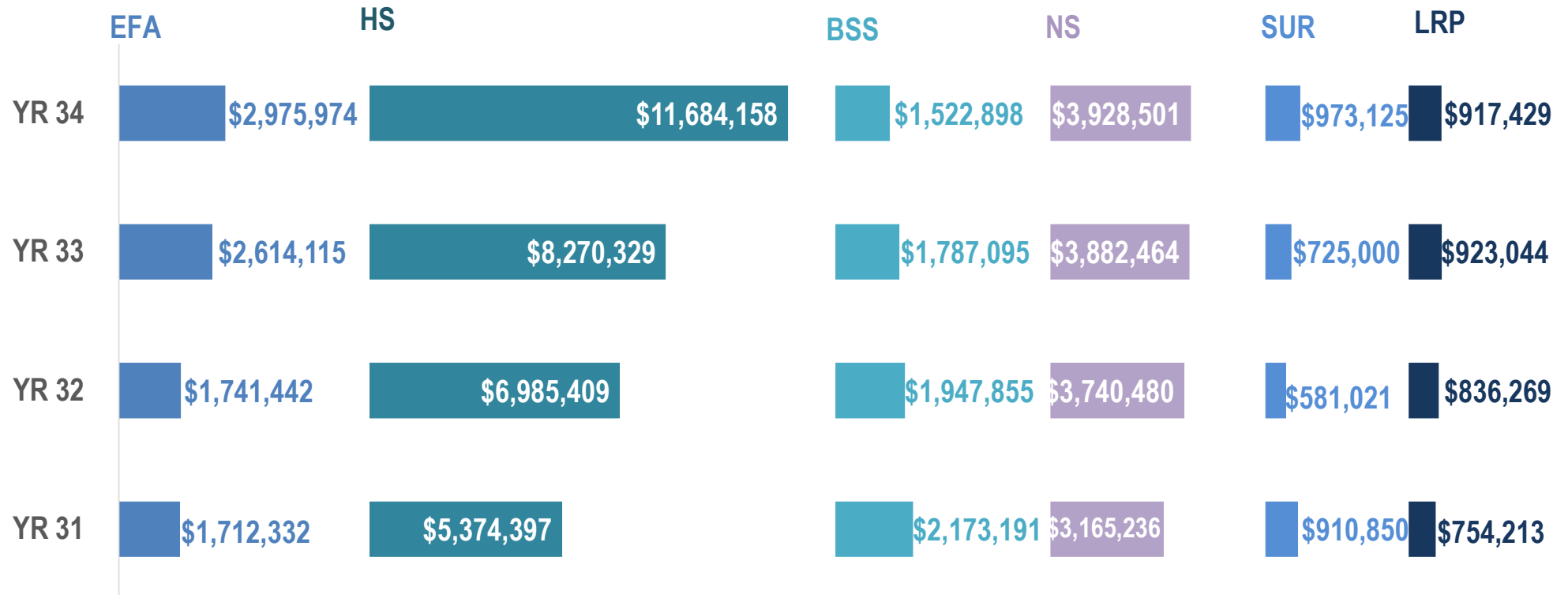
Expenditures by Support Service Category, Years 31-34



EFA, HS, NS, SUR services expenditures increased since Year 31 or 32 with the highest in Year 34.

LRP expenditures also increased compared to Years 31-32.

Expenditures for **BSS** decreased over four years.



Expenditures per Client for Support RWP Services, Year 34



- The **highest expenditures per client** were spent for **HS**, followed by **LRP** services.
- The **lowest expenditures per client** were spent for **BSS**, followed by **NS** Support services.

Service Category	Number of clients	% of RWP clients	Expenditures	% of expenditures	Expenditures per client
LRP	24	<1%	\$917,429	2%	\$38,226
HS	292	2%	\$10,412,224	18%	\$35,658
SUR	86	<1%	\$973,125	2%	\$11,315
EFA	730	4%	\$2,975,974	6%	\$4,077
NS	3,010	19%	\$3,928,501	8%	\$1,305
BSS	5,653	36%	\$1,522,898	4%	\$269

Early Intervention Services*

\$2,143,916

Legal*

\$1,073,964

Transportation*

\$738,442

*No information on these services in CaseWatch

Top 5 RWP Services Utilized

Year 34

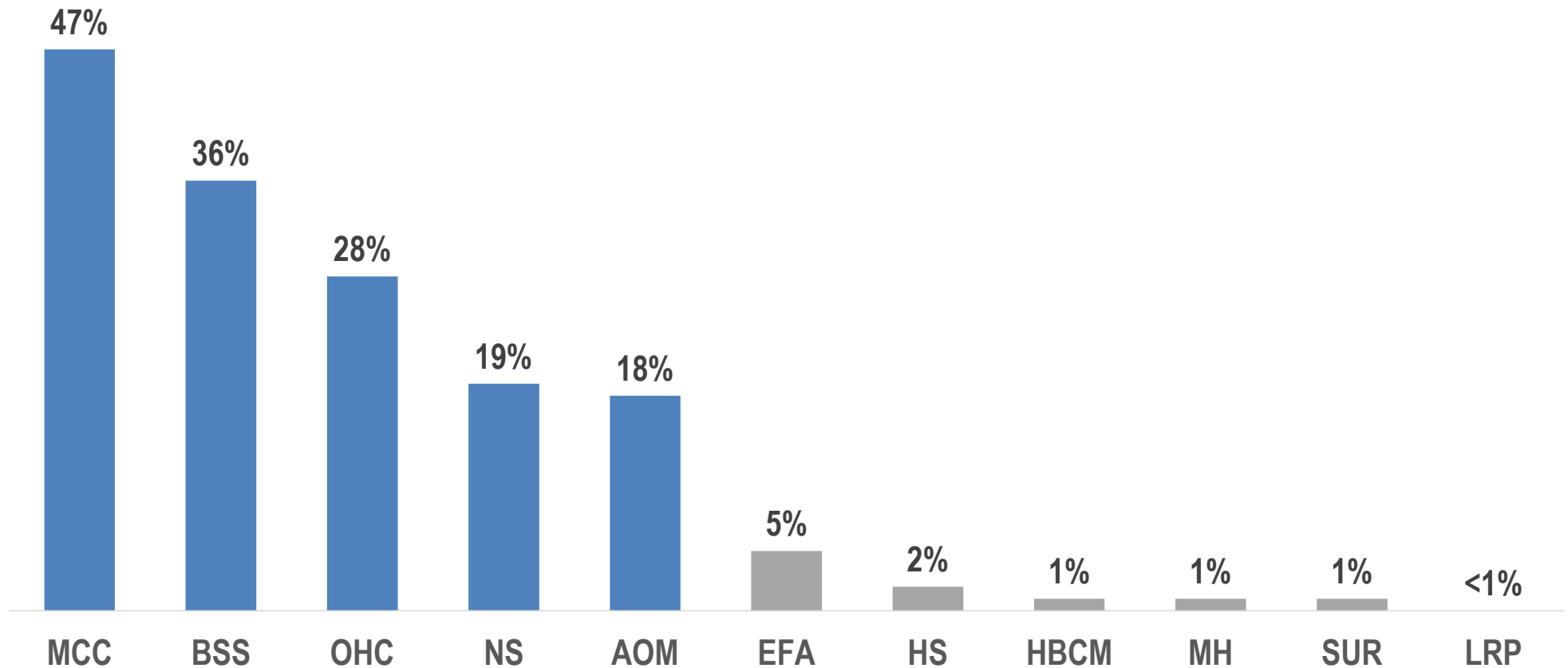


The top five services utilized by RWP clients in Year 34 were MCC, BSS, Oral Health, Nutrition Support and AOM



COUNTY OF LOS ANGELES
Public Health

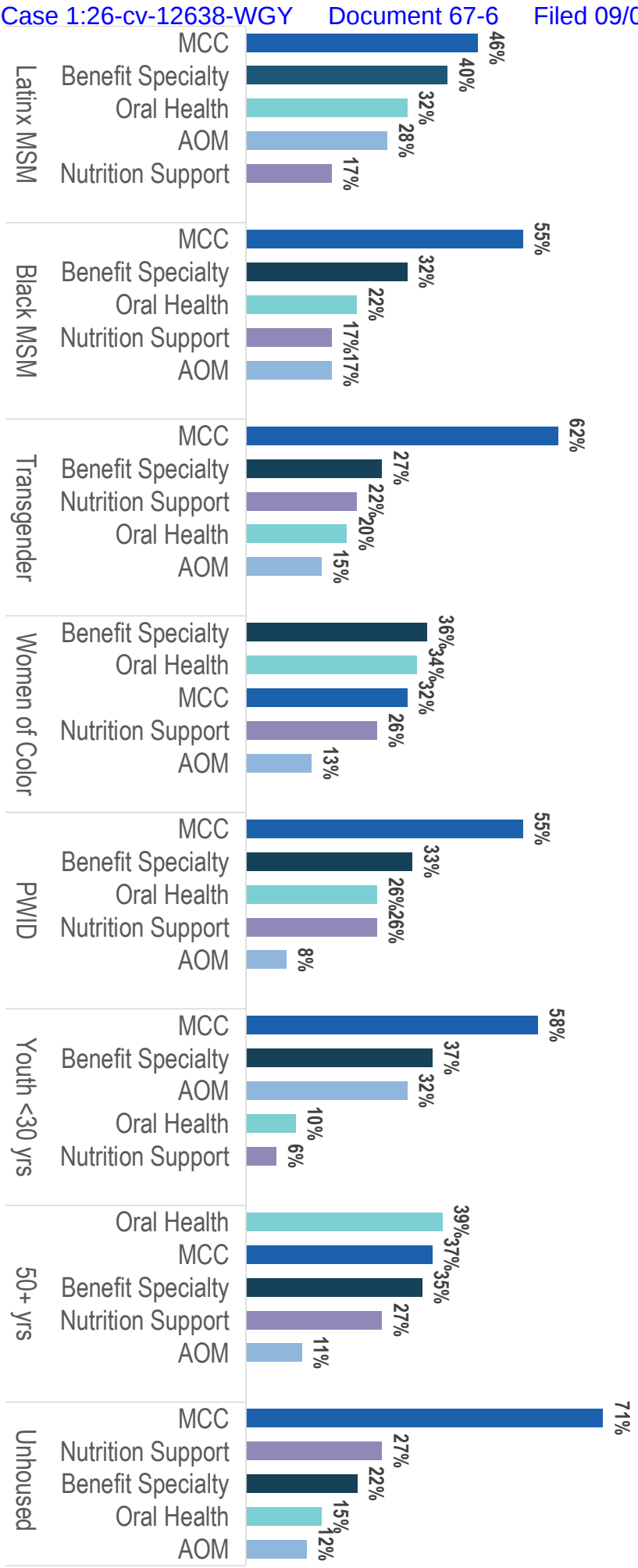
Utilization of RWP services in Year 34



The most utilized RWP service by most priority populations was MCC and the second most used service was Benefit Specialty.



Top 5 RWP Services Used by Priority Populations, Year 34



Key Takeaways

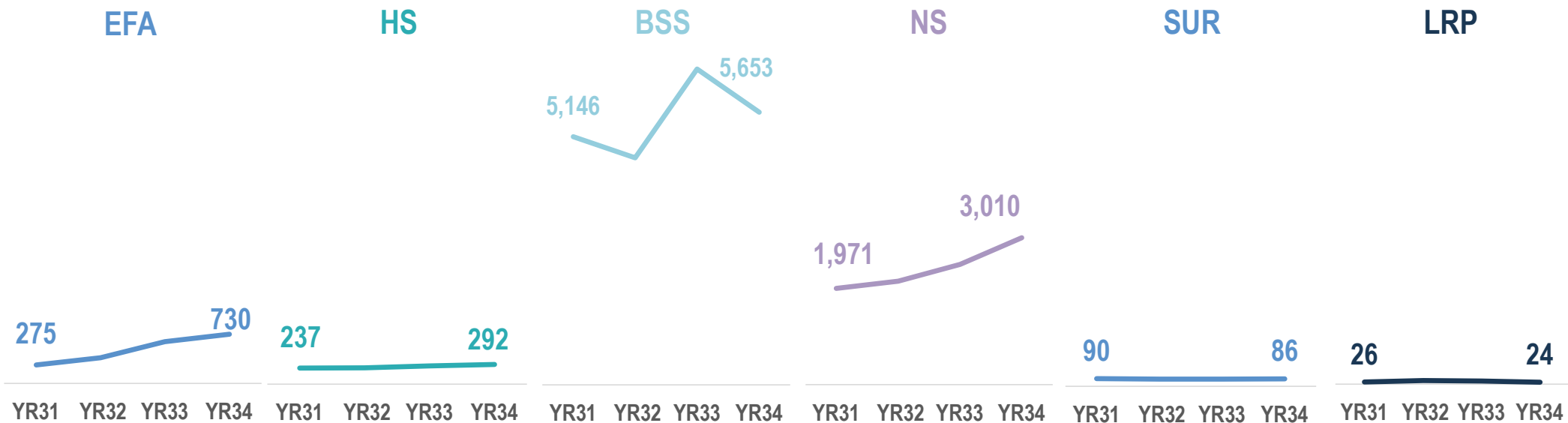
- Support Services Utilization
- Client Demographics
- HIV Care Continuum Outcomes
- Expenditures



Support Service Utilization, Years 31-34



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Public Health



Service	Year 34 Service Utilization Impact	Reasons for Year 34 Impact
EFA	Increased utilization	High demand
HS	Increased utilization	High demand
BSS	Decreased utilization	
NS	Increased utilization	High demand
SUR	No major changes in utilization	
LRP	Decreased utilization	Very small pool of clients

Key Takeaways: Client Demographics



COUNTY OF LOS ANGELES
Public Health

	RWP n=15,843	EFA n=730	HS n=292	BSS n=5,653	NS n=3,010	SUR n=86	LRP n=24
GENDER							
Men	86%	92%	79%	87%	82%	87%	21%
Women	10%	12%	14%	10%	13%	10%	79%
Transgender Women	4%	5%	7%	3%	5%	1%	**
Trangender Men	0%	<1%	<1%	<1%	<1%	**	**
Non-binary/Other	0%	1%	<1%	<1%	<1%	1%	**
RACE/ETHNICITY							
Latinx	53%	44%	53%	57%	51%	45%	63%
Black	23%	32%	26%	19%	24%	31%	33%
White	21%	21%	19%	19%	22%	19%	4%
Other/Unknown	5%	3%	2%	5%	4%	5%	
AGE							
50 and older	44%	45%	44%	43%	63%	20%	4%
40-49 years	22%	25%	22%	23%	19%	34%	21%
30-39 years	25%	24%	27%	25%	15%	36%	42%
13-29 years	9%	6%	7%	9%	3%	10%	33%

- Mostly **men** across all services, except LRP
- **Latinx** race/ethnicity was most represented across all services
- Services EFA, HS, BSS were mostly used by those age 50+
- SUR used mostly by those age 30-49 years
- LRP used mostly by those age 13-30 years

Key Takeaways: Client Demographics

- Across services, most were **English-speakers**, lived **at/below FPL**, had **public insurance**, and **no incarceration history**
- Notable exceptions
 - More individuals who were **unhoused** accessed **SUR and LRP services**
 - SUR service** had the lowest percent of **Spanish-speaking** clients
 - Higher percent of **incarceration history** among **HS, SUR, LRP** clients

	RWP n=15,843	EFA n=730	HS n=292	BSS n=5,653	NS n=3,010	SUR n=86	LRP n=24
PRIMARY LANGUAGE							
English	72%	79%	68%	67%	70%	93%	58%
Spanish	26%	20%	30%	31%	28%	7%	13%
Other	2%	1%	1%	2%	2%	**	**
INCOME							
At/below FPL	61%	66%	87%	56%	77%	94%	50%
Above FPL	38%	34%	13%	44%	22%	6%	8%
PRIMARY INSURANCE							
Public	63%	74%	83%	64%	81%	92%	62%
Private	14%	14%	4%	18%	5%	**	4%
No insurance	22%	11%	13%	18%	13%	8%	33%
HOUSING STATUS							
Permanent	87%	91%	45%	91%	81%	12%	63%
Institutional	2%	1%	19%	2%	2%	19%	8%
Unhoused	10%	8%	36%	7%	15%	58%	25%
HISTORY OF INCARCERATION							
No history	87%	87%	75%	90%	84%	70%	83%
Incarcerated > 2yrs ago	5%	10%	16%	6%	11%	17%	17%
Incarcerated within last 24 months	7%	3%	10%	4%	4%	13%	**

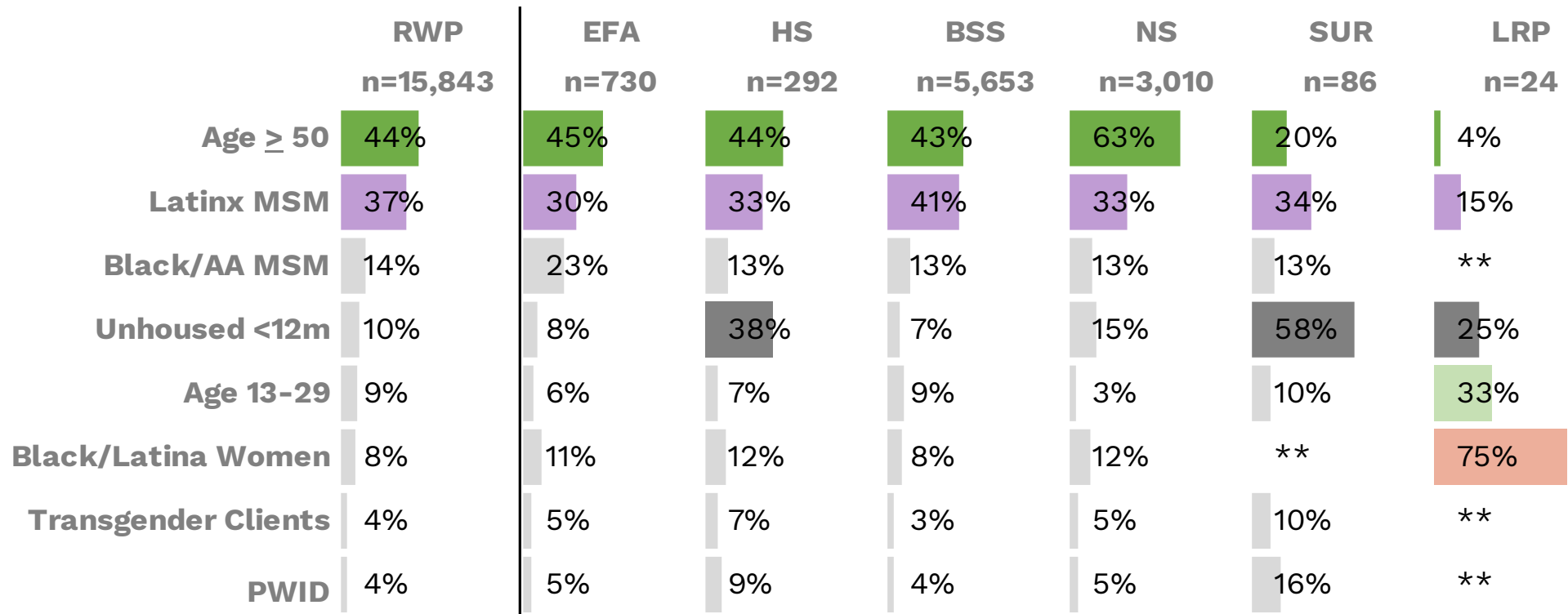
Totals may not sum to 100% due to incomplete reporting

Key Takeaways: Highest Service Utilization by Priority Population



COUNTY OF LOS ANGELES
Public Health

- **People over 50 and Latinx MSM** highest utilizers of EFA, HS, BSS, NS
- SUR most accessed by **unhoused < 12m** and **Latinx MSM**
- LRP most accessed by **women of color** and youth **age <30 year**



*Priority population groups are not mutually exclusive, clients may overlap

HIV Care Continuum Outcomes for Support Services, Year 34



COUNTY OF LOS ANGELES
Public Health

Best outcomes were observed among RWP clients using Substance Use Residential (**SUR**), Benefit Specialty Service (**BSS**), and Housing Service (**HS**)

RWP Support Services

Substance Use Residential (SUD)

Benefits Specialty (BSS)

Housing Services (HS)

Emergency Financial Assistance (EFA)

Nutrition Support (NS)

Linkage-Reengagement Program (LRP)

Engagement in Care

99%

98%

97%

97%

95%

83%

Retention in Care

93%

82%

82%

80%

80%

58%

Viral Load Suppression

95%

90%

90%

89%

85%

58%

95% benchmark

95% benchmark

Key Takeaways – Expenditures



COUNTY OF LOS ANGELES
Public Health

EFA

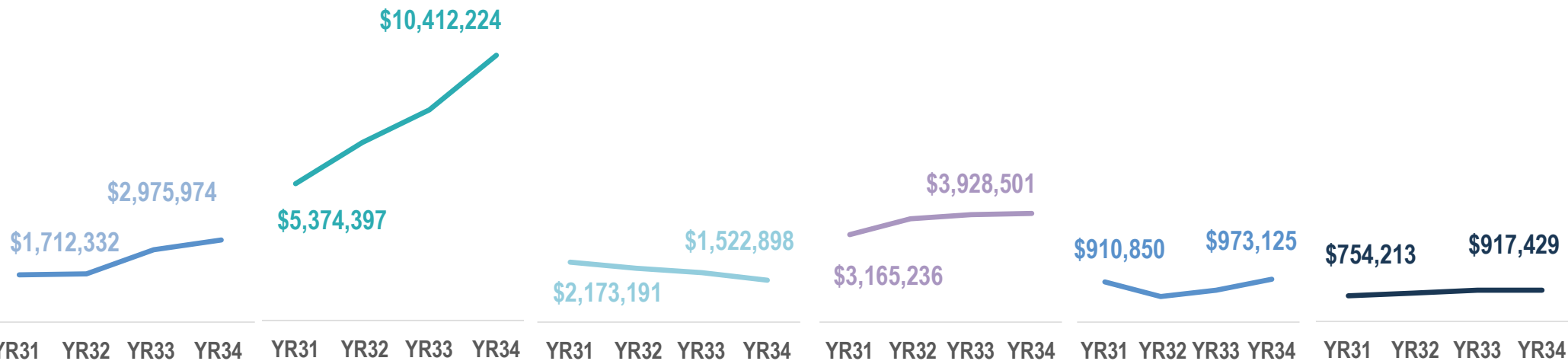
HS

BSS

NS

SUR

LRP



Service	Expenditures per Service	Expenditures per Client	Reasons for Year 34 Changes
EFA	Increased expenditures	Third lowest expenditures per client	Increase in both expenditures and the number of clients
HS	Increased expenditures	Second highest expenditures per client	Considerable increase in both expenditures and the number of clients
BSS	Decreased expenditures	Lowest expenditures per client	Decrease in both expenditures and the number of clients (vacancies?)
NS	No major changes in expenditures	Second lowest expenditures per client	Slight increase in both expenditures and the number of clients
SUR	Increased expenditures	Third highest expenditures per client	Stable number of clients, but increased expenditures (higher cost per day)
LRP	No major changes in expenditures	Highest expenditures per clients	Number of clients considerably decreased, but expenditures did not change

Next Steps



- Examine detailed utilization of RWP services within each LAC priority populations
- Examine RWP services by priority population over time



Questions/Discussion

Acknowledgements

- Monitoring and Evaluation – Siri Chirumamilla
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- RWP agencies and providers
- RWP clients



THANK YOU!



Women's Caucus

Strengthening HIV Programs for Women in Los Angeles County: Women-Centered HIV Care and Prevention Recommendations

Background

Women living with HIV in Los Angeles County face unique challenges shaped by stigma, trauma, systemic inequities, and gaps in supportive services. Listening sessions with Spanish-speaking women, South LA women, and transgender women revealed common themes of resilience and advocacy alongside unmet needs in healthcare access, mental health, and social support. These insights underscore the importance of developing programming that is inclusive, culturally competent, trauma-informed, and responsive to the realities of women's lives.

Key Findings

- **Mental Health Gaps:** Women experience depression, trauma, and stigma, yet lack access to consistent, culturally and linguistically appropriate mental health providers. Provider turnover also disrupts continuity of care.
- **Healthcare Inconsistencies:** Access to Pap smears, mammograms, STI testing, contraception, and maternal health is inconsistent across providers.
- **Stigma and Discrimination:** Stigma within families, communities, and healthcare settings discourages disclosure and limits trust. Transgender women face compounded stigma, misgendering, and outright denial of care.
- **Need for Women-Centered and Trans-Affirming Spaces:** Participants across sessions emphasized the value of women-only and trans-led spaces for safety, healing, and empowerment.
- **Structural Barriers:** Transportation, housing instability, employment challenges, and immigration-related fears limit access to consistent care.
- **Lack of Inclusive Sexual Health Education:** Heterosexual women often do not see themselves reflected in HIV prevention campaigns, and transgender women face gaps in care that integrates HIV services with gender-affirming treatment.

Recommendations

1. **Expand Mental Health Services**
 - Increase trauma-informed, culturally competent, and language-specific mental health providers.
 - Integrate mental health within HIV care.



2. **Develop Women-Centered Clinics and Programs**
 - Create dedicated women's clinics, where feasible.
 - Fund women-only (cis and trans) support groups.
3. **Strengthen Peer and Community Support**
 - Expand women's (cis and trans) peer navigation and support groups.
 - Partner with community and faith-based organizations to reduce stigma.
 - Support trans-led and peer-led safe spaces.
4. **Improve Comprehensive Sexual and Reproductive Health Access**
 - Provide consistent access to Pap smears, mammograms, STI testing, and contraception.
 - Train providers to ask comprehensive and respectful sexual health questions.
 - Expand free or low-cost sexual health supplies (condoms, Plan B, menstrual products).
5. **Address Stigma Through Education and Outreach**
 - Provide stigma-reduction and cultural humility training for providers, including front-line staff.
 - Develop inclusive HIV and PrEP education campaigns for heterosexual women, Spanish-speaking communities, and transgender women.
 - Use social media and lived-experience storytelling to normalize HIV care.
6. **Increase Accessibility and Wraparound Services**
 - Integrate housing, transportation, childcare, legal aid, and domestic violence support with HIV services, where feasible.
 - Provide reminders to consumers for preventive screenings.
 - Simplify navigation through coordinated case management.
7. **Advance Structural Supports**
 - Address immigration-related fears to ensure all women can access services safely.
8. **Ensure Gender-Affirming and Inclusive Care**
 - Train providers on integrating HIV and gender-affirming care, including front-line staff where appropriate.
 - Hire and support transgender staff and leaders across healthcare and community-based organizations.

Los Angeles County can strengthen outcomes for all women living with HIV by adopting these recommendations across healthcare, community-based, and policy systems. Immediate priorities should include expanding trauma-informed mental health services, creating women-centered and trans-affirming spaces, and integrating wraparound supports that reduce structural barriers. With investment and commitment, the County can ensure women living with HIV are supported, respected, and empowered to thrive.



Planning, Priorities and Allocations Committee Key Annual Activities & Committee Calendar

**** FOR DISCUSSION ****

- **Co-chair nominations and elections** - Each year the committee facilitates an open process to nominate and elect co-chairs who will provide leadership, ensure fair representation of stakeholders, and guide the committee's agenda and decision-making throughout the year.
- **Workplan development and review** - The committee develops an annual workplan aligned with the overall Commission's workplan and strategic goals. The workplan outlines timelines, milestones, and deliverables, and is reviewed periodically to monitor progress and make adjustments.
- **Annual directives updates*** - Directives provide guidance to the recipient on service delivery expectations and how best to meet the needs of consumers. Annual progress/updates to ensure alignment with community needs, emerging public health trends, and funding requirements.
- **Quarterly Expenditure Reports*** - Quarterly expenditure reports to monitor how allocated funds are being spent. This oversight ensures fiscal accountability, helps identify under- or over-spending, and informs potential reallocations.
- **Utilization Reports*** - Service utilization reports are examined to evaluate service usage across funded programs. These reports highlight increases or decreases in service utilization by service type, cost per service, gaps in service use, potential barriers to care, and opportunities for improving service delivery.
- **HIV/STD Surveillance Data*** - Surveillance data is reviewed to track trends in HIV and STD incidence, prevalence, and disparities. This information informs priority-setting, prevention strategies, and resource allocation.
- **Unmet Needs Reports*** - Help the committee identify services that clients require but are not currently receiving. Use findings to help inform needs assessments and funding priorities.
- **Resource Inventory*** - Review of funding and services offered via Part B funds, EHE, Prevention, and other resources. This allows the committee to determine what care/support services to fund (and at what allocation amounts) that will compliment these services.
- **2027-2031 Integrated Plan Updates and Review*** - Provide updates to the committee on the progress of the Integrated Plan progress/development and provide the committee an opportunity to provide feedback on the plan.



- **Needs Assessment Planning** - Planning for needs assessments is a critical responsibility. The committee determines target populations, defines the scope, methodology, and timeline to ensure that assessments capture the experiences and priorities of people living with and affected by HIV. May lean on specific caucuses or workgroups to assist with needs assessment planning and execution including data collection tools, outreach strategies, and final analysis.
- **Needs Assessment Data Review** – Review finds from needs assessment data to identify service gaps, barriers to access, and emerging trends. This data directly informs decision-making around funding priorities and allocations.
- **Review PSRA Framework** - Review the Priority Setting and Resource Allocation (PSRA) process for effectiveness and equity. Update criteria and scoring systems as needed. Ensures knowledge of and understanding that decision-making processes before priority setting and resource allocation.
- **Review Priorities** – Revisit annual service priorities (from 3 yr projections) to determine whether adjustments are necessary based on updated data, funding changes, or shifts in the epidemic.
- **Annual Allocations*** - Revisit annual service allocations (from 3 yr projections) to determine funding levels for each service category for the upcoming fiscal year. Compare against multi-year projections and adjust based on current data. Ensure allocations align with priorities and available resources.
 - **Contingency Planning* (as needed)** - Contingency scenarios are developed to address potential funding increases or decreases. Identify critical services that require protection during budget cuts. These plans ensure that DHSP can respond quickly while minimizing disruption to critical services.
- **Reallocations*** - Review needs assessment data, expenditures, and utilization data to identify areas for reallocation. Shift funds between service categories to optimize impact. Document and communicate reallocation decisions to DHSP and federal partners.
- **Prevention Planning** – Review prevention HIV/STI data and collaborate with prevention stakeholders to align care and prevention strategies, ensuring an integrated response that addresses both treatment and prevention priorities across the HIV continuum.



Option 1 – Monthly Meeting Calendar (March 2026 – February 2027)

Month	Key Activities
March 2026	• Co-chair nominations and elections • Review and adopt annual workplan and meeting calendar • HIV/STD Surveillance Data report*
April 2026	• Needs Assessment Planning • Resource Inventory Review • Prevention and Testing Data Report*
May 2026	• Expenditure Report* • Needs Assessment Data Review (prior year findings) • Integrated Plan Update*
June 2026	• Unmet Needs Report* • Review PSRA Framework
July 2026	• Utilization Reports*
August 2026	• Expenditure Report* • Review All Data – summaries with key info • Final Reallocations for PY36*
September 2026	• Review PY37 Priority Rankings and Allocations, revise as needed • Contingency Planning, as needed
October 2026	
November 2026	• Contingency Planning, as needed • Prevention Planning • Expenditure Report*
December 2026	
January 2027	• Directive Development (not this year but in future years)
February 2027	• Expenditure Report* • Directives Updates*

Unmet Needs Report, HIV/STI Surveillance Report – Have been presented at full COH meetings



LOS ANGELES COUNTY
COMMISSION ON HIV



Option 2 – Bi-Monthly Meeting Calendar (March 2026 – February 2027)

Month	Key Activities
March 2026	• Co-chair nominations and elections • Review and adopt annual workplan and meeting calendar • HIV/STD Surveillance Data report
May 2026	• Needs Assessment Planning • Review PSRA Framework • Integrated Plan Update* • Expenditure Report*
June 2026 (meet 2-3x)	• Resource Inventory Review • Prevention and Testing Data Report* • Unmet Needs Report*
July 2026 (meet 2-3x)	• Utilization Reports* • Needs Assessment Data Review (prior year findings) • Expenditure Report* • Review All Data – summaries with key info • Final Reallocations for PY36*
August 2026	• Review PY37 Priority Rankings and Allocations, revise as needed • Contingency Planning, as needed
November 2026	• Expenditure Report* • Prevention Planning
January 2027	• Directive Development (not this year but in future years) • Expenditure Report* • Directives Updates*



Option 3 – Bi-Monthly Meeting Calendar with Data Summit (March 2026 – February 2027)

Month	Key Activities
March 2026	• Co-chair nominations and elections • Review and adopt annual workplan and meeting calendar • Needs Assessment Planning
May 2026	• Needs Assessment Planning • Review PSRA Framework • Integrated Plan Update (Status of Submittal)
Virtual Data Summit (tentative for the month of June over the course of 2-4 days)	• Prevention and Testing Data Report* • HIV/STD Surveillance Data Report* • Unmet Needs Report* • Utilization Reports* • Needs Assessment Data Review (prior year findings)
July 2026	• Resource Inventory Review • Expenditure Report* • Review All Data – summaries with key info • Final Reallocations for PY36*
September 2026	• Review PY37 Priority Rankings and Allocations, revise as needed • Contingency Planning, as needed
November 2026	• Expenditure Report* • Prevention Planning • Directive Development (not this year but in future years)
January 2027	• Directive Development (not this year but in future years) • Expenditure Report* • Directives Updates*

EXHIBIT G

Practice Guidelines for the Care of Persons Living with HIV/AIDS

Ryan White HIV Treatment Extension Act of 2009

San Diego County

In conjunction with United States (U.S.) Public Health Service (PHS) guidelines and accepted community practices, the San Diego County HIV Planning Group's Medical Standards and Evaluation Group recommends the following practice guidelines for the management of human immunodeficiency virus (HIV) infection in patients enrolled in the Ryan White Primary Care Program of San Diego County.

Antiretroviral therapy (ART) and opportunistic infection (OI) prophylaxis (primary and secondary) are recommended in accordance with the most recent PHS guidelines. Guidelines may have been updated since the versions listed below; current versions are available at <https://clinicalinfo.hiv.gov/en/guidelines>.

For San Diego County Ryan White Clinics, chart reviews and performance assessments conducted on behalf of the County of San Diego Health and Human Services Agency (HHS) – Division of Public Health Services – HIV, STD, and Hepatitis Branch (HSHB) will be based upon these guidelines.

A. Guidelines for Staging and Baseline Evaluation (recommended to be completed within the first two visits)

- 1) Complete history, to include at least the following:
 - a. *General background:*
 - Race/ethnicity
 - Current gender identity
 - Sex assigned at birth
 - Housing status
 - Family history
 - Social history
 - Travel history
 - Country of birth
 - b. *Current/lifetime sexual history: (See Appendix A for example)*
 - Sexually transmitted infection/disease (STI/STD) history during lifetime and/or last 5 years
 - Relationship status
 - Detailed sexual history
 - Partner(s), including HIV status and history of pre-exposure prophylaxis (PrEP) use
 - Exposure sites – anorectal, genital, oropharyngeal
 - Use of condoms
 - c. *Current/lifetime substance use history:*
 - Injection drug use (IDU), during lifetime and/or last 5 years
 - Non-injection drug use, during lifetime and/or last 5 years
 - Alcohol and/or drug treatment history
 - Sexual activity under the influence of substances
 - Tobacco use, during lifetime and/or last 5 years
 - d. *HIV care history:*
 - HIV status, including recent/historical CD4+ T-cell count/HIV-1 viral load
 - Prior and current antiretroviral regimens
 - Resistance test results (if available)
 - Current prophylaxis
 - Prior HIV-related complications
 - e. *General medical history:*
 - Immunizations

- Hepatitis history
 - Tuberculosis (TB) risk
http://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/tuberculosis_control_program/SanDiegoRiskAssessment-Adults.pdf
 - Reproductive history (persons assigned female at birth), including parity, last menstrual period (LMP), and method of birth control
 - Current allergies
 - Other current medications
 - Significant childhood illnesses
 - Surgical history
 - Mental health history, past/current mental health conditions, symptoms of depression, and psychiatric medications
 - Other medical history
- 2) Review of symptoms and general physical exam, including height, weight, temperature, blood pressure, pulse, respiratory rate, general appearance, skin, head, eyes, ears, nose and throat (HEENT), ophthalmoscopy, chest, heart, lungs, abdomen, rectum, anoscopy (if anorectal symptoms), pelvic (persons assigned female at birth), breasts, genitalia, extremities, lymph nodes, mental status, nervous system including reflexes
- 3) Laboratory tests
- a. For the current list of recommended labs and periodicity, please refer to [PHS Guidelines for Laboratory Testing for Initial Assessment and Monitoring of Patients with HIV Receiving Antiretroviral Therapy](#).
 - b. STI Testing
 - Should be performed at baseline and at least annually thereafter for sexually active clients, more frequently (i.e., every three to six months) if indicated based upon the client's sexual practices.
 - Syphilis serology
 - Gonorrhea/Chlamydia – Perform three-site testing (i.e., urogenital, throat, rectum) using nucleic acid amplification testing (NAAT). If antibiotic-resistant *Neisseria gonorrhoeae* is suspected, obtain *N. gonorrhoeae* culture from all exposure sites.
 - Trichomoniasis – Screening with NAAT should be performed annually for persons having vaginal sex.
 - Anal Pap test (optional) – See **Section G – Anal Cancer Screening**.
 - Resources:
 - [Centers for Disease Control and Prevention \(CDC\) Recommendations for Providing Quality STD Clinical Services, 2020](#)
 - [CDC Interim Guidance for STD Care and Treatment During Disruption of Clinical Services](#)
 - [CDC STD Treatment Guidelines, 2015](#)
 - [Updated CDC Gonorrhea Treatment Recommendations, 2020](#)
 - [CDC Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, 2014](#)
 - c. TB Testing
 - Annual screening in the form of Annual Risk Assessment:
http://www.sandiegocounty.gov/content/dam/sdc/hhsa/programs/phs/tuberculosis_control_program/SanDiegoRiskAssessment-Adults.pdf
 - Annual screening using purified protein derivative (PPD) or interferon-gamma release assay
 - If screening test is positive, the patient should have a chest x-ray.
 - Chest x-ray: At least one should be documented in the medical record if the individual has a history of TB or a positive screening test.
 - d. Viral Hepatitis Testing
 - Hepatitis B screening should be performed by testing for hepatitis B surface antibody (HBsAb), surface antigen (HBsAg), and antibody to core antigen (anti-HBc or HBcAb). Those who are susceptible to infection should be vaccinated against Hepatitis B Virus (HBV) (see **Section C – Guidelines for Immunization**). Patients who are negative for HBsAg and

HBsAb but positive for anti-HBc should be screened for chronic HBV infection by determination of HBV deoxyribonucleic acid (DNA). Those without evidence of chronic infection should consider vaccination.

<https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-b-virus-infection?view=full>

- Hepatitis C screening with Hepatitis C Virus (HCV) antibody or, if recent (i.e., within last six months) infection is suspected, the patient has advanced immunodeficiency (CD4 count <100 cells/mm³), or the patient has a history of successfully treated or spontaneously cleared HCV infection, ribonucleic acid (RNA) testing should be performed at baseline and at least annually for persons with ongoing risk factors (e.g., IDU) and sexually active men who have sex with men (MSM). HCV RNA should be ordered for all patients with a positive HCV antibody test to assess for active HCV disease.

<https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-c-virus-infection?view=full>

e. Other Testing:

- Measles antibody titer – All persons with HIV born in 1957 or after should be tested for immunity to measles by measuring antibody titers. The measles, mumps, and rubella (MMR) vaccine should be given to persons with CD4 ≥200 cells/mm³ born in or after 1957 who have not received the vaccine or do not have immunity based on laboratory testing (see **Section C – Guidelines for Immunization**).

4) Appropriate referrals, including but not limited to:

- Treatment adherence counseling
- Ryan White dental program (recommended annually)
- Ophthalmologist if CD4 <50 cells/mm³ (recommended)
- Case management (if eligible)
- Medical nutrition therapy
- Clinical trials
- Mental health
- Substance use treatment
- Partner services/PrEP if client has not achieved sustained viral suppression

For a list of currently funded Ryan White Service Providers, please visit:

[HIV/AIDS Care and Services Resources \(sandiegocounty.gov\)](https://www.sandiegocounty.gov/hiv/aids/care-and-services/resources)

B. Guidelines for Plasma HIV RNA (i.e., Viral Load) Measurements and CD4 Counts

<https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/plasma-hiv-1-rna-viral-load-and-cd4-count-monitoring?view=full>

- 1) HIV-1 RNA (i.e., Viral Load) – should be performed upon entry to care, before initiation of ART (if initiation of ART is deferred after entry to care), and within 2-4 weeks but no later than 8 weeks after ART initiation. After initiation or modification of ART, repeat at 4-8-week intervals until undetectable. Continue to monitor every 3-4 months during the first 2 years of ART, and then frequency can be decreased to every 6 months if the viral load is consistently undetectable for two years and the CD4 is >500 cells/mm³.
- 2) CD4+ T-cell Count (i.e., CD4 Count) – should be performed upon entry to care and three months after initiation of ART (every 3-6 months in patients who defer ART). After initiation or modification of ART, repeat every 3-6 months during the first 2 years or if the CD4 count is <300 cells/mm³ or if there is any viremia while on ART. May monitor every 12 months if the patient has consistently been on ART with a suppressed viral load and CD4 count 300-500 cells/mm³. Optional once CD4 is consistently >500 cells/mm³ and viral load has been undetectable for >2 years.

C. Guidelines for Immunization

[Adult Immunization Schedule by Vaccine and Age Group | CDC](https://www.cdc.gov/vaccines/imz/adult/schedule)

[Vaccines Indicated for Adults Based on Medical Indications | CDC](https://www.cdc.gov/vaccines/imz/adult/indications)

- 1) Should be offered as soon as possible after initial evaluation at recommended doses.
- 2) Viral loads should not be measured within three weeks of an immunization.
- 3) Pneumococcus (both types), influenza, tetanus, Hepatitis B (if not immune), Hepatitis A (if not immune), human papillomavirus (HPV), meningococcal

- 4) Influenza vaccine: recommended yearly with trivalent inactivated vaccine (live attenuated vaccine is contraindicated in persons living with HIV or PLWH).
- 5) HPV: Recommended for all PLWH through age 26 years as a three-dose series, regardless of the age at initial vaccination. Vaccination may be considered, based on shared clinical decision-making, for persons aged 27-45 years.
<https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm>
- 6) Varicella zoster: Two doses of the Shingrix vaccines should be given to patients over the age of 50 years with CD4 count >200 cells/mm³.
- 7) Hepatitis Vaccines:
 - a. Hepatitis B: Recommended in persons with negative serology or isolated positive core antibody (i.e., negative surface antigen and antibody). Double dosing (i.e., 40 μ g) of single-antigen three-dose vaccines is recommended to increase seroconversion rates. For those patients who do not seroconvert after the first series, a second series is recommended. If these persons do not seroconvert, they are unlikely to respond to a third series. The safety and efficacy of the two-dose vaccine has not been evaluated in PLWH but is an option if a two-dose regimen is preferred. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/hepatitis-b-virus-infection?view=full>
 - b. Hepatitis A: Seroconversion rates are likely related to CD4 counts. The vaccine may be given in persons who are seronegative. However, if there is no response and the CD4 counts are less than 500 cells/mm³, persons can receive a repeat series when CD4 counts are higher.
- 8) Pneumococcal: Both the 13-valent pneumococcal conjugate vaccine (PCV13) and the 23-valent pneumococcal polysaccharide vaccine (PPV23) are recommended, with the final dose of PPV23 given at ≥ 65 years of age and ≥ 5 years after previous PPV23 doses given before age 65 years. For specific recommendations regarding timing of PCV13 and PPV23 doses, see <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/community-acquired-pneumonia-cap?view=full>.
- 9) Meningococcal: Vaccination against serogroups A, C, W, and Y is recommended for all persons living with HIV aged ≥ 2 years. <https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm>. Vaccination against serogroup B is recommended for persons aged ≥ 10 years who are at increased risk for serogroup B meningococcal disease due to certain underlying conditions or a serogroup B outbreak. HIV disease is not one of the underlying conditions for which serogroup B vaccination is recommended. Serogroup B vaccination may be considered for adolescents and young adults aged 16-23 years on the basis of shared decision-making.
<https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm>
- 10) Tetanus vaccines: Recommended every 10 years. Recommend that the next booster contain pertussis booster (Tdap) (make sure the patient has had the pertussis vaccine)
- 11) Live Vaccines (Live attenuated influenza vaccine, Varicella or Zoster vaccine, Vaccinia (small pox), Yellow Fever, Live Oral Polio, Measles*, Typhoid) are contraindicated in persons with severe immunosuppression based on the person's age (per Advisory Committee on Immunization Practices or ACIP): CD4 <750 for those younger than 12 months, <500 for those aged 1-5 years, and <200 for those >6 years old.
*The MMR vaccine should be given to persons with CD4 ≥ 200 cells/mm³ born in or after 1957 who have not received the vaccine or do not have immunity based on laboratory testing.
- 12) Booster doses as recommended by CDC guidelines.

D. Treatment:

- 1) All PLWH should receive ART, regardless of CD4 count, to reduce morbidity and mortality, improve health outcomes, and prevent transmission of HIV to others.
- 2) Whenever possible, treatment should be initiated immediately (or as soon as possible) after diagnosis.
 - a. Same-day treatment should be offered if there are no medical indications to defer therapy (e.g., signs/symptoms of intracranial OI).
 - b. If treatment is offered before the results of treatment-naïve genotype are available, an integrase inhibitor-based regimen is recommended.

- 3) All PLWH should be informed that maintaining a plasma HIV RNA (viral load) of <200 copies/mL, including any measurable value below this threshold value, with ART prevents sexual transmission of HIV to their partners. Patients may recognize this concept as Undetectable = Untransmittable or U=U.
- 4) Guidelines on antiretroviral treatment regimens can be found at <https://aidsinfo.nih.gov/guidelines>.
- 5) At the time of revision, an extended-release, injectable drug regimen (coformulation of cabotegravir and rilpivirine) was approved by the Food and Drug Administration (FDA) to replace the current antiretroviral regimen for patients with viral suppression on a stable ART regimen without history of treatment failure and with no known or suspected resistance to either agent. Long-acting injectable ART may be considered for eligible patients and should be administered according to Department of Health and Human Services guidelines: <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hhs-adults-and-adolescents-antiretroviral-guidelines-panel>.
- 6) For patients with HBV coinfection, as determined by a positive HBsAg or HBV DNA test result, tenofovir disoproxil fumarate or tenofovir alafenamide, plus either emtricitabine or lamivudine, should be used as part of the ART regimen to treat both HBV and HIV.
- 7) Patients with HCV coinfection should be managed based on the most up-to-date recommendations (<http://www.hcvguidelines.org>). In general, the goals of therapy, treatment regimen, and monitoring parameters for HIV/HCV-coinfected patients are similar to those recommended for HCV-monoinfected patients.

E. Metabolic and Other Noncommunicable Comorbidities Associated with HIV, ART, and Aging

- 1) The availability of highly effective HIV treatment has resulted in longer life expectancy for PLWH and a larger proportion of PLWH who are aged 50 years or older.
- 2) For all PLWH aged 50 years or older, providers should closely monitor for and promptly evaluate signs or symptoms of the following conditions that are associated with advanced age, long-term HIV infection, ART, or a combination of these:
 - a. Cardiovascular disease and associated risk factors (e.g., hyperlipidemia, glucose intolerance or diabetes mellitus, hypertension, smoking)
 - b. Osteoporosis and bone mineral density loss
 - c. Hypogonadism
 - d. Neurocognitive decline
 - e. Mental health conditions, such as depression
 - f. Polypharmacy
 - g. Kidney disease
 - h. Certain non-acquired immune deficiency syndrome (AIDS)-related cancers
- 3) Specific recommendations regarding metabolic and noncommunicable comorbidities include:
 - a. Check lipid levels prior to and within 1-3 months after starting ART. Patients with abnormal lipid levels should be managed according to national guidelines.
 - b. Random or fasting blood glucose and hemoglobin A1c (HbA1c) should be obtained prior to starting ART. If random glucose is abnormal, fasting glucose should be obtained. After ART initiation, only plasma glucose criteria should be used to diagnose diabetes. Patients with diabetes mellitus should have an HbA1c level monitored every 6 months with an HbA1c goal of <7%.
 - c. Baseline bone densitometry (DXA) screening for osteoporosis in post-menopausal women and men aged ≥50 years. Screening for transgender persons should follow national recommendations based on sex assigned at birth and individualized risk of osteoporosis.
 - d. Testosterone replacement therapy for cisgender men should be prescribed with caution and only in those with symptomatic hypogonadism diagnosed based on the presence of symptoms plus low serum testosterone documented on two separate morning lab tests.

Primary Care Guidance for Persons with Human Immunodeficiency Virus: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America:

<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1391/5956736>

F. Additional Guidelines for Care of Persons Assigned Female at Birth

- 1) Guidelines for Cervical Neoplasia (modified Algorithm 6 of AHCPR 94-0573):

<https://hab.hrsa.gov/sites/default/files/hab/About/clinical-quality-management/adolescentadultmeasures.pdf>

- a. Age <21 years: Pap test within one year of sexual activity and no later than age 21
 - b. Age 21-29 years: Pap test at time of HIV diagnosis. Repeat yearly for three years. If all tests are normal, repeat Pap test every three years thereafter.
 - c. Age <30 years: No HPV testing should be performed unless abnormalities are found on Pap test.
 - d. Age ≥30 years: Pap only (same as for 21-29 years) or Pap with HPV testing. If both tests are negative, repeat Pap with HPV test every three years thereafter.
 - e. If three consecutive Pap tests are normal, then a follow-up test should be done every three years.
 - f. Patients with abnormal Pap smears or a history of an untreated abnormal Pap smear should be referred for colposcopy and should receive same management and follow-up as the general population.
Refer to American College of Obstetrics and Gynecology (ACOG) guidelines for management of abnormal cervical cancer screening results:
<https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/10/updated-guidelines-for-management-of-cervical-cancer-screening-abnormalities>
 - f. Cervical cancer screening should continue throughout the patient's lifetime and not, as in the general population, end at 65 years of age.
- 2) Annual mammograms initiated at age 50 or earlier depending on history
 - 3) Treatment for pregnant persons living with HIV – recommend referral to specialist (i.e., UCSD Maternal, Child & Adolescent Program)

G. Anal Cancer Screening:

- 1) Persons with a history of receptive anal intercourse or abnormal cervical Pap tests and all persons with genital warts should have an anal Pap test if access to appropriate referral for follow-up, including high-resolution anoscopy, is available.
- 2) Digital anorectal exam should be performed at least annually for asymptomatic persons.

H. PrEP and Partner Prevention Services – Assess HIV status of partner(s) and evaluate for PrEP referral for all patients living with HIV who have not achieved sustained viral suppression. Please note that Ryan White does not provide reimbursement for PrEP services for HIV-negative partners.

- 1) For guidelines regarding evaluation for and provision of PrEP, please refer to the U.S. PHS Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update. Please note that parts of these guidelines may be outdated, as a second agent (coformulation of emtricitabine and tenofovir alafenamide) received FDA approval for use as PrEP for persons assigned male at birth and may be preferred for certain patients at higher risk of renal and/or bone toxicity.
<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
- 2) For guidelines regarding partner services for PLWH, please refer to the Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection.
<https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm>

I. HIV Management Guidelines for Transgender Individuals – Primary care of transgender PLWH should address the specific needs of this population and include careful attention to potential interactions between gender-affirming therapy and ART and/or OI prophylaxis medications. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People, from the Center of Excellence for Transgender Health at the University of California, San Francisco, include recommendations for transgender individuals living with HIV and can be accessed at <https://transcare.ucsf.edu/guidelines>.

J. Interim Guidance for COVID-19 and PLWH – At the time of revision, the County of San Diego was in a state of emergency due to the rapidly evolving Coronavirus Disease 2019 (COVID-19) pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

While the limited data currently do not indicate that the course of COVID-19 in PLWH differs from that in persons without HIV, caution is warranted. Some people with HIV may have comorbidities (e.g., cardiovascular disease, lung disease, chronic smoking) that increase risk of more severe disease.

- 1) All patients should maintain on-hand at least a 30-day (and ideally a 90-day) supply of ART.
- 2) Influenza and pneumococcal vaccinations should be kept up to date.
- 3) COVID-19 vaccination should be administered based on CDC and Advisory Committee on Immunization Practices (ACIP) guidance.
<http://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.
- 4) All patients should receive COVID-19 vaccination when eligible based on California state guidelines.
- 5) Telephone and virtual visits for routine non-urgent care should be considered as an option to encourage retention in care.
- 6) For further guidance, please refer to the U.S. PHS Interim Guidance for COVID-19 and Persons with HIV, available at <https://clinicalinfo.hiv.gov/en/guidelines/covid-19-and-persons-hiv-interim-guidance/interim-guidance-covid-19-and-persons-hiv>.

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<https://www.cdc.gov/mmwr/volumes/68/rr/rr6805a1.htm#:~:text=CDC%20organized%20the%20recommendations%20for,STD%20or%20STD-related%20conditions>.
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<https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf>
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APPENDIX A

SAMPLE Sexual Health Risk Assessment Form

Sexually transmitted diseases (STDs) raise the amount of HIV in the body and can make HIV easier to pass to another person. Alcohol and drugs can harm your immune system, stop HIV medication from working properly and increase side effects. To help your doctor help you stay healthy and lower your risk of passing HIV and STDs to others, please answer the following questions honestly. Your answers are entirely confidential.

1. Have you had sex (oral, vaginal, anal) within the **last 3 months**? ☐ Yes / ☐ No / ☐ Decline
(If you answered No please skip to #6)
2. In the **last 3 months**, how many sexual partners did you have? # _____ Male / # _____ Female / # _____ Transgender
3. How often did you use condoms?
☐ Always (100%) / ☐ Most of the Time (75% or more) / ☐ Sometimes (50%) / ☐ Seldom (25%) / ☐ Never (0%)
4. In the **last 3 months** how many times have you had sex without using a condom?
_____ Oral / # _____ Vaginal / # _____ Anal; check one: ☐ Insertive (top) / ☐ Receptive (bottom) / ☐ Both
5. In the **last 3 months** what was the HIV status of your sex partner(s)? (Check all that apply)
☐ Positive / ☐ Negative / ☐ Unsure
6. Have you had any of the following symptoms in the **last 3 months**? **Yes** **No**

Discharge from penis/vagina	☐ ☐
Burning feeling with urination	☐ ☐
Sores on your genitals	☐ ☐
Anal discharge or pain	☐ ☐
Mucous or blood in your stool	☐ ☐
Throat sores or pain	☐ ☐
Skin rash	☐ ☐
7. Have you been diagnosed with a sexually transmitted disease (STD, such as Syphilis, Chlamydia, Gonorrhea, NGU, Genital Warts, and Genital Herpes) in the **last 3 months**? (Check one): ☐ Yes / ☐ No / ☐ Don't know
If you answered yes, did you complete treatment? (Check one): ☐ Yes / ☐ No / ☐ Don't know
8. In the **last 3 months** have you used **non-injection** street drugs 9i.e. marijuana, meth, crystal, speed, glass, crack, ecstasy. cocaine)? ☐ Yes / ☐ No
9. Have you **ever injected** steroids, hormones, vitamins or street drugs? ☐ Yes / ☐ No
a. If you answered yes, when was the last time you injected? _____
b. Did you ever share needles? ☐ Yes / ☐ No
10. In the **last 3 months** do you feel that your alcohol or drug use caused you to engage in risky activities (i.e. unprotected sex, needle sharing), even once? ☐ Yes / ☐ No
11. Would you be interested in help to inform your sex and/ or needle sharing partner(s) of possible HIV exposure? ☐ Yes / ☐ No / ☐ Maybe

If you answered Yes or Maybe and would like to speak to a Counselor, please tell us the best way to contact you:

Phone: _____ Can we leave a confidential message? ☐ Yes / ☐ No

Text: _____ Email: _____

Provider/Staff Signature: _____

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Medical Standards and Evaluation Group participants who contributed to the revised document include:

Jeannette Aldous, MD San Ysidro Health Center
Joe Burke, South Bay Alliance
Beth Davenport, LCSW, MBA San Diego LGBT Community Center
David Grelotti, MD UC San Diego
Bob Lewis, Family Health Centers of San Diego
Susan Little, MD UC San Diego
Katherine Penninga, LCSW San Ysidro Health Center
Shannon Ransom, MSW UC San Diego
Stephen Spector, MD UC San Diego
Lisa Stangl, NP UC San Diego
Winston Tilghman, MD County of San Diego
Karla Torres, San Ysidro Health Center

EXHIBIT H

STATE OF FLORIDA Integrated HIV Prevention and Care Plan



2022-2026

Prepared for

Division of HIV/AIDS Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and
TB Prevention

Centers for Disease Control and Prevention

HIV/AIDS Bureau

Health Resources and Services Administration

Submitted by

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2.0	10/10/2022	Department/ISF	Additional content added, edits made
3.0	10/18/2022	Department/ISF	Draft to walkthrough at FCPN
4.0	10/31/2022	Department/ISF	FCPN feedback incorporated
5.0	11/10/2022	ISF	Final design incorporated
6.0	11/28/2022	Department/ISF	Department feedback merged with final design
7.0	1/19/2023	Department	Final revisions incorporated

Acronyms

Acronym	Definition
ADAP	AIDS Drug Assistance Program
AETC	AIDS Education and Training Center
AHCA	Agency for Health Care Administration
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy/Treatment
ARTAS	Antiretroviral Treatment and Access to Services
ARV	Antiretrovirals (medication)
AZT	Azidothymidine
BRTA	Business Responds to AIDS
CBI-HIV	Capacity Building Initiative
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CHARTS	Florida Community Health Assessment and Resource Tool Set
CHD	County Health Department
CHW	Community Health Worker
CLAS	National Culturally and Linguistically Appropriate Services Standards
Department	Florida Department of Health
D2C	Data to Care
DIS	Disease Intervention Specialist
DUA	Data Use Agreement
EBI	Evidence-based Interventions
ED	Emergency Department
EHE	Ending the HIV Epidemic
EMA	Eligible Metropolitan Areas
FCHAR	Florida Consortium for HIV/AIDS Research
FCPN	Florida Comprehensive Planning Network
FDA	U.S. Food and Drug Administration
FDC	Florida Department of Corrections
FDCF	Florida Department of Children and Families

Acronym	Definition
FDOE	Florida Department of Education
FLHRC	Florida Harm Reduction Collective
FOCUS	Frontlines of Communities in the United States Initiative
FQHC	Federally Qualified Health Centers
FRTA	Faith Responds to AIDS
F.S.	Florida Statute
HAPC	HIV/AIDS Program Coordinator
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIE	Health Information Exchange
HIP	High-Impact Prevention
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HOPWA	Housing Opportunities for People with AIDS
HRSA	Health Resources and Services Administration
IDU	Injection Drug Use
HUD	U.S. Department of Housing and Urban Development
IBM	Insurance Benefits Management
IDEA	Infectious Disease Elimination Act
IPC	Integrated Prevention and Care
JLP	Jail Linkage Program
MAI	Minority AIDS Initiative
Marketplace®	Affordable Care Act Health Insurance Marketplace®
MAT	Medication Assisted Treatment
MHS	Molecular HIV Surveillance
MMP	Medical Monitoring Project
MMSC	Male-to-Male Sexual Contact
MSM	Men who have Sex with Men
NHAS	National HIV/AIDS Strategy

Acronym	Definition
NCHHSTP	National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NHBS	CDC National HIV Behavioral Surveillance
OD2A	Overdose Data to Action
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PRPP	Pre-Release Planning Program
PWH	People (or Person) with HIV
PWID	Persons Who Inject Drugs
RFA	Request for Application
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SCSN	Statewide Coordinated Statement of Need
SDOH	Social Determinants of Health
SPNS	Special Projects of National Significance
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
T&T	Test and Treat
TCE	Targeted Capacity Expansion
TH	Telehealth
TIC	Trauma Informed Care
TOPWA	Targeted Outreach for Pregnant Women Act
U=U	Undetectable=Untransmittable
UM-AETC	University of Miami AIDS Education and Training Center
USPSTF	U.S. Preventive Services Task Force
US	United States
VA	Veteran's Administration
VL	Viral Load
WCBA	Women of Childbearing Age
WICY&F	Women, Infants, Children, Youth, and Families

1 Executive Summary and Statewide Coordinated Statement of Need (SCSN)

The United States (U.S.) has taken on a bold plan to end the HIV epidemic by the year 2030. In order to reach national goals of reducing new HIV infections by 75% by 2025 and by 90% by 2030, the country must take aggressive actions by scaling up key HIV prevention and treatment strategies. The presentation of **Florida’s HIV Integrated Prevention and Care (IPC) Plan, 2022–2026** is the culmination of several local (rapid HIV antiretroviral start programs), state (Data to Care programs), and federal initiatives including:

- *National HIV/AIDS Strategy, 2022–2025 (NHAS)*
- *Ending the HIV Epidemic (EHE) in the United States (2019)*
- *National Strategic Plan: A Roadmap to End the Epidemic for the United States, 2021–2025*

These plans work in unison to achieve national goals. This plan builds upon the previous work in Florida’s Statewide Integrated HIV Prevention and Care Plan, 2017–2021 and Florida’s Unified Ending the HIV Epidemic (EHE) Plan, 2020.

The impact of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) in Florida is far reaching with 120,502 persons with HIV (PWH) living in the state as of 2021, which represents only 86% of PWH—the remainder of whom are unaware of their status (approximately 14%). We believe people in Florida have the right to:

- Know their HIV status.
- Access Pre-Exposure Prophylaxis (PrEP) if they are negative but at risk for developing the disease.
- Receive services needed to achieve or maintain a high quality of life if they have tested positive.
- Obtain health care, free of stigma.
- Be a voice in their local communities to effect positive change.

According to the Centers for Disease Control and Prevention (CDC), in 2020 (the most recent data available), Florida was ranked third highest (15.7 per 100,000 population) for new HIV diagnosis rates in the United States (including the District of Columbia). In 2021, 4,708 persons received an HIV diagnosis in Florida, a 37% increase from the 3,441 HIV diagnoses in 2020. In 2021, 83% of those newly diagnosed were linked to HIV-related care within 30 days of diagnosis. The number of AIDS cases diagnosed in 2012 in Florida was 2,846, and in 2021 case numbers dropped to 1,860. The current estimate of 14% of PWH in Florida not knowing their status, along with the substantial decrease in AIDS cases over a 10-year period, together underscore the importance of HIV prevention and care service delivery in Florida.

The seven Florida EHE counties make up approximately 11% of the total national HIV burden as outlined in the EHE plan and represent 72% of the total persons with an HIV diagnosis in Florida. Five of the EHE

counties, Pinellas (77%), Hillsborough (71%), Orange (72%), Broward (70%), and Duval (69%) had a viral suppression rate equivalent to or greater than the state rate of 69%, while Palm Beach (65%) and Miami-Dade (63%) had lower viral suppression rates than the state at the end of 2021.

Florida is a large and diverse state. It has both rural and metropolitan areas, an extensive mix of cultures, and an oscillating population due to seasonal residents, tourists, and itinerant workers. These factors can challenge the planning processes of disease control. The IPC Plan is designed to demonstrate coordinated HIV prevention and care activities by assessing resources and service delivery needs across HIV prevention and care systems to ensure the allocation of resources based on data.

Florida receives funding for and implements a wide range of programs and services for persons with and those at increased risk for HIV, including: the AIDS Drug Assistance Program (ADAP), Ryan White HIV/AIDS Program (RWHAP) patient care programs, prevention (HIV testing, PrEP, linkage), housing, substance use disorder and mental health, and other programs.

Core medical and support services are provided by the federal RWHAP to low-income Floridians living with HIV or AIDS who have inadequate or no health insurance and are ineligible for Medicaid, Medicare, or any other public insurance programs through different entities. Services such as medical care, pharmaceuticals, dental services, payment of health insurance premiums, laboratory services, counseling and treatment for substance use disorder, and medical case management are provided through the various parts of the RWHAP. Each part has separate eligibility criteria that clients must meet.

Ending HIV requires partnership and collaboration. This IPC Plan was developed through collaborative efforts that span the continuum of HIV prevention and care, and with representatives from the Florida Comprehensive Planning Network (FCPN) and associated advisory groups, local HIV planning bodies, Department of Health staff, and communities living with and affected by HIV/AIDS. The IPC Plan also aligns with the previously submitted Florida EHE Plan (2020), Florida's 4 Key Component Plan (2016), and the NHAS goals and strategies.

Florida's IPC Plan encompasses the state's entire system of HIV prevention and care. The IPC Plan was reviewed with members of Florida's integrated HIV prevention and care planning body, FCPN, during the Fall 2022 meeting held in Lutz, Florida, October 18–19, 2022. During the two-day meeting, FCPN members and other stakeholders in attendance had an opportunity to provide feedback and suggestions on the draft plan. Concurrence for the plan was gained on October 19, 2022, through a vote of FCPN members. The Department of Health (Department) is pleased to present Florida's IPC Plan, which is intended to re-energize and strengthen a whole-of-society response to the epidemic while supporting PWH in Florida and reducing HIV-associated morbidity and mortality.

1.1 Approach and Partnerships

Critical information about the IPC Plan has been organized in the following sections:

- Community Engagement and Jurisdictional Planning Process (Section 2)
- Contributing Data Sets and Assessments (Section 3)
- Situational Analysis (Section 4)
- Calendar Year (CY) 2022–2026 Goals and Objectives (Section 5), organized by the goals of the National HIV/AIDS Strategy and inclusive of the four pillars of the EHE initiative: Diagnose, Treat, Prevent, and Respond.
- 2022–2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up (Section 6)

Plan development was facilitated by The AIDS Institute through multiple meetings with the FCPN. The FCPN became an integrated HIV prevention and care planning body in 2017 and is made up of representatives from HIV prevention, care, all parts of the RWHAP, federally qualified health centers (FQHC), state and local government, academia, service providers, consumers, and advocates as seen in the figure below. The FCPN is made up of three representatives per each of Florida's 14 HIV partnership areas—a prevention representative, patient care representative, and a Department representative (42 seats). In addition, there are five at-large representative seats—proposed and voted upon by FCPN—which represent specific populations and/or areas of practice (e.g., behavioral science). Each of Florida's six RWHAP Part A jurisdictions also have a representative at the FCPN table (six seats).

FIGURE 1: FCPN MEMBERSHIP DIAGRAM



The FCPN typically meets twice per year, in-person (with virtual meeting options for those unable to attend in person) and the FCPN committees (i.e., Membership, Nominations, and Bylaws Committee;

Medication Access Committee; Coordination of Efforts Committee; Needs Assessment Committee; and Executive Co-Chairs Committee) and associated advisory groups (Florida Gay Men’s HIV Workgroup, Community HIV Advisory Group) meet monthly via videoconference.

In 2021, in preparation for developing the IPC Plan, the Department, in collaboration with the FCPN and RWHAP Part A partners, hosted a series of virtual webinars delivered statewide to share information from the Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022–2026, released by CDC and Health Resources and Services Administration (HRSA) in June 2021. The figure below summarizes the key meetings held. Detailed descriptions of each meeting are bulleted after the figure.

FIGURE 2: PLAN DEVELOPMENT MEETINGS



- In January 2022, an integrated HIV planning kick-off meeting was held with Florida’s State Surgeon General, the FCPN Executive Co-Chairs’ Committee, representatives from Florida’s six RWHAP Part A areas (Fort Lauderdale, Miami, Tampa/St. Petersburg, Orlando, West Palm Beach, Jacksonville), The AIDS Institute, and the Department’s Division of Disease Control and Health Protection leadership, and HIV, sexually transmitted disease (STD), and viral hepatitis staff to discuss Florida’s approach to developing the statewide HIV IPC Plan for 2022–2026. There were 31 participants (29 in-person and 2 virtual).
- The first full-body FCPN meeting was held in April 2022 and was an in-person meeting with virtual attendance options. This meeting was used to develop goals, objectives, and strategies that were taken back to local planning bodies for discussion and feedback. There were 150 meeting participants (68 in-person and 82 virtual), representing all 14 HIV partnership areas.
- In August 2022, the FCPN met again as a full body to develop activities for the strategies that aligned with NHAS. This meeting included small-group exercises to ensure everyone around the table and attending virtually could provide input and actively participate in the activity development process. All proposed activities were collected, and a survey was distributed after the meeting to allow all attendees to vote on prioritized activities for inclusion in the IPC Plan.

Additionally, acquired consulting services from ISF, Inc. to assist in stakeholder coordination, research, reporting and writing for the 2022–2026 IPC Plan. ISF performed key stakeholder group interviews in each of Florida’s 14 HIV partnership areas and each group included lead representatives for the Department, RWHAP Part A, Part B, and local community planning group members. There were 165 meeting participants (52 in-person and 113 virtual), representing all 14 HIV partnership areas.

- The FCPN fall 2022 meeting was held in October and used to review the first draft of the IPC Plan, solicit public comment, and input, and conduct a concurrence vote with the full membership of FCPN. There were 149 meeting participants (53 in-person and 96 virtual), representing all 14 HIV partnership areas.

Letters of concurrence were drafted in November 2022 and subsequently signed by the community co-chairs of the FCPN for inclusion into the IPC Plan. The Department also worked to finalize and ultimately submit the IPC Plan in January 2023.

The Department prioritizes a collaborative approach and works directly with the six RWHAP Part A areas. Ongoing coordination efforts include monthly calls with RWHAP Part A and B programs which split responsibilities of running calls (each call hosted by one of Florida’s Ryan White Part A areas); the monthly calls are used to discuss major issues including the IPC Plan.

A data-informed approach was used to develop the IPC Plan, taking into account data and activities from Florida’s approach to HIV prevention and care, including routine HIV screening, rapid access to treatment and care (Test & Treat), epidemiologic data, HIV Care Continuum outcomes, and other data which help identify priority populations and HIV health disparities. The Department’s High-Impact Prevention (HIP) funding opportunity was developed with the HIV status-neutral approach at the forefront, and funds 44 community and faith-based organizations statewide to provide HIV testing and linkage to care, prevention, and essential support services. Florida also maintains more than 1,600 registered HIV test sites statewide. The HIV status-neutral approach to reducing new HIV diagnoses involves initial HIV testing services as the entry point to HIV prevention and/or care services irrespective of a positive or negative test result. The Department has also engaged in HIV stigma reduction efforts, participating in the University of Florida (UF) stigma workgroup, and contracting with UF for the provision of evaluation and planning activities that will be used to develop program interventions addressing the stigmas related to HIV. Information from Florida’s EHE plan was also used to develop content for the updated IPC Plan.

Florida’s RWHAP Part A areas have developed their own local integrated HIV prevention and care plans which, like the state’s plan, align with the NHAS goals and objectives, but contain locally developed activities tailored to each geographic region. Florida’s statewide IPC Plan and the RWHAP Part A IPC Plans will work in concert to advance the goals and objectives of the NHAS and build a pathway to end the HIV epidemic. Links to each of the RWHAP Part A IPC Plans are provided in Table 1.

TABLE 1: RWHAP PART A IPC PLAN LINKS

Grantee	Link
Fort Lauderdale (Broward County)	https://www.broward.org/RyanWhite/Pages/Default.aspx
Jacksonville (Duval County)	https://www.coj.net/rwpc
Miami (Miami-Dade County)	https://www.miamidade.gov/global/service.page?Mduid_service=ser1482944607068715
Orlando (Orange County)	https://www.ocfl.net/familieshealthsocialsvcs/hiv.aspx#.YFyrkj_-h9A
Tampa/Saint Petersburg (Hillsborough and Pinellas counties)	https://www.hillsboroughcounty.org/en/residents/social-services/health-care-plan/ryan-White-program
West Palm Beach (Palm Beach County)	https://discover.pbcgov.org/communityservices/Pages/Ryan-White-CARE.aspx

HIV service regions are broken down into 14 partnership areas, each with an HIV/AIDS Program Coordinator (HAPC) to oversee prevention and care program operations in the area and assure that program activities are planned in an inclusive and collaborative manner to ensure the other local resources and specific client needs are considered and addressed. They work closely with RWHAP recipients, health district resources, other county programs, and academic and university resources as available.

The HIV/AIDS Section also works closely with many organizations to ensure coordination of effort because of the co-morbidities often associated with HIV/AIDS and their impacts on public health. These organizations include STD, TB, and Viral Hepatitis and Outbreak Response Sections; Children’s Medical Services; local community-based organizations (CBOs) and county health departments (CHD); universities; the Florida Department of Corrections; the Department’s state laboratories in Jacksonville and Miami; and the Department’s central pharmacy.

The six RWHAP Part A Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs), and the RWHAP Part C, D, and F programs collectively bring more than \$94.6 million annually to Florida and are key resources in meeting the service needs of PWH in their service area. The RWHAP Part C program directly funds local projects to support service capacity building as well as early intervention services; there are 20 RWHAP Part C programs in Florida. The RWHAP Part D program directly funds a local Tampa project that provides clinical services to women, infants, children and youth (WICY); there are six RWHAP Part D programs in Florida.

The Department HIV Surveillance Program works closely with each local area to provide customized data reports that reflect key information about the epidemic in each area. These data reports are provided to the local CHDs, planning bodies, and each of the RWHAP Part A areas to assist them in preparing grant applications and other reports. Local planning bodies use epidemiologic data, demographic, and service

data, focus groups, resource inventories, and client and provider satisfaction surveys to gauge areas of program strengths and weaknesses.

The Department's HIV Prevention Program collaborates with the Patient Care, ADAP, Medical, and Surveillance programs to deliver comprehensive HIP strategies and services with overarching goals of reducing the number of new HIV transmissions, increasing the proportion of persons living with HIV who know their status, linking PWH to care and support services, and reducing risk behaviors that may lead to HIV and STD diagnoses. Florida's HIP program is multi-faceted and includes HIV testing, linkage to care, peer navigation programs, comprehensive prevention interventions for PWH, partner services, PrEP and post-exposure prophylaxis (PEP), perinatal HIV prevention, corrections initiatives, condom distribution, community outreach (traditional and Internet-based) and engagement, and other services. The Prevention Program also collaborates with the RWHAP Part A programs, FQHCs, CBOs, academia, PWH, and other stakeholders to implement many HIP interventions and strategies. These essential partnerships help to ensure individuals are receiving comprehensive HIV prevention services along the HIV care continuum, leading to improved health outcomes for those living with HIV/AIDS.

Stakeholder engagement occurs on a regular basis through the FCPN and assists the Department in planning patient care and prevention activities. The FCPN is composed of representatives from the Department, all parts of the RWHAP, FQHCs, academia, service providers, CBOs, PWHs, and advocates. The FCPN reviews and gives feedback on projects the HIV/AIDS Section develops, such as the Needs Assessment, the SCSN and statewide IPC Plan, other programs funded with state general revenue, as well as various program standards, and guidelines.

The HIV/AIDS Section routinely communicates with the RWHAP Part A administrators to ensure that they are informed of program activities and have an opportunity to comment and contribute to various projects. Areas of collaboration have been on the transition of RWHAP clients to the Affordable Care Act (ACA) Marketplace® (Marketplace®), work on the Statewide IPC Plan, and development of the ADAP HCV treatment pilot project.

Over the past two years, there have been multiple meetings to plan for a uniform methodology to select insurance plans and move clients to the Marketplace®. Determining eligibility criteria for insurance coverage, planning for the provision of wrap around services, and the potential local coverage of additional clients were main topics of discussion. This project has been very successful; clients, regardless of whether they receive services from RWHAP Part A or Part B ADAP, or are mutual clients, have the same options for insurance selection criteria and process to enroll in the Marketplace® for insurance coverage.

Collaborations, partnerships, and stakeholder engagement exist in many forms throughout Florida; however, opportunities exist to expand partnerships further and engage new and non-traditional partners in more regular communication (for example, Department of Veterans' Affairs and Indian Health Service) to further the objectives and support the strategies of Florida's statewide IPC Plan.

1.2 Documents Submitted to Meet Requirements

In order to meet the submission requirements of the IPC Plan, as outlined in the CDC and HRSA Integrated HIV Prevention and Care Planning Guidance (2021), Table 2 provides descriptions for each document referenced in the IPC Plan. Documents have also been flagged where new material was created specifically for the IPC Plan or where existing material was used. These documents have also been linked in the Appendix, Section 9.5.

TABLE 2: SUPPORTING DOCUMENTATION

Document	Description	Developed for this plan?
CDC and HRSA Integrated HIV Prevention and Care Planning Guidance, 2022–2026	Developed to support the submission of the IPC Plan for each state for the 2022–2026 cycle.	No (Existing)
Florida’s Unified EHE Plan, 2020	Unified plan representing the state and the seven counties identified as Phase 1 EHE jurisdictions: Broward, Duval, Hillsborough, Miami-Dade, Orange, Palm Beach, and Pinellas.	No (Existing)
State of Florida IPC Plan, 2017–2021	Developed collaboratively across Florida stakeholders to eliminate HIV transmission and reduce HIV related deaths for the 2017–2022 cycle.	No (Existing)
Meeting Notes from the August and October FCPN Meetings	The August FCPN meeting was used to identify Florida specific activities to address the Goals, Objectives and Strategies identified by the CDC. The October FCPN meeting was used to review the IPC Plan DRAFT with stakeholders, receive their feedback, and incorporate that feedback into the FINAL version of the IPC Plan.	Yes (New)
Local Area Resource Inventories	Includes recipients’ and community resources for prevention and patient care across 14 partnership areas in the state of Florida.	No (Existing)
Local Area Interview Questionnaires	Interviews were held with all 14 partnership areas and questions were raised to gather feedback in supporting multiple areas of the IPC Plan.	Yes (New)
Local Area Engagement Activities	Provided meeting summaries and feedback from a variety of engagement activities such as local area town halls.	No (Existing)
Documentation of Community Engagement	Describes Florida’s partners and the voices engaged along with engagement efforts at the statewide level and seven major metropolitan areas. Interviews were held with all HIV partnership areas to identify community groups active on local planning councils.	No (Existing)
Florida HIV Continuum of Care Dashboards	Consolidates “Resource Inventories” across the state.	No (Existing)

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Document	Description	Developed for this plan?
Florida’s Ryan White (RW) HIV Care Needs Assessment: Key Findings 2019	Survey to determine met and unmet service needs for PWH in Florida.	No (Existing)
RWHAP Part A Plans	Represents the latest collaborative effort for each Part A partnership area in developing their unique IPC Plan	No (Existing)
PS19-1906 EHE Plan Executive Summary Florida	Key points, including strategic partnerships and planning support, from Florida’s EHE Plan	No (Existing)

2 Community Engagement and Jurisdictional Planning Process

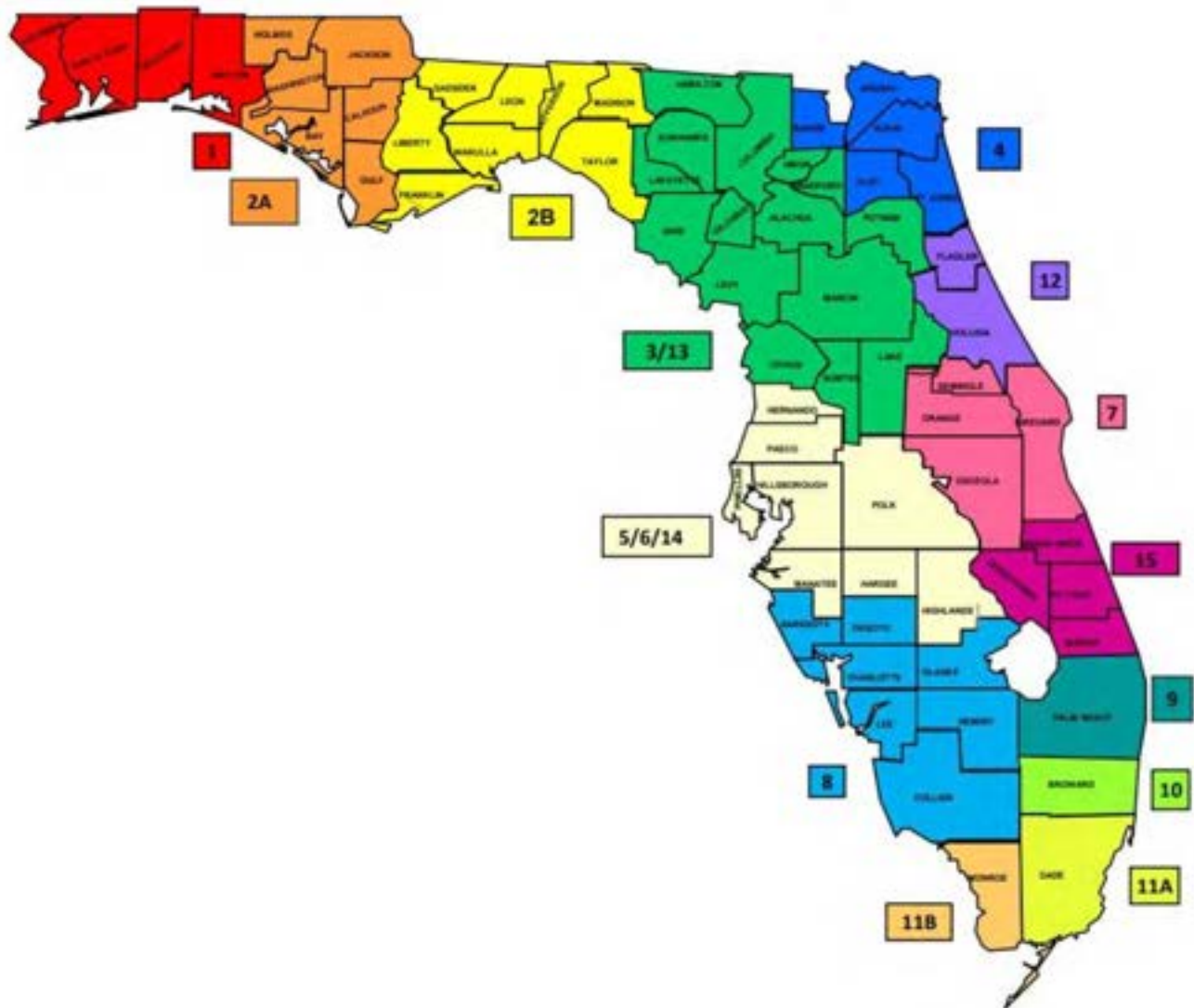
Community engagement is an overarching element of Florida’s 4 Key Component Plan which intersects with the four pillars of the EHE initiative and the NHAS. Community members were engaged in all phases of the planning process and will continue with the implementation of strategies and activities to build a pathway to eliminate HIV transmission in Florida.

During 2021 and 2022, varying degrees of community engagement took place at state and local levels in preparation for developing the IPC Plan. In addition to community engagement activities performed October 2019 through October 2020 for EHE planning and implementation, additional community engagement activities were conducted in each HIV partnership area to ensure stakeholders were included in the integrated HIV planning process.

The HIV Planning Process

Florida’s HIV planning process operates with the principle that determining the best way to support HIV prevention and care needs is through coordinated decision making with local entities, which collectively informs the overall statewide IPC Plan. As such, the Department engaged stakeholders and community members to create an IPC Plan for HIV efforts across the state. The remainder of this section outlines the planning process, inputs into the IPC Plan, analysis performed, priority goals and objectives, and a detailed plan to support successful implementation.

The Department arranges the state into 14 HIV partnership areas (shown in Figure 3), each with an HAPC to oversee prevention and care program operations in each HIV partnership area. HAPCs ensure that program activities are planned in an inclusive and collaborative manner to ensure other local resources and specific client needs are considered and addressed.

FIGURE 3: FLORIDA HIV PARTNERSHIP AREAS

Consortia are community-based regional planning entities established by RWHAP Part B recipients. The consortia plan and prioritize RWHAP Part B funds allocated to their area, promote coordination of services, and serve as a community forum. Representatives of local public and non-profit health and support service providers serve as consortium members. Lead agencies are member agencies in the consortium designated to perform contract administration as a fiscal agent.

Local jurisdictions around the state drive community engagement with the goal to educate and raise awareness about HIV and ensure programs and services are culturally and linguistically appropriate and developed with input from the populations intended to be reached. The local jurisdictions host focus groups, town halls, events for HIV/AIDS observance days, multiple outreach events, media interviews; teach public health classes at local universities; and use their social media presence.

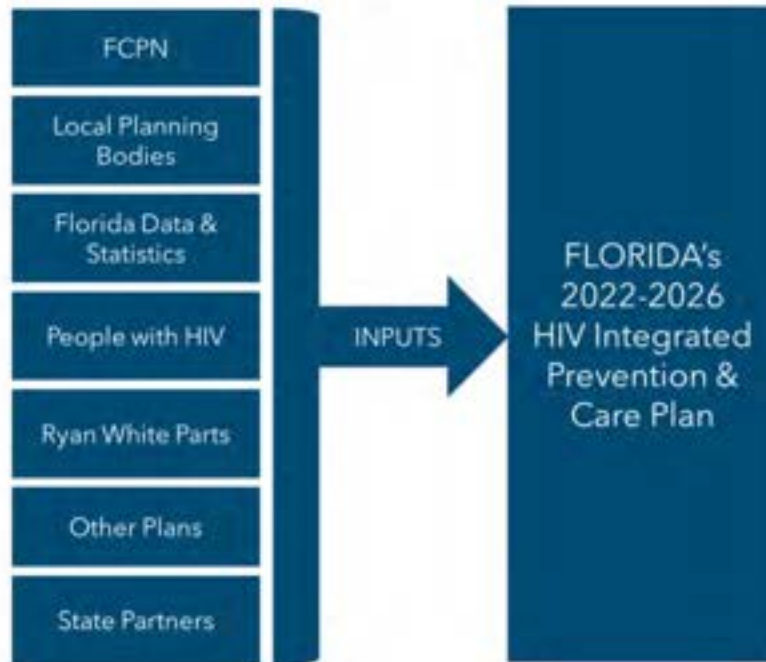
Table 3 provides an example of different groups that participate in the community engagement and planning processes.

TABLE 3: HIV PREVENTION AND CARE PLANNING PARTICIPANTS

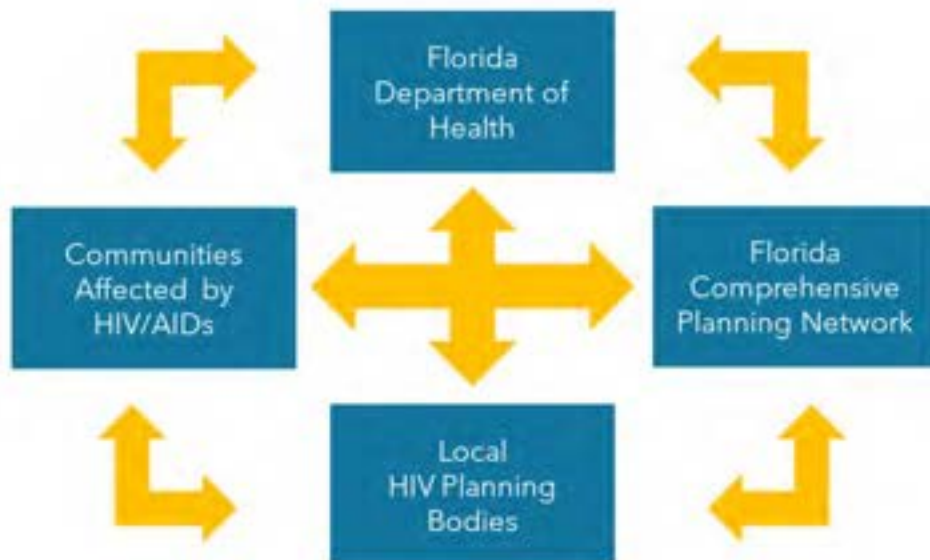
Local Jurisdiction Partnership Groups
• Existing community advisory boards • Community members resulting from new outreach efforts • Community members that represent the demographics of the local epidemic (e.g., race, ethnicity, gender, age, and others.) • Community members unaligned or unaffiliated with agencies currently funded through HRSA and CDC • STD clinics and programs • City, county, tribal, and other state public health department partners • Local, regional clinics, and school-based health care facilities; clinicians; and other medical providers • Behavioral health care agencies • Federally qualified health centers and community health centers • Medicaid/Medicare partners and private payors • Strategic planning and quality management collaboratives • Correctional facilities, juvenile services, local law enforcement and related service providers • Community- and faith-based organizations, including civic and social groups • Professional associations • Local businesses • Local opioid advisory groups • Local academic institutions • Commercial and retail pharmacies • Pharmaceutical and biomedical industry partners • Diagnostic industry partners • Digital media service providers • Adult entertainment industry partners

For a full list of specific community resources by partnership area, please refer to Appendix Section 9.3: Partnership Area Resource Inventories.

Florida's new IPC Plan for 2022–2026 was built upon the foundational goals, strategies and activities from the Florida Statewide Integrated HIV Prevention and Care Plan, 2017–2021; Florida's Unified Ending the HIV Epidemic Plan, 2020; the National HIV/AIDS Strategy; and input from local planning bodies and community members. Figure 4 shows the different inputs used to develop the 2022–2026 IPC Plan.

FIGURE 4: INPUTS TO THE 2022–2026 INTEGRATED HIV PREVENTION AND CARE PLAN

The Department's HIV/AIDS Section works in partnership with Florida's statewide integrated HIV planning body, FCPN. Members of FCPN include PWH and representatives across the state representing patient care and prevention groups, local planning bodies, state and local advisory groups, CBOs, academic institutions, local and regional clinics, city, and county governments, RWHAP programs and recipients, advocacy groups, substance use, mental health and social service providers and behavioral science groups. Figure 5 shows a representation of the community engagement and planning groups involved across the state.

FIGURE 5: COMMUNITY ENGAGEMENT AND PLANNING

In describing how the jurisdiction approached the planning process, the subsequent sections address steps used in the planning process, the groups involved, and representation from the priority populations:

- Entities Involved in the Process (Section 2.1)
- Role of Planning Bodies and Other Advisory Groups (Section 2.2)
- Engagement of People with HIV (Section 2.3)
- Social Determinants of Health (Section 2.4)
- Priorities (Section 2.5)
- Updates to Other Strategic Plans Used to Meet Requirements (Section 2.6)

2.1 Entities Involved in the Process

Florida has a long history of both engaging PWH and the broader community in developing plans for prevention and care services. This has been accomplished primarily through what is now known as the FCPN, which has been in existence since 1993. The available seats for FCPN are made up of three representatives from each of Florida's 14 HIV partnership areas—one representative each for prevention, patient care, and the Department of Health (total of 42 seats). Additionally, there are five at-large representative seats—proposed and voted upon by FCPN—which represent specific populations and/or areas of practice (e.g., behavioral science, substance use). Each of Florida's six RWHAP Part A jurisdictions also has a representative at the FCPN table (6 seats). There is a combined total of 53 representative, at-large, and RWHAP Part A seats available on the FCPN. Currently, 41 of the 53 FCPN representative seats are filled. Members of FCPN include PWH and other individuals across the state representing local partnerships. FCPN members are recruited statewide to represent local or at-large positions from patient care and prevention groups, local planning bodies, community and faith-based organizations, academic institutions, recipients of HIV prevention and care services, local and regional clinics, city, and county governments, RWHAP recipients, advocacy groups, substance use disorder and social service providers and behavioral science groups. The Department, in collaboration with the FCPN Membership, Nominations and Bylaws Committee will develop a plan of action to recruit for the remaining vacant seats.

Of the current FCPN member base—10 members disclosed living with HIV, 28 members disclosed they were not living with HIV, and 3 chose not to disclose their HIV status altogether. Nearly 60% of the current FCPN members are from the ages of 50 to 60+ years of age; followed by 30 to 39 years of age (20%); 40 to 49 years of age (15%); and 20 to 29 years of age (7%). Of the 41 current members, 49% are male, 46% female, and 5% are transgender. Approximately 54% of members reported their sexual orientation as heterosexual; 41% reported as gay, bisexual, and/or lesbian; and 5% chose not to disclose their sexual orientation. Race/ethnicity for members is as follows: White (52%), Black (18%), Hispanic/Latino (20%), Asian/Pacific Islander (6%), multi-racial/other (2%), and American Indian/Alaskan Native (2%).

Prior to 2017, the FCPN was made up of two planning bodies: the Patient Care Planning Group and the Prevention Planning Group. In 2017, the FCPN became fully integrated—merging prevention and care

planning bodies. Membership of the integrated planning body is made up of persons with and those affected by HIV; Department staff; representatives from mental health and substance use organizations; psychologists; social workers; case managers; AIDS service organizations; CBOs; RWHAP Part A, B, C, and D providers; RWHAP Part B lead agencies; advisory groups; and FQHCs. The FCPN maintains a biannual, integrated meeting structure and members are responsible for disseminating information from the meetings back to their respective areas of representation, as well as bringing concerns from those same areas to such meetings, ensuring that the voice of PWH in Florida are part of the integrated planning process. The HIV/AIDS Section oversees the composition of these groups, ensuring that they are representative of Florida's HIV epidemic in the various geographic regions, using the principle of Parity, Inclusion and Representation.

The Department routinely communicates and coordinates with other state partners such as The AIDS Institute; health planning councils; Medicaid/Medicare; Agency for Health Care Administration; Department of Corrections (FDC); Department of Children and Families (DCF); Department programs such as the STD, Viral Hepatitis, and TB programs and other state partners; and the Florida HIV/AIDS Advocacy Network (FHAAN). The AIDS Institute is a national nonprofit organization that promotes a full spectrum of HIV activities including prevention, care, and treatment, through public policy, research, advocacy, and education. Medicaid, FDC, DCF, and the STD, Viral Hepatitis, and TB programs are all state programs that impact and serve PWH. Medicaid is the single largest funder of HIV care in Florida. The HIV/AIDS Section contracts with FDC for pre-release planning services that link discharged inmates with HIV services upon release. DCF oversees mental health services and several housing and homeless programs. The STD Section is a key partner to the HIV Prevention Program, with Disease Intervention Specialists (DIS) providing partner services and following up with newly diagnosed individuals. FHAAN is a statewide effort comprising of PWHs, community advocates, HIV/AIDS and industry professionals, and anyone wanting to be involved to coordinate HIV advocacy efforts.

Collaborations, partnerships, and stakeholder engagement exist in many forms throughout Florida; however, opportunities exist to expand partnerships further and engage new and non-traditional partners in more regular communication (for example, federal Department of Veterans' Affairs and Indian Health Service) to further the objectives and support the strategies of Florida's statewide IPC Plan.

2.2 Role of Planning Bodies and Other Advisory Groups

The Department's HIV/AIDS Section receives advisement on HIV programs and services from various community partners and workgroups, some of which report out directly to the FCPN. These various groups consist of both members of the community, as well as PWH. These groups consist of the Florida Gay Men's HIV Workgroup, the HIV Section Medication Formulary Workgroup, and the Community HIV Advisory Group. Other groups operating in the state but not directly under the FCPN include the Florida Harm Reduction Collective, the Florida Black Leaders Group, and the Florida HIV Justice Coalition. The Department will develop a plan to ensure these groups have a representative at the FCPN table.

For the workgroups that report directly to the FCPN—the Florida Gay Men’s HIV Workgroup, the HIV Section Medication Formulary Workgroup, and the Community HIV Advisory Group—each group consists of PWH who use HIV services and community members selected through an application process and reflective of the profile of the HIV/AIDS epidemic in Florida. Members are appointed for a period of two years and may reapply for subsequent terms. These groups exist to provide a mechanism in which PWH and the community have meaningful input into the development of policies and programs to address their needs with and under the auspices of the Department and the HIV/AIDS Section.

Local Area Interview Results

To better understand the process of community engagement at the local level, interviews were held with each HIV partnership area, with a total of 72 participants. Participants included local Department staff, RWHAP Part A and B representatives, lead agencies, and other community planning body members. During each interview, participants were asked to report on membership, community engagement, outreach activities and keys to success.

Membership: Membership in area partnerships is consistent with all 14 partnership areas having county health departments and CBOs serving populations affected by HIV, as well as HIV service providers. Thirteen out of 14 areas include populations at risk for or with HIV representing priority populations, STD clinics and programs, and HIV clinical care providers and clinicians as part of their voting membership. Only 3 out of 14 partnership areas have epidemiologists and only 4 have representatives from state or local law enforcement or correctional facilities among voting members.

When asked about entities or organizations they would like to have in their planning body, but have not yet been able to secure, areas reported: pharmacists, a school system representative, local school-based clinics, elected officials, representatives from youth organizations, colleges and universities, health promotion groups, an epidemiologist, transportation agencies; faith-based organizations, the Association of Free and Charitable Clinics, and more staff to coordinate the planning body.

Community Engagement: All partnership areas report robust, comprehensive community engagement in each of their counties. All but one area reports challenges with maintaining representation from PWH receiving HIV care services (e.g., RWHAP Part A or B services). Most local areas report having PWH represent approximately 33% of their voting membership; however, these individuals may be staff at local community- and faith-based organizations or on local boards and not necessarily receiving HIV care services through the RWHAP. Several strategies have been used to try and encourage “everyday PWH” to become part of the local planning bodies. Many areas offer incentives and others send out mailers to PWH emphasizing the opportunity to have their voice heard and help the greater good. Other members that areas have difficulty recruiting and keeping are elected officials, faith-based leaders, hospital and health care planning agencies, and law enforcement.

One area restructured planning body meetings from formal events to more informal meetings using lay language and fewer acronyms. They reported that building planning activities around less structure

creates more freedom to speak. Additionally, the planning body keeps meetings to no longer than two hours, food is provided, and agenda items are suggested by members, so they drive future meetings.

To incorporate the perspective of PWH, almost every area sends surveys to clients about services they received and how satisfied they were with those services. This information is used to determine whether some services need to be enhanced, reworked, or streamlined. It is also used for gap analysis purposes and to determine future funding.

About half of the areas report a working relationship with local prisons and jails but felt more could be done to increase testing and treatment efforts. Areas overwhelmingly found value in monthly calls hosted by the Department's HIV/AIDS Section and saw them as a chance to exchange best practices.

Outreach Activities: Partnership areas report hosting focus groups and town hall meetings. Twelve areas held topic-focused community discussions and collaboration building meetings with new partners. Areas also rely on social media to reach PWH engaged in services; however, three areas report that different local restrictions present challenges. Some examples of outreach activities include harm-reduction events, annual surveys to RWHAP recipients, surveys to funded providers, local street fairs and block parties, and events planned around World AIDS Day and other key HIV observance days.

Keys to Success: Partnership areas identified several different ways they have built successful programs:

- Ability to work together to make service delivery appear seamless to clients, regardless of what organization was providing the service.
- Longevity in leadership positions and the sharing of funds between services.
- Consulting with adjacent partnership areas and assisting when possible.
- Having a continuous calendar of events and meetings.
- Participation in statewide calls.
- Collaboration and cohesiveness among partners.
- Cultivating a culture of trust and transparency.

Department Collaboration with RWHAP Parts

RWHAP Parts A, B, C, and D and ADAP programs are key local partners and are at the table as planning activities are performed since no single RWHAP part can meet the needs for all services. The RWHAP Part F program collectively funds Special Projects of National Significance (SPNS), as well as the AIDS Education and Training Centers (AETC) that provides support and training to the medical community in treating patients, and dental programs for PWH.

The planning process is guided by local resource inventories, demographics, satisfaction surveys and service needs expressed locally by PWH who use services. Given the multitude of RWHAP parts, as well as programs funded by other federal, state, and local sources, funding allocation necessitates collaboration and coordination at the local planning body level. Therefore, consortia and planning councils require coordination in RWHAP planning, which involves consideration of other programs in

such areas as assessment of needs, priority setting and resource allocation. Planning bodies must analyze existing resources, regardless of funding stream, to identify areas of unmet need. Likewise, in setting priorities, other resources must be considered in terms of how they help meet service demands so that RWHAP resources can be used to fill gaps.

The Department's HIV/AIDS Section routinely communicates with the RWHAP Part A administrators to ensure they are informed of program activities and have an opportunity to comment and contribute to various projects. Regular monthly calls are used to communicate program updates and policy changes, opportunities for collaboration, and solicitation of feedback. The hosting of the calls rotates, with one of the six RWHAP Part A areas leading the call each month. Examples of collaboration include the transition of RWHAP clients to the Marketplace®, work on the statewide IPC Plan, developing the ADAP HCV treatment project, developing reciprocal eligibility and Notice of Eligibility, data sharing, coordination with ADAP related to the changes in the pharmacy benefits manager, and ADAP formulary updates.

The Department's HIV/AIDS Section allocates RWHAP Part B funding for administration, planning and evaluation, clinical quality management and core medical and support services to 14 lead agencies annually to perform planning activities in their respective areas. Upon receiving RWHAP Part B funds from the Department, each lead agency is required to provide administrative assistance to the planning body (consortium) in the program area. The planning bodies serve as the entities that meet the RWHAP planning requirements for the program area and advise the lead agencies during the priority setting and resource allocation process. Lead agencies facilitate a provider selection process (internal services, external vendors, or competitive procurement process) through a network of local partners (CBOs, CHDs, consumers, planning bodies, and others).

There has also been collaboration with RWHAP Part A partners through EHE initiatives, as RWHAP Part A partners receive EHE funding directly from HRSA to address pillars 2 and 4 (Treat and Respond). The Department receives EHE funding directly from CDC and distributes the funds to the seven EHE counties (county health departments and community and faith-based organizations). Throughout the EHE planning and implementation process (2019 to present), it has been imperative that the Department and RWHAP partners coordinate to maximize efforts, promote information sharing, and ensure resources are used efficiently.

As the recipient of RWHAP Part B funds, the Department is required to develop and maintain a clinical quality management (CQM) program to ensure quality health care services are provided to persons living with HIV. The purpose of the HIV/AIDS Patient Care CQM Program is to provide a systematic approach for planning, measuring, implementing, evaluating, and improving the quality of RWHAP-funded care services delivered to PWH in Florida. Routine review of established performance measures leads to the identification of specific CQM goals for each quality improvement project. Stakeholders who are internal and external to the CQM committee review measures through formally established mechanisms using evidence-based quality improvement methods. This CQM requirement is also mandated by HRSA for each sub-recipient, at the local level. This includes having a formal quality committee and a local CQM plan. For 2019–2022, the following CQM goals were identified:

- **Percentage of Patients on ART (Antiretroviral Therapy)**—Ensure equitable access to RWHAP-funded HIV services in the state for PWH and ensure equitable results in HIV health outcomes; patients receiving ambulatory outpatient care are also on ART.
- **Improving Viral Suppression for PWH**—Drive maximum viral suppression for PWH in the state, with 90% of PWH achieving viral suppression by 2022.
- **Eligibility**—Ensure PWH in the state have complete eligibility documentation for all services received. Complete eligibility documentation prevents gaps in care and can help identify additional services for which the client has need. The goal is 90% of all clients having accurately completed eligibility documentation by 2022.

2.3 Engagement of People with HIV

Florida strives to actively involve key partners, stakeholders, and PWH and, in doing so, incorporates feedback received, for the IPC Plan, on an ongoing basis. The jurisdiction understands that to best serve those most marginalized, their voices must be involved in all aspects of the process. “Nothing about us, without us” is a call to action that informs the need for cultural shifts in programming, provisions of services, and community engagement. Changes have already been made to the planning process with a greater focus placed on creating an environment that is more welcoming to prospective members who represent communities most affected by HIV.

PWH were influential in the development of the statewide IPC Plan. PWH contributed by participating in the Statewide Needs Assessment and serving on local RWHAP Part B consortia, local prevention planning bodies, RWHAP Part A planning councils as well as RWHAP Parts C and D consumer advisory boards. There are also many robust peer-driven navigation and prevention programs that contribute greatly to PWH involvement on many different levels. They have helped identify what is working well (or not), barriers to care, and in accessing prevention and patient care services, and helping to develop the state’s unmet need matrix.

Further, PWH have participated widely in providing feedback to the Department by attending various town hall meetings that have helped develop goals and improve service delivery around eligibility, medical case management guidelines, HIP, PrEP, post-exposure prophylaxis (PEP), ADAP and many of the other programs overseen by the state. They have also played a key role in the success of the medical monitoring project (MMP) in Florida by willingly volunteering their time to be interviewed for this significant program. Florida has a very active Community HIV Advisory Group (CHAG) which also serves as the MMP’s Community Advisory Board. Proposed changes in policy are reviewed and feedback is provided by this group of dedicated individuals. Table 4 shows some of the community engagement and planning efforts across the state.

TABLE 4: COMMUNITY ENGAGEMENT EFFORTS

Location	Involvement
Statewide	Community engagement activities including: five ad-hoc consultations with representatives from priority populations (30+ participants per session) and launched Florida’s Undetectable=Untransmittable (U=U) campaign. The Department’s HIV/AIDS Section hosted virtual meetings (180+ reached) for FCPN and community guests to refine the elements of the unified EHE plan from a statewide perspective.
Area 1 Counties: Escambia, Santa Rosa, Okaloosa, Walton	Community engagement activities were conducted, including the implementation of a U=U campaign, launched with a press conference inviting local civic leaders and community partners. A meeting was also held with the superintendent of schools and a school board member to provide information on local HIV data.
Area 2A Counties: Bay, Calhoun, Gulf, Holmes, Jackson, Washington	Partnered with BASIC NWFL for HIV and HCV testing and condom distribution. PanCare of Florida (FQHC) conducted mobile HIV testing.
Area 2B Counties: Franklin, Gadsden, Jefferson, Leon, Liberty Madison, Taylor, Wakulla	Partnered with 4 community resources for the provision of ART, 3 community resources for HIV testing and diagnosis, 1 partner for HIV education/community outreach, town hall meeting (10 clients attended), and mailed 14 surveys
Area 3/13 Counties: Alachua, Citrus, Lake, Marion, Putnam, Hamilton, Suwannee, Columbia, Lafayette, Gilchrist, Dixie, Levy, Bradford, Sumter	Conducted a town hall meeting in Area 3/13 and results were shared at the April 2022 FCPN meeting. Draft goals and objectives were sent out to the local consortium via email for review and then discussed at the June 2022 consortia meeting.
Area 4 Counties: Nassau, Baker Duval, Clay, St Johns	Community engagement activities such as: 2 provider meetings and town halls, the creation of a local EHE committee, provider survey (68 reached), community-wide listening sessions (115+ reached), faith-based workshops to address stigma and the social justice aspect of the HIV epidemic, and exclusive focus groups (50+ reached) with priority populations.
Area 5/6/14 Counties: Hernando, Pasco, Pinellas, Hillsborough, Manatee, Polk, Hardee, Highlands	Community engagement activities such as: an online community survey (72 reached), focus groups (8 reached) with youth, community members, and private sector leaders; individual phone interviews (39 reached); virtual town hall meetings per pillar (34 across all meetings); and an HIV care needs survey (600+ reached). Additional activities included: focus groups facilitated by representatives of key priority populations (55 reached across all sessions); a virtual interview with local radio station to engage the community (1,000+ reached); virtual EHE Advisory Council meetings to engage new and existing stakeholders; Teen Talk Thursdays, monthly webinars facilitated by representatives revered by youth (50+ reached per meeting) and listening sessions with HIV service providers (45 reached).

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Area 7 Counties: Seminole, Orange, Osceola, Brevard	Community engagement activities such as: conducted 3 town hall meetings; key informant interviews (27 reached); EHE and HIV stigma conversations on Facebook Live with iHeart Media; 8 virtual town hall meetings with key priority populations (98 individuals participated across all town halls, viewed by 3,356 individuals on Facebook Live); quarterly provider meetings to discuss EHE plans and implementation; 8 pop-up HIV testing events; listening sessions with HIV service providers; and community-wide surveys (300+ reached)—one tailored to the community members and the other tailored to providers.
Area 8 Counties: Sarasota, Desoto, Charlotte, Glades, Lee, Hendry, Collier	Community engagement activities were conducted throughout the area, including health education and outreach, community forums and meetings, and testing events.
Area 9 County: Palm Beach	Community engagement activities such as: service provider interviews (19 reached); focus groups with PWH (10 reached); and Palm Beach resident phone interviews in English, Haitian-Creole, and Spanish (253 reached).
Area 10 County: Broward	Community engagement activities such as: 28 community presentations; community-wide listening session; listening session with youth (9 reached); outreach sessions with college students (40+ reached); 5 focus groups with providers, transgender individuals, men who have sex with men (MSM), Black heterosexual women, and Latino individuals; student survey (130 reached); 40 key informant interviews with community members and service providers; and needs-based surveys for providers (430 reached) and community members (1,780 reached) in multiple languages.
Area 11A County: Miami-Dade	Community engagement activities including: several listening sessions at different venues; met with workgroups; and focus groups outside the RWHAP or the Miami-Dade CHD. Additional activities included: key informant interviews with local CBOs and local government (23 reached); 2 needs-based surveys tailored to HIV service providers (37 reached) and community members (1,158 reached) in multiple languages; online community forums and focus groups representing priority populations (250+ reached); 11 community listening sessions with community mobilization groups that primarily serve Black and Latino populations. Mobilization also occurred among transgender individuals.
Area 11B County: Monroe	Engagement activities including quality management patient surveys in ADAP, customer satisfaction surveys in RWHAP Part B, focus group activities in the Client Advisory Board, multiple discussions in the Florida Keys Community Planning Partnership, and monthly Teams meetings, in which all prevention providers meet to discuss awareness day activities, nationally recognized testing day activities and ongoing local prevention activities (e.g.,

	testing sites, outreach activities and involvement and partnership with the Gay Men's Health Summit and Miami-Dade County).
Area 12 Counties: Volusia, Flagler	Various community engagement activities were conducted throughout the area and included numerous health fairs and HIV observance day events (e.g., health fairs at Bethune Cookman University, Stetson University and Daytona Beach College; HIV Testing Day; World AIDS Day; New Smyrna Beach Senior Summit; One Voice Volusia Health Summit; and HOPE Fest Community Outreach with Hope Church).
Area 15 Counties: Indian River, Okeechobee, St. Lucie, Martin	Conducted focus groups with PWH (25 reached); facilitated HIV needs assessment survey (175 reached); partnered with United Against Poverty St. Lucie County for HIV and sexually transmitted infection (STI) screenings and condom distribution (20+ reached); facilitated an HIV/AIDS symposium where attendees were community members, PWH, and service providers (100 reached); participated in Annual Showcase of Services community event and provided resource information to local social service agencies and community members (70 reached); conducted HIV and STI screening at local substance use disorder treatment centers (20 reached); participated in community health resource fair and provided HIV and STI screenings as well as condom distribution (100+ reached); hosted National Latino AIDS Awareness Day testing event (6 reached); and facilitated weekly HIV and STI testing and awareness events in 4 area counties (number reached varied), where all events were conducted in multiple languages.

2.4 Social Determinants of Health

To reduce new HIV diagnoses in Florida, it is critical to ensure that everyone with HIV is aware of their status, is linked to and retained in HIV medical care, and maintains viral suppression. Collaborative efforts from prevention and patient care programs at the state and local levels, including by CHDs, RWHAP partners, CBOs, and health care providers are an integral part of ending the HIV epidemic in Florida. There must also be a focus on the social determinants of health that preclude people from engaging in prevention activities, seeking treatment, and acquiring an adequate level of health literacy. Lower health literacy has been tied to poorer health outcomes in PWH; therefore, ensuring basic levels of health literacy is essential to ensure medication and treatment adherence and ultimately, viral suppression. Social determinants of health (as shown in Figure 6) include food and housing insecurity, geographic location, educational status, poverty, racism, violence, and stigma.

FIGURE 6: DEMOGRAPHIC HIV STATISTICS

In the past decade, Florida has seen a general decline in HIV diagnoses in Florida; however, Black and Hispanic/Latino populations are disproportionately impacted with higher rates of new diagnoses compared to the White population. Additionally, late-stage HIV or AIDS is also higher in the Black population. For males diagnosed with HIV in 2021, Black males were 6 times more likely to be diagnosed with HIV compared to the White males; additionally, Hispanic/Latino males were 4 times more likely to be diagnosed with HIV compared to White males. Similar trends are observed for females, where Black and Hispanic females were 12 and 3 times, respectively, more likely to be diagnosed with HIV compared to White females.

With respect to mode of transmission, in 2021, the majority (61%) of new HIV diagnoses were a result of male-to-male sexual contact (MMSC), followed by 31% who were persons who had heterosexual contact, and 4% who were persons who inject drugs (PWID). Through the identification of priority populations disproportionately impacted by HIV, Florida will continue to engage with and seek input from members of those communities to address health disparities and social determinants of health.

Florida's incorporation of the status-neutral approach and Undetectable=Untransmittable (U=U) into HIV prevention and care service delivery is a key component in addressing social determinants of health and stigma that may prevent individuals from engaging in HIV care services. In June 2020, the Department announced its endorsement of the Prevention Access Campaign's U=U. In becoming a U=U partner, the Department joined nearly 1,000 organizations around the world supporting the science-backed message that PWH who use antiretroviral therapy and have an undetectable viral load in their blood have effectively no risk of sexually transmitting HIV.

Florida will work to ensure programs and services for PWH and those at increased risk for acquiring HIV align with the National Culturally and Linguistically Appropriate Services (CLAS) Standards

(<https://thinkculturalhealth.hhs.gov/Assets/Pdfs/EnhancedNationalCLASStandards.Pdf>), which provide a structure to implement culturally and linguistically appropriate services, and increase the ability of the state to address health care disparities.

2.5 Priorities

The IPC Plan priorities are based on the four goals of the NHAS, 2022–2025:

1. Prevent new HIV infections.
2. Improve HIV-related health outcomes for people with HIV.
3. Reduce HIV-related disparities and promote diverse community wellness.
4. Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and stakeholders.

For the complete list of unique activities to support each strategy, please refer to Appendix Section 9.1 Strategy and Activity Table.

Additionally, the RWHAP Part A's local priorities align with the NHAS, and the four pillars outlined in the EHE: diagnose, treat, prevent, and respond. All goals and objectives include various local initiatives with some overlap between several CDC and HRSA grants.

Based on the most recent HIV data trends for the state (2017–2021) and feedback from community engagement activities conducted in preparation for the IPC development, Florida's integrated HIV prevention and care planning body (FCPN), along with the RWHAP Part A partners, has determined to focus on PWH, Black and Latino populations, LGBTQ communities, PWID, and youth populations.

The planned outcomes of the IPC include reducing HIV-related disparities and promoting diverse community wellness by expanding targeted efforts to prevent HIV transmission using innovative and evidence-based approaches, decreasing the annual HIV diagnosis rate, ensuring early linkage to care, and increasing the number of PWH who are retained in care and virally suppressed. Progress on these outcomes will be ongoing throughout the project period and will benefit the overall community by improving population-level health and reducing the incidence of HIV/AIDS.

While setting goals and priorities, *Demanding Better: An HIV Federal Policy Agenda by People Living with HIV* (<https://www.pwn-usa.org/wp-content/uploads/2021/07/Networks-Policy-Agenda-FINAL.pdf>) was referenced to ensure the Meaningful Involvement of People with HIV/AIDS (MIPA) in decision-making, at every level of the response. In *Demanding Better*, the U.S. People Living with HIV Caucus outlines five recommendations which must be included in every aspect of the federal HIV response:

1. Concretely elevating the meaningful involvement of people living with HIV and disproportionately impacted communities in the HIV response.
2. Proactively creating an affirming human rights environment for people living with HIV.

3. Addressing inequities in the federal response by attending to racial and gender disparities.
4. Adding sex workers and immigrants living with HIV as priority populations.
5. Affirmatively committing to improving quality of life for people living with HIV.

MIPA requires dedication, planning and assessment, organizational buy-in, and a champion to help usher its development and continued assessment. Although the U.S. Department of Health and Human Services (HHS) *National Strategic Plan: A Roadmap to End the Epidemic for the United States, 2021–2025* (<https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>) largely did not address these recommendations in the final version, Florida’s statewide IPC Plan will do so to the greatest extent possible, as they were created by and for people living with HIV.

2.6 Updates to Other Strategic Plans Used to Meet Requirements

Local jurisdictions perform an annual needs assessment, based on core questions developed through the FCPN Needs Assessment Committee. The needs assessments are created using multiple sources of information from PWH and other stakeholders. Interviews are conducted with PWH and stakeholders to incorporate their feedback and needs. Additionally, surveys are sent out to clients and focus groups are held with the community to understand any changing of needs and priorities. Ongoing feedback of PWH and stakeholders is accomplished by broadly advertising public meetings, allowing public access to all draft, and completed reference documents through online postings, and encouraging participation by members and guests at all meetings. Following completion, the IPC Plan will be presented to the groups who contributed to ensure ongoing community engagement. With greater representation comes additional perspectives that are pivotal to evaluating and improving all planning processes, including the IPC Plan.

Florida’s new IPC Plan for 2022–2026 was built upon the foundational goals, strategies, and activities from the Florida Statewide Integrated HIV Prevention and Care Plan, 2017–2021, Florida’s Unified Ending the HIV Epidemic Plan, 2020, the National HIV/AIDS Strategy, and input from local planning bodies and community members.

3 Contributing Data Sets and Assessments

In analyzing contributing data sets and assessments used to describe how HIV impacts the jurisdiction, the subsequent sections will detail HIV prevention services, barriers to accessing those services, and gaps in the service delivery system:

- Epidemiological Snapshot (Section 3.1)
- Data Sharing and Use (Section 3.2)
- HIV Prevention, Care and Treatment Resource Inventory (Section 3.3)
- Gaps, Needs and Barriers (Section 3.4)
- Needs Assessment including Methodology, Approach, Priorities, and Actions Taken (Section 3.5)

3.1 Epidemiologic Snapshot

The full Epidemiological Profile of HIV in Florida, 2017-2021 will be provided separately. Below is a brief snapshot of the key points.

According to the CDC, in 2020,⁴² Florida had the third highest number of HIV diagnoses and was the third highest for new HIV diagnosis rates per 100,000 population in the U.S., including the District of Columbia. In 2021, 4,708 persons received an HIV diagnosis in Florida, a 37% increase from the 3,441 HIV diagnoses in 2020; however, these data should be interpreted with caution due to impacts from the COVID-19 pandemic which impacted testing, access to care and surveillance activities. In 2021, 83% of those newly diagnosed were linked to HIV-related care in 30 days of diagnosis. There were 120,502 PWH, regardless of AIDS status, living in Florida through 2021 which represents only 86% of all the PWH in Florida. The remainder of whom are living with the disease but are unaware of their HIV status. Among the PWH, 73% were retained in care and 69% had a suppressed viral load at the end of the year. Twenty percent (20%) of PWH had no care in 2021.

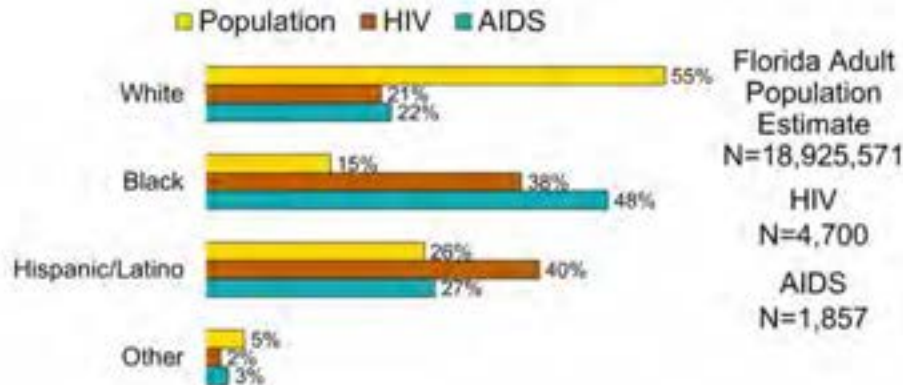
Geographical Region and Socio-Demographic Characteristics of Florida

Florida is a southern state that spans a geographic region of 53,624 square miles, comprises 67 counties and 283 cities, and has a mix of urban, suburban, and rural areas. The 2021 population in Florida was 22.0 million residents, with an average of 410 residents per square mile. Approximately 20% of the population is under the age of 18 and 21% is over the age of 65. According to the U.S. Census Bureau, in 2020, 12.4% of Floridians were living in poverty and 16% of Floridians under the age of 65 were without health insurance. The population of Florida is very diverse, with approximately 20.8% of persons residing in the state being foreign born (born outside the continental U.S.). Although most new HIV diagnoses in 2021 were among those born in the U.S. (58.1%), 41.9% of people newly diagnosed with HIV in Florida were born outside the U.S. mainland.

The racial distribution among the adult population (age 13 and above) in Florida in 2021, was 55% White, 15% Black, 26% Hispanic/Latino, and 5% other races including American Indian, Asian, or

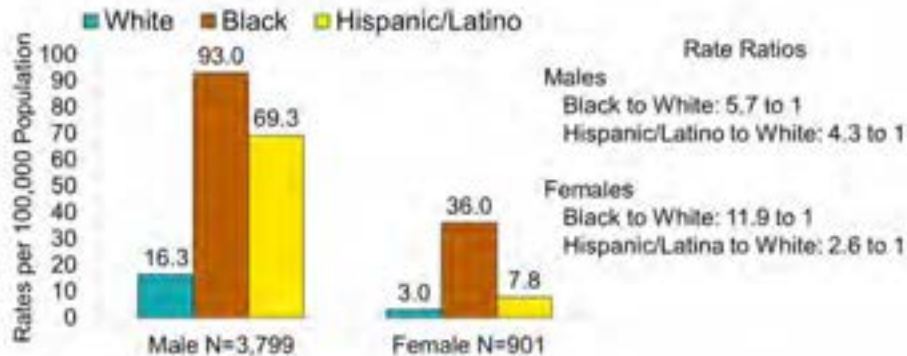
multiracial. There were 4,708 HIV diagnoses among adults in 2021. The greatest burden was among the Black population, which received 38% of the new HIV diagnoses in 2021 despite only representing 15% of the adult population in Florida. Hispanic/Latino people were also disproportionately represented for new HIV diagnoses, with 40% of the new HIV diagnoses, compared to 21% among White people as shown in Figure 7.

FIGURE 7: ADULT (AGE 13+) HIV AND AIDS DIAGNOSES AND POPULATION BY RACE/ETHNICITY, 2021, FLORIDA



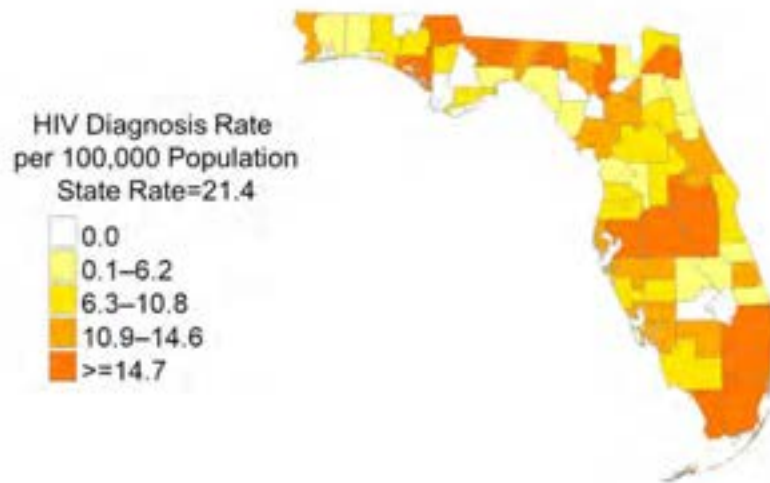
In 2021, Florida continued to see disparities in HIV diagnoses among adults, despite an annual decrease in the HIV diagnosis rate among Black persons in the past five years. The HIV diagnosis rate per 100,000 population among Black males (93.0) was nearly six times higher than for White males (16.3) and the rate for Hispanic/Latino males (69.3) was more than four times higher than for White males. The HIV diagnosis rate among Black females (36.0) was 12 times higher than for White females (3.0); the rate for Hispanic/Latina females (7.8) was more than two times higher than for White females (see Figure 8). Black persons had a lower statewide viral suppression (<200 copies/mL) rate of 64% compared to 77% for White persons and 71% for Hispanic/Latino persons.

FIGURE 8: ADULT (AGE 13+) HIV DIAGNOSIS RATES BY SEX AND RACE/ETHNICITY, 2021, FLORIDA



In 2021, there was at least one HIV diagnosis in all but 7 counties in Florida and the state HIV diagnosis rate was 21.4 per 100,000 population (see Figure 9). Miami-Dade (42.1), Broward (33.5), Orange (30.3), Duval (30.2), and Palm Beach (21.7) counties had rates higher than that for the state in 2021. The greatest numbers of HIV diagnoses were from the seven counties identified in the national EHE initiative: Miami-Dade (N=1,204), Broward (N=652), Orange (N=439), Hillsborough (N=323), Duval (N=300), Palm Beach (N=322) and Pinellas (N=130). These seven counties diagnosed a combined total of 3,370 cases in 2021, or 72% of the statewide total.

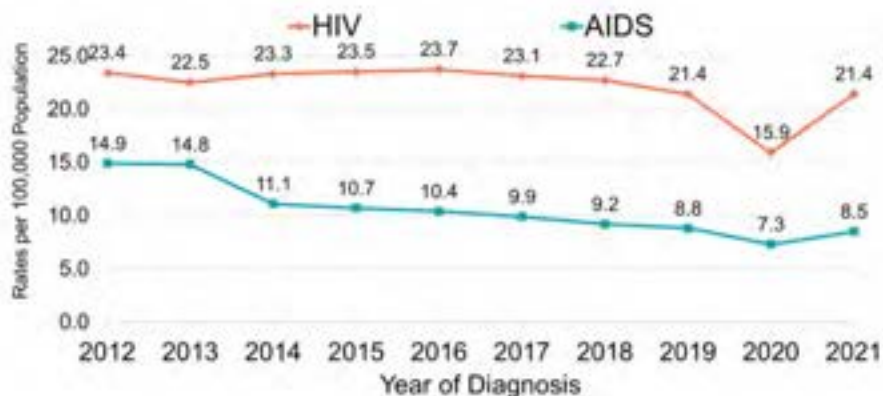
FIGURE 9: HIV DIAGNOSIS RATE BY COUNTY IN 2021, FLORIDA



Trends in HIV Diagnosis

Data for 2020 and 2021 should be interpreted with caution due to the impact of COVID-19 on HIV testing, care-related services, and case surveillance activities in state and local jurisdictions. Figure 10 shows that over the past 10 years (2012–2021), the rates of diagnosed HIV and AIDS in Florida have decreased 9% and 43%, respectively.

FIGURE 10: TEN-YEAR TREND (2012–2021) OF HIV AND AIDS RATES PER 100,000 POPULATION IN FLORIDA



The number of HIV diagnoses decreased by 4% from 2018 to 2019 and increased by 3% from 4,556 (2019) to 4,708 (2021). Additionally, the number of new HIV diagnoses increased by 6% among adult men and decreased by 6% among adult women from 2019 to 2021. The number of new HIV diagnoses over the past 5 years (2017–2021) decreased among all but two age groups: persons aged 30 to 39 (15% increase) and persons aged 40 to 49 (2% increase). The number of new HIV diagnoses over the past five years decreased among all race/ethnicity groups except Hispanic/Latino persons, where a 25% increase was observed.

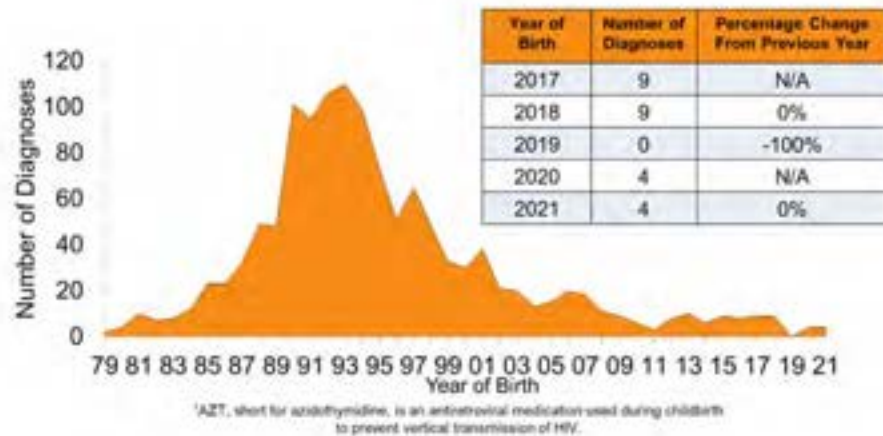
With respect to mode of exposure, male-to-male sexual contact continues to be the primary mode of exposure for HIV among males (77% in 2021), followed by heterosexual contact (18%) and injection drug use (IDU) (3%). Over the past five years (2017–2021), transmissions among males that observed an increase in HIV diagnoses were MMSC (1%) and IDU (28%), whereas transmissions that decreased were MMSC/IDU (12%) and heterosexual contact (1%).

Among females, heterosexual contact is the primary mode of exposure for HIV (92% in 2021), followed by IDU (8%). Over the past five years (2017–2021), decreases in HIV diagnoses among females were observed among both transmissions: heterosexual contact (11%) and IDU (13%).

Thirty-eight out of the 67 counties (57%) saw a decrease in new diagnoses of HIV from 2018 to 2019. Twenty-eight out of the 67 counties (42%) saw a decrease in new diagnoses of HIV from 2019 to 2021. All but two of the seven EHE counties in Florida saw a decrease in HIV diagnoses from 2019 to 2021 (Pinellas [32%], and Orange [5%]). Palm Beach County saw a 31% increase from 2019 (N=245) to 2021 (N=322), and Hillsborough County saw a 12% increase from 2019 (N=288) to 2021 (N=323). The three remaining EHE counties (Duval, Miami-Dade, and Broward) all saw a 3% increase from 2019 to 2021. Challenges exist with many new HIV diagnoses being among people who may be new to the county, state, or country and who may not have benefited from the robust prevention activities available throughout Florida; yet the new (or re-diagnoses) count toward new HIV diagnoses for local jurisdictions and the state.

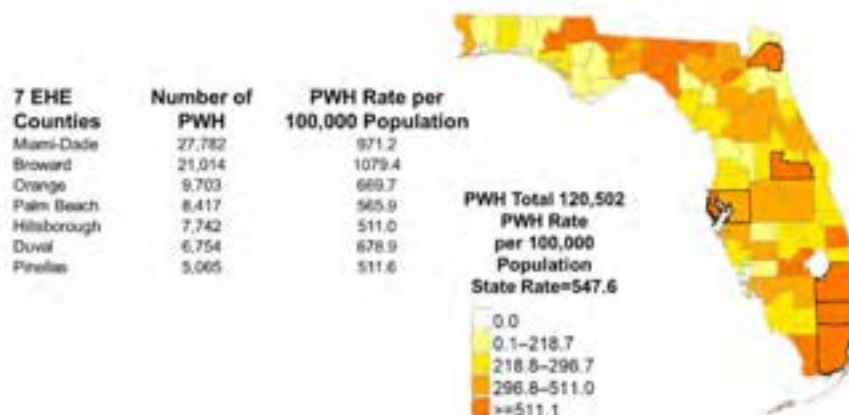
Perinatal HIV Transmission

A strategic long-term goal in Florida is to reduce or eliminate the annual number of babies born in Florida with perinatally acquired HIV. Since the introduction of azidothymidine (AZT) in 1994, perinatally acquired HIV diagnoses have drastically declined (see Figure 11). Over the past three years (2019 to 2021), there were eight perinatally acquired HIV diagnoses with an average transmission rate of 0.006. For the first time in the history of the HIV epidemic, there were no perinatally acquired HIV diagnoses born in Florida in 2019. There were four in 2020, and four in 2021.

FIGURE 11: PERINATALLY ACQUIRED HIV DIAGNOSES, 1979–2021, BABIES BORN IN FLORIDA

Prevalence of PWH in Florida

The rate of PWH in Florida in 2021 was 547.6 per 100,000 population, with the majority of PWH living in the large metropolitan areas and the seven counties outlined in the EHE plan. However, there is also a high rate of PWH living in smaller, more rural counties, such as those in northern Florida (see Figure 12). There were 120,502 PWH living in Florida in 2021. Among the adult PWH (N=120,379), 44% were Black, 28% were White, 26% were Hispanic/Latino, and 2% were American Indian, Asian, or multiracial. More than one-half (57%) were over the age of 50. MMSC was the mode of exposure for 71% of males. Heterosexual contact was the mode of exposure for 86% of females. Ten percent (10%) of PWH had a history of IDU. Among the PWH in 2021, 503 (0.4%) were transgender individuals and the primary mode of transmission was sexual contact (90%).

FIGURE 12: PWH, LIVING IN FLORIDA, BY COUNTY OF RESIDENCE, YEAR-END 2021

Late HIV Diagnosis and Resident Deaths Due to HIV/AIDS

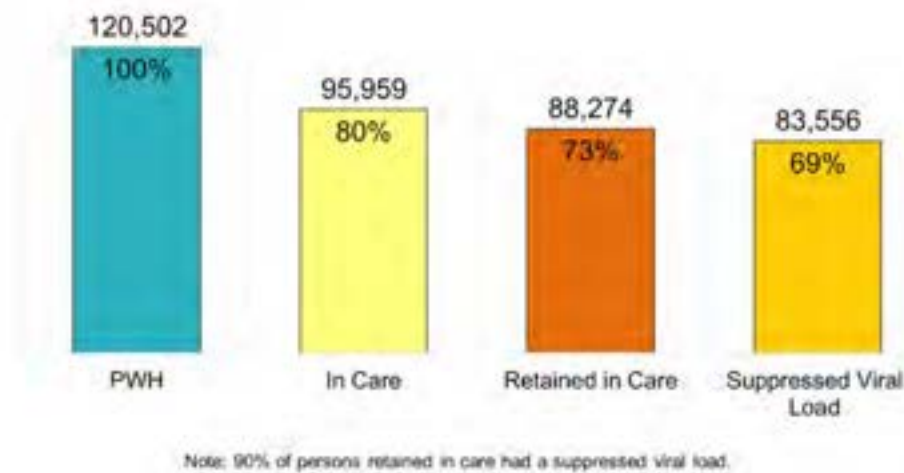
HIV/AIDS-related deaths in Florida decreased markedly (30%) from 1995 (N=4,004) to 1996 (N=2,796) after the advent of highly active antiretroviral therapy (HAART) in 1996. Furthermore, HIV-related deaths in Florida from 2012 to 2021 decreased 34% over the past 10 years, 16% over the past five years, and 7% in the past year from 659 in 2020 to 612 in 2021. The Black community has been disproportionately affected by HIV in Florida since the epidemic began in 1981 and despite a large decrease in the rate of HIV-related deaths among Black persons (43% since 2012), HIV disparities still exist among Florida's Black population. In 2021, rates of HIV-related deaths were five times higher for Black males (11.9 per 100,000 population) compared to White males (2.6 per 100,000 population) and nearly 11 times higher for Black females (7.5 per 100,000 population) compared to White females (0.7 per 100,000 population) with HIV.

Of the 4,708 HIV diagnoses in 2021, 19% (N=895) were late diagnoses, which are defined as persons receiving an AIDS diagnosis within 90 days of their confirmed HIV diagnosis. By race/ethnicity, 20% of Black persons, 21% of White persons, and 16% of Hispanic/Latino persons were late diagnoses. Among adults (age 13+), the two groups with the highest proportion of late diagnoses by age and mode of exposure were persons aged 50 and over (29%) and males with a history of IDU (29%), respectively.

HIV Care Continuum

The HIV Care Continuum is a diagnosis-based model that reflects the series of stages from initial diagnosis to being retained in care and achieving viral suppression. The HIV Care Continuum has four main stages: HIV diagnosis, linkage to care, retention in care, and viral suppression. It demonstrates the proportion of individuals diagnosed and living with HIV who are engaged at each stage. This model is used by federal, state, and local agencies to identify issues and opportunities related to improving the delivery of services to PWH across the entire continuum.

In 2021, despite the COVID-19 pandemic, of the 120,502 PWH in Florida, 80% (N=95,959) were reported to be in care (received at least one documented VL (viral load) or CD4 lab, medical visit, or HIV-related prescription in 2021), 73% (N=88,274) were retained in care (had HIV-related care two or more times at least three months apart), and 69% (N=83,556) were virally suppressed. As Figure 13 shows, of the persons retained in care, 90% had a suppressed viral load (<200 copies/mL). Twenty percent (20%) (N=24,543) did not receive any HIV-related care in 2021.

FIGURE 13: PWH LIVING IN FLORIDA ALONG THE HIV CARE CONTINUUM, YEAR-END 2021

The seven EHE counties make up approximately 11% of the total national HIV burden as outlined in the EHE plan and represent 72% of the total persons living with an HIV diagnosis in Florida.

Five of the EHE counties, Pinellas (77%), Hillsborough (71%), Orange (72%), Broward (70%) and Duval (69%) had a viral suppression rate equivalent to or greater than the state rate of 69%, while Palm Beach (65%) and Miami-Dade (63%) had lower viral suppression rates than the state at the end of 2021. It's important to note that PWH who receive services from the RWHAP and ADAP tend to have better results of viral suppression. For example, although Miami's overall viral suppression rate was 63%, approximately 82% of the 8,418 clients served by Miami's RWHAP Part A and Minority AIDS Initiative (MAI) program in fiscal year 2021 were virally suppressed.

The five populations ranked lowest in the percentage of suppressed VL (<200 copies/ml) in 2021, in descending order, were as follows:

1. Male PWID (58%)
2. Black Males with Heterosexual Contact (59%)
3. Black Males with MMSC (65%)
4. Persons 25–39 years of age (66%)
5. Persons 13–24 years of age (67%)

When compared with the HIV Care Continuum for Florida, the above five populations demonstrated disparities, particularly in the last stage, suppressed VL (<200 copies/ml). In 2021, 69% of PWH in Florida had a suppressed viral load. The five populations of concern in this section show suppressed VL percentages below 69%. This is significant to note in observing the ultimate health outcome of treatment adherence and an individual living with HIV leading a healthier life.

HIV-Related Co-Morbidities

STIs and hepatitis B virus (HBV) and (HCV have been steadily increasing in Florida over the past five years, including a 4% increase in chlamydia, a 40% increase in gonorrhea, and an 88% increase in early syphilis. Co-infection of PWH with STIs also increased during this same time period, with an increase of 67% for HIV/gonorrhea, 72% for HIV/chlamydia, and 76% for HIV/early syphilis. In 2021, there were 302 adults who were also co-infected with HBV, 86% of whom were male; 59% of the males reported MMSC exposure, and 30% of females reported IDU exposure. There were 537 PWH who were coinfecting with HCV in 2021, the majority of whom were males (82%) with MMSC (66%), IDU (13%), or heterosexual (11%) exposure. Forty-eight percent (48%) of female PWH with a co-occurring HCV diagnosis had IDU exposure. An increase in routine screening of all STIs, HIV, and hepatitis is needed to capture and prevent disease burden.

HIV Transmission Clusters and Networks

One aspect of the Florida IPC and the Florida EHE plans is to detect and respond to rapidly growing HIV transmission clusters and networks and prevent future HIV diagnoses using data and laboratory results collected through routine public health surveillance. Transmission cluster network analyses are conducted using data from point-of-care HIV-1 genotypic resistance testing to identify genetic (molecular) links of similar virus strains by comparing those with similar HIV genetic sequences. Those data are then used to identify networks of recent and rapid transmission for prevention and linkage-to-care interventions. The observed HIV transmission rate in molecular clusters identified across the U.S. is, on average, 11 times higher than the transmission rate in the general HIV population, thus indicating the importance of quickly using proven interventions to stop further transmission of HIV. HIV molecular clusters are considered rapidly growing when there have been five or more new HIV diagnoses in the previous 12 months. The Department is actively conducting surveillance and investigation for HIV clusters. The Department routinely conducts monthly analysis to detect rapidly growing molecular clusters and time-space clusters of public health significance. Additionally, a state level HIV cluster review committee is convened monthly to review cluster data, discuss challenges, and brainstorm strategies to improve the statewide response. Since fall 2021, the Department's Bureau of Communicable Diseases has established routine communication with CHDs experiencing clusters to coordinate and guide local responses to investigate and respond to clusters. Florida's updated HIV Cluster Detection and Response plan was submitted to CDC in fall 2021 and will be updated in 2023.

Since the beginning of the Department's HIV transmission cluster detection program in November 2017, the HIV/AIDS Section has identified 64 clusters at a 0.5% genetic distance between strain of HIV demonstrating rapid growth. These molecularly linked transmissions comprise a total of 772 persons receiving an HIV diagnosis in Florida with a much larger, often underdefined transmission and risk network. Though members of molecular clusters live across the state, 554 (72%) have a current residence in one of the seven EHE counties. The state has also taken a collaborative approach to responding to other outbreaks that impact the care and treatment of PWH (e.g., COVID-19, Mpox, hepatitis A, and meningococcal disease), providing trainings, developing messaging, and promoting health resources and services.

3.2 Data Sharing and Use

De-identified HIV, viral hepatitis, STD, and TB data are routinely shared via ad-hoc requests to surveillance programs with outside entities including, but not limited to, academic institutions, community partners, RWHAP parts, internal agency partners and collaborators, and the public. Each of these programs provide annual data which are uploaded into FLHealth CHARTS (Florida Community Health Assessment and Resource Tool Set) (<https://www.flhealthcharts.gov/charts/CommunicableDiseases/default.aspx>). In addition, the Department is updating the FLHealth CHARTS website (a web-based platform that provides easy access to health indicator data at the community and statewide level for the state of Florida from a multitude of sources) with a new dashboard (at the county level) that will incorporate a multitude of HIV/AIDS indicators including but not limited to, demographic and socio-economic indicators, partner services data, testing and treatment facilities, PrEP, and other data not previously included on FL Health CHARTS.

By ensuring all these data and information are made readily accessible and user-friendly, the new dashboard will help local and state planning bodies develop more effective and efficient programs and corresponding activities and monitor progress of IPC strategies and activities. All data are protected securely and confidentially, adhering to the Department's internal policies and strictly adhering to CDC's, *National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Data Security and Confidentiality Guidelines*.

Summarized ad-hoc data requests are honored based on the ability of the program to generate the requested data within the time constraints of the request. Data requests for ZIP code data will receive suppressed data (data by ZIP code with three or more cases) based on internal Department ZIP code suppression rules.

Epidemiologic Data

Summarized annual data are uploaded to the Department's HIV/AIDS Section web page (<http://floridaaids.org>) and are also available on a SharePoint site for internal use at the state and CHD level. Annual data releases include a comprehensive epidemiological profile for the state and for each partnership area, a state slide set presented annually to FCPN, and other annual data products. The epidemiological profiles are an expanded Excel workbook with multiple tabs containing 5-year trend analyses of HIV (demographics, diagnosis, AIDS, deaths, and continuum of care), STIs, HBV, HCV, and TB.

Factsheet and Slide Sets to Support Stakeholder Engagement and Planning

Various factsheets are generated to portray epidemiology and disease highlights for a demographic population. These fact sheets address various HIV/AIDS awareness day topics as well as highlight summary data for high-risk population groups. These fact sheets are updated annually, shared with community stakeholders, and uploaded to the Department's external web and internal SharePoint sites. Integrated slide sets and epidemiological profile tables are generated to support stakeholder engagement and planning. The Department's HIV/AIDS Section has generated comprehensive slides sets

and epidemiologic profiles specifically for each of the 14 partnership areas each year since the 1990s. These slide sets and profiles are shared with the RWHAP Part A entities, community stakeholders, field surveillance staff, and others who may request these data. These data are frequently used as tools for program planning and evaluation.

Other Data Sources

Along with HIV data, the Department summarizes data from MMP and CDC's National HIV Behavioral Surveillance (NHBS) surveillance project, along with Department PrEP, Test and Treat, and HIV counseling and testing data. Data from the needs assessments are also shared in reports sent out to FCPN membership. Other data sources include the RWHAP Eligibility Portal, CAREWare, and Provide Enterprise (an online care management system).

Data Sharing Agreements

For persons requesting de-identified data in a database format that can be analyzed for public health research purposes, the researcher must first submit a concept proposal with research aims, benefit to public health, and required data variables and time frame for the requested data. An internal Department research committee reviews the feasibility of the project, including for potential human subjects impacts and ethical considerations. Once approved, the requestor must complete a Data Use Agreement (DUA) and obtain a study approval or study exemption letter from the Department's Institutional Review Board. Once received, the DUA is routed for legal review and signatures. Data are provided via secure FTP format and can only be housed on secure servers as part of the DUA.

Any program outside of the Department that is approved to receive HIV data through a Data Sharing Agreement (DSA) for the purpose of linking or re-engaging HIV clients into care must be in full compliance with the NCHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD, and TB Programs, Department security and confidentiality policies, Health Insurance Portability and Accountability Act (HIPAA) guidelines and have documented active-client consent to share. Data sharing with programs outside the Department requires approval of the overall responsible party, HIV/AIDS Section administrator and legal counsel. A memorandum of understanding or DSA must be completed between the Department and the program requesting data. The HIV Surveillance Program will provide only the minimum data required to conduct linkage and reengage to HIV care and services.

In partnership with the six RWHAP Part A programs located in the seven EHE counties and through funding received by Georgetown University, the Department has developed and is preparing to implement a data sharing and Data to Care (D2C) effort to improve linkage to HIV care for persons out of care in those jurisdictions.

Some challenges exist with data sharing; for example, the Department's data sharing agreement with the Florida Agency for Health Care Administration (AHCA) for Medicaid does not allow the Department to share data on Medicaid enrollments of the same clients receiving services in and from the RWHAP

Part A jurisdictions. This leads to duplicative and sometimes costly efforts for the RWHAP Part A programs to run Medicaid verification checks on the clients for eligibility assessments.

3.3 HIV Prevention, Care, and Treatment Resource Inventory

To ensure that the state is meeting the goals and objectives set forth to best address the needs of PWHs, Florida must prioritize the financial resources and assess the capacity to provide the services outlined. The following section provides a comprehensive HIV financial resources inventory for Florida. Components include, but are not limited to, statewide public and private funding sources for HIV prevention, care, and treatment services; the dollar amount and the percentage of the total available funds for each funding source; program or service delivery; and what step of Florida's HIV Care Continuum is impacted.

Resource inventories have been provided by all 14 HIV partnership areas in the state of Florida. Each partnership area provided separate inventories for prevention and patient care, which can be found in Appendix Section 9.3 Partnership Area Resource Inventories. Table 5 represents Florida-specific funding from various sources for HIV-related services statewide, where available, for FY 2021.

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TABLE 5: FUNDING RESOURCE INVENTORY

Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted¹
HRSA RWHAP Part A (EMA/TGA)²	\$76,146,512	12.67%		
Fort Lauderdale	\$15,724,848		Medical case management (including treatment adherence), oral health care, EIS, mental health services, substance abuse treatment (outpatient), case management (nonmedical), food bank/home-delivered meals, health education/risk reduction, housing services, legal services, medical transportation services, psychosocial support services	2,3,4,5
Jacksonville	\$5,886,669			
Miami	\$26,432,895			
Orlando	\$10,445,207			
Tampa	\$10,352,255			
West Palm Beach	\$7,304,638			
HRSA EHE–RWHAP Part A Jurisdictions²	\$10,780,783	1.79%		
Fort Lauderdale	\$2,075,933		Linkage services for PWH who are either newly diagnosed or are diagnosed but currently not in care, to essential HIV care and treatment and support services.	2,3,4,5
Jacksonville	\$1,086,820			
Miami	\$2,887,384			
Orlando	\$1,667,000			
Tampa	\$1,667,000			
West Palm Beach	\$1,396,646			
HRSA RWHAP Part B³	\$282,240,453	46.96%		
Base	\$30,031,995		Medical case management services (including treatment adherence), case management (non-medical), food bank/home-delivered meals, health education/risk reduction, psychosocial support services, quality management, and evaluation	2,3,4,5
MAI	\$1,253,307			
ADAP Earmark	\$84,839,389			
ADAP Rebates	\$165,647,438			
Emerging Communities	\$468,324			
HRSA RWHAP Part B³ – Supplemental	\$2,888,725	0.48%	ADAP medications	3,4,5
HRSA RWHAP Part B³ – ERF	\$5,211,950	0.87%	ADAP medications	3,4,5

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
HRSA RWHAP Part C -Early Intervention	\$10,668,448	1.78%		
Borinquen Health Care Center, Inc. (Miami)	\$699,183		EIS (management and administration EIS), core medical services, support services, quality management and administration.	1,2,3,4,5
Empower U (Miami)	\$679,903			
University of Miami (Miami)	\$933,332			
Charlotte De Soto County Health Department (Arcadia)	\$273,835			
Collier Health Services (Immokalee)	\$468,290			
Duval County Health Department (Jacksonville)	\$300,912			
Hendry County Health Department (Labelle)	\$317,459			
Manatee County Rural Health Services, Inc. (Palmetto)	\$499,050			
Monroe County Health Department (Key West)	\$521,839			
Neighborhood Medical Center, Inc. (Tallahassee)	\$545,577			
North Broward Hospital District (Fort Lauderdale)	\$875,925			
Okaloosa County Health Department (Fort Walton Beach)	\$306,167			
Orange County Health Department (Orlando)	\$1,072,229			
Pancare of Florida, Inc. (Panama City)	\$300,000			
Polk County Health Department (Bartow)	\$546,633			
St. Johns County Health Department (St. Augustine)	\$357,926			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
The McGregor Clinic, Inc. (Fort Myers)	\$339,544			
Unconditional Love, Inc. (Melbourne)	\$346,828			
University of Florida (Gainesville)	\$350,484			
HRSA RWHAP Part D	\$7,593,769	1.26%		
Bond Community Health Center, Inc. (Tallahassee)	\$493,499		Medical services, clinical quality management, support services, and administration.	1,2,3,4,5
Children's Diagnostic & Treatment Center, Inc. (Fort Lauderdale)	\$2,016,919			
Florida Department of Health (Tallahassee)	\$829,678			
University of Florida (Gainesville)	\$729,616			
University of Miami (Miami)	\$2,058,949			
University of South Florida (Tampa)	\$1,465,108			
HRSA RWHAP Part F				
NOVA Southeastern University, Inc. (Fort Lauderdale)	\$219,230	0.04%	Assistance for accredited dental schools, post-doctoral dental programs, and dental hygiene education programs for uncompensated costs incurred in providing oral health treatment to patients with HIV infection.	3
CDC Integrated Prevention and Surveillance	\$38,756,445	6.45%		
Florida Department of Health in Tallahassee (State Health Office)	\$30,671,550		Core prevention and surveillance programs including HIV testing and linkage to care; comprehensive prevention services for HIV-positive individuals; condom distribution; policy initiatives; interventions for at-risk populations; social marketing, media, and mobilization; HIV prevention planning; PrEP and PEP initiatives; capacity-building and technical assistance; program planning, monitoring, and evaluation; and quality assurance.	1,2,3,4,5
The Department's Statewide total distribution (counties)	\$8,084,895			
CDC Ending the HIV Epidemic (EHE)	\$11,280,419	1.88%		
State Health Office	\$2,613,537			1,2,3,4,5

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Broward	\$1,949,187		Prevention and surveillance programs which complement existing work under the state's HIV prevention and surveillance cooperative agreement (CDC-PS18-1802) and use innovative strategies addressing ending the HIV epidemic.	
Duval	\$615,372			
Hillsborough	\$674,419			
Miami-Dade	\$2,624,940			
Orange	\$880,968			
Palm Beach	\$794,010			
Pinellas	\$457,986			
CDC Medical Monitoring Project	\$861,929	0.14%	Population-based project which provides information about the behaviors, clinical outcomes, quality of care, and barriers to care and viral suppression among people with diagnosed HIV.	4,5
CDC National HIV Behavioral Surveillance (NHBS)	\$433,710	0.07%	National HIV Behavioral Surveillance Study (Miami)	1,2
CDC Integrated Hepatitis Surveillance Prevention	\$774,500	0.13%	Improve hepatitis surveillance data collection systems to systematically collect, analyze, interpret, and disseminate data. Increase hepatitis testing and vaccination for high-risk populations.	1,2
CDC STD Grants	\$35,813,552	5.96%		
Strengthening STD Prevention and Control for Health Departments (STD PCHD)	\$5,696,617		Surveillance, investigation and intervention for syphilis, gonorrhea, chlamydia, and HIV. Limited clinical support.	1,2,3
DIS Workforce Development Supplement	\$29,068,863		Expanding public health workforce capacity to respond to infectious disease outbreaks.	1,2,3,4
STD Surveillance Network (SsuN)	\$340,000		Enhanced surveillance of gonorrhea via extended patient and provider interviews.	1,2
Epidemiology and Laboratory Capacity (ELC)	\$633,071		Routine syphilis screening at non-traditional venues (hospital emergency department and syringe services program) to reduce congenital syphilis rates.	1,2
Childbearing Capacity in Jails (NACCHO)	\$75,000		Routine syphilis screening for women of child-bearing age to reduce congenital syphilis rates.	1,2
State General Revenue	\$42,210,855	7.02%		

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
State Health Office	\$22,748,209		HIV prevention and care staff, services, and supplies.	1,2,3,4,5
County Health Departments ⁴	\$12,427,076			
Pharmacy	\$7,035,570		HIV prevention and treatment medications	4
State Line-Item Appropriations	\$1,739,000	0.29%		
UM Center for AIDS Research	\$1,000,000		HIV cure research.	
TOPWA	\$500,000		Perinatal HIV prevention services.	1,2,3,4,5
Hispanic & Haitian Outreach	\$239,000		HIV outreach and education to Hispanic and Haitian communities.	1,2
HOWPA (HUD)-State				
The Department Statewide	\$8,364,929	1.39%	Housing assistance and related support services for low-income persons with HIV/AIDS and their families.	3,4,5
HOWPA (HUD)-Direct Funding to Cities	\$34,257,931	5.70%		
Fort Lauderdale	\$7,088,032		Housing assistance and related support services for low-income persons with HIV/AIDS and their families.	3,4,5
Jacksonville	\$2,601,336			
Miami	\$11,924,914			
Orlando	\$4,586,699			
Tampa	\$4,378,068			
West Palm Beach	\$3,202,608			
Key West (competitive)	\$476,274			
DIRECTLY-FUNDED ORGANIZATIONS				
CDC Directly-Funded HIV Service Providers				
CDC-PS21-2102 ⁵	\$4,857,875	0.81%	Comprehensive high-impact HIV prevention programs for community-based organizations	1,2,3,4,5
AIDS Service Association of Pinellas, Inc. dba EPIC (Clearwater)				
BASIC NWFL, INC. (Panama City)				
Borinquen Health Care Center, Inc. (Miami)				
Care Resource Community Health Centers, Inc. (Miami)				

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
FoundCare Inc. (West Palm Beach)				
Health Care Center for the Homeless, Inc. dba Orange Blossom Family Health (Orlando)				
Hope and Help Center of Central Florida, Inc. (Winter Park)				
Latinos Salud, Inc. (Wilton Manors)				
Metropolitan Charities dba METRO Inclusive Health (St. Petersburg)				
Treasure Coast Health Council, Inc dba Health Council of Southeast Florida (Palm Beach Gardens)				
Village South, Inc. (Pembroke Pines)				
CDC-PS17-1704	\$1,063,791	0.18%	Comprehensive high-impact HIV prevention programs for young MSM and transgender individuals of color.	1,2,3,4,5
Care Resource Community Health (Miami)	\$354,597			
Jacksonville Area Sexual Minority Youth Network (JASMYN) (Jacksonville)	\$354, 597			
Latinos Salud (Miami Beach)	\$354, 597			
CDC Division of Adolescent School Health (DASH), CDC-PS-18-1807 ⁶	\$2,100,000	0.35%	Promoting adolescent health through school-based HIV prevention through HHS, CDC, NCHHSTP.	1
Broward County				
Duval County				
Hillsborough County				
Orange County				
Pasco County				
Palm Beach County				
HRSA Directly-Funded HIV Service Providers				

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
HRSA EHE Primary Care HIV Prevention	\$6,361,483	1.06%	Funding provided to health centers to expand access to medication to prevent HIV (including PrEP and related services), connect people to care, and ensure care services are well coordinated.	1,2,3,4,5
Agape Community Health Center, Inc. (Jacksonville)	\$254,811			
Borinquen Health Care Center, Inc. (Miami)	\$284,779			
Broward Community and Family Health Centers, Inc. (Hollywood)	\$266,341			
Care Resource Community Health Centers Inc. (Miami)	\$269,322			
Citrus Health Network, Inc. (Hialeah)	\$270,825			
Community Health Centers of Pinellas, Inc. (St. Petersburg)	\$286,640			
Community Health South Florida, Inc. (Miami)	\$300,697			
Empower U, Inc. (Miami)	\$253,689			
Florida Community Health Centers, Inc. (West Palm Beach)	\$276,697			
FoundCare Inc. (West Palm Beach)	\$268,470			
Health Care Center for the Homeless, Inc. (Orlando)	\$263,810			
I.M. Sulzbacher Center for the Homeless, Inc. (Jacksonville)	\$254,995			
Jessie Trice Community Health System, Inc. (Miami)	\$284,758			
Miami Beach Community Health Center, Inc. (Miami)	\$308,991			
North Broward Hospital District (Fort Lauderdale)	\$251,614			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Pinellas, County of (Clearwater)	\$162,412			
Tampa Family Health Centers, Inc. (Tampa)	\$305,605			
Banyan Community Health Center (Miami, FL)	\$343,379			
Central Florida Family Health Center (Sanford, FL)	\$361,799			
Community Health Centers (Winter Garden, FL)	\$373,076			
Genesis Community Health (Boynton Beach, FL)	\$340,385			
Suncoast Community Health (Ruskin, FL)	\$378,388			
Substance Abuse and Mental Health Services Administration (SAMHSA) FUNDING				
Florida Department of Children and Families (FDCF)				
Substance Abuse Prevention and Treatment Block Grant, HIV Early Intervention Services Set Aside	\$ 5,569,266	0.93%	Funding for HIV testing in substance use disorder treatment facilities.	1,2,3
SAMHSA-Directly Funded Organizations	\$9,814,811	1.63%		
Broward House, Inc. (Fort Lauderdale)	\$485,000		Minority AIDS Initiative-service Integration	1,2,3,4
FoundCare Inc. (West Palm Beach)	\$445,987		Minority AIDS Initiative-service Integration	
Guidance/Care Center, Inc. (Key West)	\$479,325		Minority AIDS Initiative-service Integration	
Banyan Community Health Center, Inc. (Miami)	\$257,354		Capacity Building Initiative (CBI-HIV) for substance abuse and HIV prevention services for at-risk racial/ethnic minority youth and young adults.	1,2,3,4
BASIC NWFL, Inc. (Panama City)	\$255,000		CBI-HIV	
Bethel Family Enrichment Center, Inc. (Miami Gardens)	\$257,166		CBI-HIV	

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Gang Alternatives, Inc. (Miami)	\$257,245		CBI-HIV	
26 Health, Inc. (Orlando)	\$199,774		Substance Abuse (SA) and HIV Prevention Navigator Program	1,2,3,4
Aspire Health Partners, Inc. (Orlando)	\$200,000		SA and HIV Prevention Navigator Program	
Borinquen Health Care Center, Inc. (Miami)	\$200,000		SA and HIV Prevention Navigator Program	
Community Rehabilitation Center, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Orange County (Orlando)	\$200,000		SA and HIV Prevention Navigator Program	
Gang Alternatives, Inc. (Miami)	\$199,996		SA and HIV Prevention Navigator Program	
New Breed Creation Life Center, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Pridelines Youth Services, Inc. (Miami)	\$200,000		SA and HIV Prevention Navigator Program	
River Region Human Services, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Aspire Health Partners, Inc. (Orlando)	\$525,000		Targeted Capacity Expansion (TCE-HIV) HIV Program: substance use disorder treatment for racial/ethnic minority populations at high risk for HIV/AIDS	1,2,3,4
Bethel Family Enrichment Center, Inc. (Miami Gardens)	\$461,175		TCE-HIV	
Borinquen Health Care Center, Inc. (Miami)	\$525,000		TCE-HIV	
Broward House, Inc. (Fort Lauderdale)	\$520,693		TCE-HIV	
Community Rehabilitation Center, Inc. (Jacksonville)	\$425,000		TCE-HIV	
Gateway Community Services, Inc. (Jacksonville)	\$525,000		TCE-HIV	
Guidance/Care Center, Inc. (Key West)	\$499,179		TCE-HIV	
Health Care Center for the Homeless, Inc. (Orlando)	\$525,000		TCE-HIV	
Lakeview Center, Inc. (Pensacola)	\$521,965		TCE-HIV	

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Metropolitan Charities, Inc. (dba Metro Inclusive Health) (St. Petersburg)	\$525,000		TCE-HIV	
The Village South, Inc. (Miami)	\$524,952		TCE-HIV	
Veteran's Affairs⁷	—		Funding to support services for Florida veterans	1,2,3,4,5
Medicaid-funded HIV Services⁷	—		Funding to support PWH medical services	1,2,3,4,5
Indian Health Service		0.16%	Funding to support services for Florida's federally-recognized tribes and tribal organizations	1,2,3,4,5
Seminole Tribe of Florida (HHS Substance Abuse and Mental Health Services Projects of Regional and National Significance)	\$402,265		Funding to support services for tribal opioid response.	
Seminole Tribe of Florida (HHS, CDC Funds for Public Health Response, COVID-19)	\$311,730		Funding to support tribal response to public health or health care crises (COVID-19 response funds).	
Miccosukee Tribe of Indians of Florida (HHS, CDC Funds for Public Health Response, COVID-19)	\$259,456		Funding to support tribal response to public health or health care crises (COVID-19 response funds).	
PRIVATE FOUNDATIONS⁸				
The Campbell Foundation	\$20,000	0.003%		
AH Monroe, Inc. (Key West)	\$2,000		HIV-related services	
Broward House, Inc. (Fort Lauderdale)	\$2,000			
Care Resource, Inc. (Miami, Fort Lauderdale)	\$2,000			
Children's Diagnostic & Treatment Center, Inc. (Fort Lauderdale)	\$2,000			
Compass, Inc. (West Palm Beach)	\$2,000			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Empath Health/EPIC, Inc. (St. Petersburg)	\$2,000			
Latinos Salud, Inc. (Wilton Manors, Miami)	\$2,000			
McGregor Clinic, (Fort Myers)	\$2,000			
Poverello, Inc. (Wilton Manors)	\$2,000			
SunServe, Inc. (Wilton Manors)	\$2,000			
TOTAL	\$601,003,817			

¹ HIV Care Continuum: 1 = HIV Testing and Diagnosis: Staff, services and systems that help to identify and test persons who are unaware of their HIV status; 2 = Linkage to Care: Staff, services, and systems that help connect newly diagnosed PWHA to care; 3 = Retention in Care: Staff, services, and systems that help PWH remain engaged in care and treatment services; 4 = Provision of ART: Staff, services, and systems that help PWH access and remain adherent to antiretroviral medication; 5 = Viral Suppression: Staff, services and systems that help PWH achieve and maintain viral suppression.

² RWHAP Part A figures represent FY2021 funding amounts.

³ The State Health Office is the recipient of HRSA RWHAP Part B funds.

⁴ State General Revenue to County Health Departments includes 4B000, 4BNWK, and 4BAPS.

⁵ CDC-PS21-2102: Unable to obtain exact funding amounts. Average funding award for each provider was approx. \$441,625.

⁶ CDC-PS18-1807: Unable to obtain exact funding amounts. Average funding awards approx. \$350,000.

⁷ Unable to obtain Florida-specific funding levels.

⁸ Additional private foundation awards exist; however, recipients and award amounts are unknown.

Other sources of funding include funds from the state of Florida general revenue, Housing Opportunities for Persons with AIDS (HOPWA), U.S. Department of Housing and Urban Development (HUD), RWHAP all parts, CDC Integrated HIV Prevention and Surveillance, CDC MMP, CDC NHBS, CDC and HRSA EHE funds, SAMHSA, tribal organization funding, and private foundation funding, where available. More work is needed to identify Florida-specific funds related to HIV services from the Veteran’s Administration (VA) and Medicaid.

The Florida HIV Care Continuum Dashboard Tool was developed as a mechanism to gather information related to how funds are distributed statewide and RWHAP services are delivered by geographic area. The purpose and goal of the tool was to provide a snapshot of HIV prevention and patient care funding and assess HIV prevention and patient care activities across the care continuum by each of the 14 HIV partnership areas.

The tool provides a listing of resources in CHDs and local communities, as well as illustrating gaps and unmet needs by contrasting regional differences and highlighting areas of need. The information in the Florida HIV Care Continuum Dashboard Combined Tool was self-reported by each local area; therefore, slight differences may appear in terms of funding or data reported. Additionally, specific caveats may apply since they may have alternate funding streams coming into their local areas or enhanced best practices or collaborative efforts which result in increased funding as reported by the state.

The purpose of this inventory is to provide a snapshot of HIV prevention and patient care funding by area. The goal of this inventory is to help assess HIV prevention and patient care activities across the continuum of care by area. The inventory provides a snapshot of resources in CHDs and communities. Individual area resource inventories can be found in Appendix Section 9.3 Partnership Area Resource Inventories.

3.4 Gaps, Needs and Barriers

Through the development of Florida’s Unified EHE Plan and through local community engagement activities, additional gaps, needs, and barriers were identified which span across all pillars as described in Table 6:

TABLE 6: GAPS, NEEDS AND BARRIERS

Summary	Description
Meaningful Community Engagement with Priority Populations	The Department received feedback from community partners on the perceived effectiveness of current public health initiatives. Partners identified across all IPC pillars determined there is a need for increased and meaningful community engagement with all of Florida’s populations that are disproportionately affected by and living with HIV, including Black and Hispanic/Latino populations and the LGBTQ community. The Department recognizes that Florida’s racial/ethnic minority populations continue to increase in size and continues to address gaps in diverse community

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Summary	Description
	wellness throughout the state. Improvements in HIV outcomes over the last decade have had great strides. However, populations of racial and ethnic minorities should continue to be prioritized to improve prevention and care access. For Florida’s racial/ethnic minority populations, HIV outcomes should improve among all populations at the same rate – especially among Florida’s diverse population. While Florida has maintained the Business Responds to AIDS (BRTA) and Faith Responds to AIDS (FRTA) initiatives for over a decade, additional efforts are needed to involve faith-based and business leaders. Faith-based leaders, as trusted members of their communities, are well-poised to educate and mobilize Black and Hispanic populations around HIV/AIDS. Feedback indicates there would be a benefit for leaders of faith-based institutions to engage in HIV education and awareness. Challenges exist around maintaining community engagement with and representation from PWH who receive services directly through the RWHAP, both at state and local levels.
Geography and Transportation	Whereas there are major metropolitan areas in the state, 30 of Florida’s 67 counties (45%) are designated as rural per the 2010 U.S. Census.³⁹ Many Floridians live in areas that have both rural and urban characteristics, which makes addressing the needs of these communities challenging. Transportation is often a barrier for clients attempting to access HIV care services and can lead to missed appointments, decreased medication adherence, and disengagement from care.²⁰ County size and lack of affordable, safe, and timely transportation options are also factors contributing to barriers in accessing care. For example, in Miami-Dade County, some clients who live in far south Dade, and fear stigma of accessing HIV care closer to home, opt to ride hours on public transportation, often in inclement weather, to access services near downtown Miami.
Poverty and Education	In 2020, 13% of people living in Florida reported living below the federal poverty level.²⁰ Counties with the highest poverty rates included DeSoto, Hamilton, Hardee, Hendry, and Madison. In 2016–2020, 88.5% of people aged 25 years and older living in Florida had at least graduated from high school (compared to 89.4% for the U.S.).²⁰ Counties with the fewest individuals with at least a high school diploma included DeSoto, Glades, Hamilton, Hendry, and Lafayette. Counties with the lowest education levels were found in central and northern Florida.
Mental Health and Substance Use Disorders	Persons experiencing mental health and substance use disorders are at increased risk for HIV and frequently lack access to HIV and STI education, prevention, and care services.²² In 2020, nearly 18% (7,842) of the 44,577 reported drug overdose deaths in Florida involved opioids.²³ There was an approximate 28% increase in the number of persons treated for addiction with self-reported IDU between 2014 and 2018.²⁴ There was a 2% increase in HIV diagnoses from 2017–2021 among persons with an IDU-related mode of exposure.⁶ Over that same time period, acute HCV infections

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Summary	Description
	increased by 366% in Florida; injection drug use is the primary mode of exposure among persons diagnosed with acute HCV. Efforts are needed to ensure organizations providing behavioral health and substance use treatment services are providing education around HIV, STIs, and HCV and are knowledgeable about local testing and treatment resources. According to the FDCF, 2020 Florida Youth Substance Abuse Survey (FYSAS) State Report, substance use among students in Florida continues to decline. Among middle and high school students in Florida, between 2010 and 2020, the prevalence of lifetime alcohol use decreased from approximately 52% to 35% and the past-30-day prevalence of alcohol use decreased from 29% to 15%. Regarding marijuana use, the prevalence of lifetime and past 30-day marijuana use among middle and high school students also decreased between 2010 and 2020. According to estimates from the 2022 FYSAS among high schoolers, the lifetime prevalence is 2.8% for opioid misuse, 4.1% for stimulant misuse, and 5.7% for opioid and stimulant misuse.⁴⁵ Methadone- or buprenorphine-assisted maintenance treatment (including psychosocial support as needed and if desired) is the evidence-based standard of care used to treat opioid use disorders. According to an analysis of 25,866 Florida Medicaid enrollees diagnosed with opioid use disorders only about 28% go on to initiate medication-assisted treatment. About 56% of newly diagnosed individuals who began methadone treatment continued for 180 days, compared about 19% of newly diagnosed individuals who began treatment with buprenorphine.⁴⁶
Multicultural and Multilingual Issues	Florida population estimates for 2020 show racial/ethnic distributions as follows: 51.5% White (non-Hispanic), 14.5% Black (non-Hispanic), 3.0% Asian American, and 0.2% Native American. Hispanic/Latino persons make up over a quarter (26.5%) of the population. Florida ranks in the top five states with the highest Hispanic/Latino populations in the U.S. and has one of the largest Black/African American populations in the country. Florida's Asian population is growing, particularly in Gulf Coast locations. The state is home to two federally recognized American Indian tribes (the Seminole and the Miccosukee in South Florida) and many more non-federally recognized tribes, bands, and clans. The Miami metropolitan area (along with New York City) maintains one of the highest populations of Caribbean immigrants, with approximately 63% of Caribbean immigrants in the U.S. living in these two metro areas. Just over 20% of Florida's population is foreign-born and nearly 30% of households in Florida speak a language other than English.⁵ There is a lack of bilingual and multilingual health care providers and media and marketing messages in certain regions of the state.²⁵ Florida works to ensure programs and services for PWH and those at increased risk for acquiring HIV align with the National CLAS Standards and that translation services are made available to all clients receiving services at CHD clinics and through funded HIV prevention and care service providers.

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Summary	Description
Racism, Discrimination, and Medical Mistrust	Persons experiencing racism and discrimination are less likely to remain adherent to care and more likely to have poorer health outcomes.²⁶ Medical mistrust tends to be higher among Black and American Indian populations in Florida. The Tuskegee Study conducted by the U.S. Public Health Service left lasting impacts on the way Black persons view health care, particularly public health.²⁷ Similarly, studies have shown the sterilization of American Indian women by the Indian Health Service in the 1960s and 1970s created a culture of distrust of government-funded health care services.²⁸
In-Migration, Tourism, Seasonal, and Mobile Populations	Florida sees more than one-hundred million tourists each year, many of whom are drawn to popular beach towns and cities like Miami, Fort Lauderdale, and Key West.²⁹ Its many theme park attractions and over 8,400 miles of coastline make Florida a destination for tourists from around the world. According to VISIT FLORIDA's latest estimates, during Quarter 1 of 2022 (January–March), Florida saw a total of 36 million visitors. This represents a 14% increase from Q4 2021, and the third consecutive quarter that overall visitation has surpassed pre-pandemic levels. Approximately 34.1 million domestic visitors traveled to Florida in Q1 2022, and there were approximately 1.3 million travelers from overseas who visited the state during that same time period (represents an increase of nearly 169% from Q1 2021).⁴⁷ The state also has a large population of seasonal residents—students, seasonal workers (in industries such as hospitality, agriculture, and tourism), and persons who reside here part time to avoid harsh winters. In addition, Florida is home to several state and private higher-learning institutions, including Historically Black Colleges and Universities (HBCUs). These colleges and universities are often located in Florida's major metropolitan areas, which have higher than average HIV incidence. If tourists, visitors, and persons migrating into the state receive their original HIV diagnosis in Florida, that case counts toward Florida's overall HIV prevalence. The Department's surveillance unit works with other states and jurisdictions to perform deduplication efforts to ensure that persons initially diagnosed in another state or jurisdiction are not counted toward Florida's overall prevalence.
Immigration and Refugee Services	Over the past few years, foreign-born individuals and individuals born in U.S.-dependent areas immigrating to Florida have accounted for roughly half of the population's growth; more than one in five Florida residents is an immigrant.³⁰ Individuals born outside the continental U.S. comprise roughly 20% of the state's population, and in Miami-Dade County, more than 60% of the population is foreign-born. Among non-U.S. born residents in Florida, persons born in Haiti, Cuba, Venezuela, and Colombia experienced the highest numbers of HIV diagnoses in 2021. This presents a need for increased cultural humility to ensure health education, prevention, and care services are delivered in a culturally and linguistically appropriate manner (i.e., National CLAS Standards).

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Summary	Description
	FDCFs Refugee Services Program is federally funded by the Office of Refugee Resettlement in HHS to assist refugees to achieve economic self-sufficiency and social adjustment in the shortest possible time after their arrival in the United States. While in recent years the number of arrivals has decreased nationwide, the state of Florida's refugee program is the largest in the nation, receiving more than 5,000 refugees, asylees, and Cuban/Haitian entrants each year. Eligibility for programs of Refugee Services is determined by federal law and includes the following: Refugees; Cuban/Haitian Entrants; Asylees; Afghan and Iraqi Special Immigrants; and Certified Victims of Human Trafficking.⁵¹ FDCF Refugee Services currently manages more than a dozen refugee services contracts with state agencies, local governments, and community-based organizations. Through their Refugee Health Program, the Department's CHDs provide health screenings to ensure newly arrived refugee clients do not have communicable diseases and to identify health issues. AHCA provides payment for Refugee Medical Assistance services with federal funding and in accordance with Medicaid rules. Of Florida's 67 counties, approximately 32 counties receive refugees for health services on a regular basis. Geographically, new arrivals tend to resettle more frequently in one of the nine following Florida counties: Miami-Dade, Hillsborough, Duval, Palm Beach, Broward, Orange, Collier, Lee, or Pinellas.⁵² From the latest data available from FDCF, in 2021, 30,092 refugees arrived or became eligible for Refugee Services in Florida. Additionally, over the last five years (2017–2021), 97,492 refugees arrived or became eligible for Refugee Services. Florida received refugees from 47 different countries last year, of which 72% of refugees were Cubans, and 50% of refugees settled in Miami-Dade County. Cuban, Haitian, Afghan, Mexican, and Chilean were the top nationalities of new refugees in 2021.⁵³
Criminal Justice	According to the National Corrections Institute, Florida's incarceration rate (prisons and jails) was 371 per 100,000 population in 2020.⁴⁸ In 2020, the U.S. Bureau of Justice Statistics ranked Florida eleventh among states in terms of incarceration rates.³² Most incarcerated PWH were diagnosed prior to entering the correctional system; however, HIV testing in a correctional setting may be the first time persons who are incarcerated take advantage of testing and prevention education. Although condom provision is one of the simplest harm-reduction interventions to control HIV, STIs, and viral hepatitis, condoms are prohibited in correctional settings. Section 945.355, Florida Statutes (F.S.), requires inmates of FDC to be offered HIV testing prior to release, while jails (which are governed by each county) do not have uniform statewide HIV testing policies. Over time, the Department has built relationships with county jails to establish HIV testing and linkage programs. Increased partnerships with county jails are needed to expand HIV, STI, and HCV testing.

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Summary	Description
HIV Criminalization	Established in 1990, section 384.24, F.S., criminalizes non-disclosure of STI status, and separately HIV status, prior to sex. The offense requires the person to be aware of their STI and HIV status, to be informed of the risks of transmission through sex, and to go on to have sex with another person. At the time the law was established there was a modest understanding of how HIV transmission occurred, and treatment options were limited. After 30 years of research and advancements in HIV treatment, the law does not take into account the latest science and measures to prevent transmission (e.g., viral suppression, U=U). Persons with HIV and other community members have reported that criminalization laws may be discouraging HIV testing and perpetuating stigma against persons with HIV.
Environmental Impacts	Severe weather events can disrupt and interrupt HIV prevention and care delivery systems. Florida is a state particularly vulnerable to frequent hurricanes. When Hurricane Michael hit the Florida Panhandle in October 2018 as a category 5 storm, it caused mass destruction. Thousands of homes were destroyed, and many residents were displaced. PWH in the area had trouble accessing services and medications due to widespread devastation. Many people were forced to find housing elsewhere in Florida or even in other states. Emergency medication fills were available through the Department’s ADAP program; however, increased efforts are needed to identify PWH in need of reengagement in care and ancillary services following a natural disaster. Most recently, on September 28, 2022, Hurricane Ian made landfall on Florida’s southwest coast (Fort Myers area) as a category 4 storm, with Lee and Charlotte counties bearing the greatest impacts. More than 100 people lost their lives in Hurricane Ian, with most deaths being attributed to drowning—the record-breaking storm surge reached as high as 18 feet in some areas. Hurricane Ian is being categorized as the deadliest storm to hit Florida since the 1935 Labor Day Hurricane. The Department used the federal emergency declaration to ensure that ADAP clients had access to medication refills ahead of the storm and worked with ADAP staff statewide to communicate to clients that they had the ability to get prescriptions filled at any pharmacy location in their local areas.
Homelessness and Housing Instability/Insecurity	In 2021, the Florida Housing Coalition reported Florida having the third-highest homeless population of any state in the nation, with 27,640 people living in homeless shelters and on the streets. Before the COVID-19 pandemic, 875,259 very low-income Florida households—including hardworking families, seniors, and people with disabilities—paid more than 50% of their incomes for housing. For PWH, housing is one of the primary predictors of their access and adherence to treatment, other health outcomes, and life expectancy. There are several definitions of homelessness or unstable housing, such as lacking a fixed, regular, or adequate nighttime residence, but also including residing in a motel, doubling up with friends or family, or “couch-surfing.” People fleeing domestic violence are also considered unstably housed if they do not have the resources and support to obtain other

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Summary	Description
	permanent housing. Responses from Florida’s 2019 HIV Care Needs Assessment survey indicated that, of persons who experienced housing-related barriers, the top three barriers were not having money to pay rent, being afraid of others knowing their HIV status, and not having enough food to eat.⁵⁵
Food Insecurity	The latest data from Feeding America show that in 2020, Florida’s overall food insecurity rate was 10.6% (approximately 2.3 million people). Although Florida’s overall food insecurity rate is lower than the U.S. average of 11.8%, 42 out of 67 Florida counties (63%) have food insecurity rates at or above the national average (>11.8%). Florida’s 2019 HIV Care Needs Assessment Survey revealed that for PWH who reported experiencing housing-related barriers, one of the top three issues reported included not having enough food to eat. Many antiretroviral medications used to treat HIV require they be taken with food and ensuring proper nutrition for PWH is paramount to medication adherence and improved health outcomes.⁵⁶
Persons with HIV Aged 50+	Improvements in ART for HIV over the years have led to people with diagnosed HIV living longer and healthier lives, especially when diagnosed early, maintained on ART, and virally suppressed. In 2021, persons with HIV aged 50 and older living in Florida made up nearly 57% of the state’s total population of persons diagnosed and living with HIV. Persons aged 50 and older living with HIV face several health challenges—HIV-related and other comorbidities (e.g., cardiovascular and liver disease, neurocognitive impairment), concurrent use of multiple medications (i.e., polypharmacy), oral health problems (e.g., tooth loss), and mental health and substance use disorders.
Outbreak Response for Syndemics	Over the past several years, the state has taken a collaborative approach, with RWHAP and other community-based partners, to responding to other outbreaks that impact the care and treatment of PWH (e.g., COVID-19, Mpox virus, hepatitis A, and meningococcal disease), providing trainings, developing messaging, and promoting access to available health resources and services (e.g., vaccine promotion events for hepatitis A and meningococcal disease). Greater coordination is needed to ensure these intersecting conditions are addressed holistically (e.g., whole-person care).
HIV Workforce Infrastructure (public and private)	Current challenges exist with the HIV workforce—both public and private. The Department’s Bureau of Communicable Diseases experienced a high degree of turnover in key leadership positions in 2022, beginning in spring and continuing into fall 2022. Key positions such as the Bureau Chief of Communicable Diseases, HIV/AIDS Section Administrator, Statewide HIV Planning/EHE Coordinator, HIV Patient Care unit manager, Communications unit manager, and Clinical Quality Management Liaison all became vacant during that time. Other positions that had

Summary	Description
	been vacant prior to 2022 are still in need of being filled and include the Performance and Quality unit manager and Statewide Minority AIDS Coordinator. High turnover and staff reaching retirement age have led to gaps in historical program knowledge and staff having to assume interim roles or double-up on responsibilities. Staffing shortages and recruiting challenges have also been reported from CBOs and private sector agencies (e.g., difficulties recruiting health care professionals).
Vulnerable Populations—Human Trafficking, Domestic/Intimate Partner Violence	According to the Florida Alliance to End Human Trafficking, Florida ranks third in the nation for the number of human trafficking cases reported and ranks second in the nation for the number of labor trafficking cases reported. The majority (71.4%) of cases are sex trafficking cases, followed by labor trafficking (14.3%), unspecified trafficking (9.0%), and sex/labor trafficking (5.1%). Persons experiencing exploitation are particularly vulnerable to exposure to HIV, STIs and viral hepatitis due, in part, to substance use, lack of access to health care, lack of autonomy, and exposure to violence.⁵⁷ In 2020, 106,515 crimes of domestic violence were reported to Florida law enforcement agencies and during FY 2020–21 and Florida’s certified domestic violence centers provided 412,360 nights of emergency shelter to 10,287 survivors of domestic violence and their children. Many more survivors of domestic violence are not reporting their abusers to the police or accessing services at domestic violence services due to reasons such as shame, fear, or being prevented from doing so by their abusers. For this reason, the number of cases is thought to be underreported. Women in violent relationships are at a four times greater risk for contracting STIs, including HIV, than women in non-violent relationships and women who experience intimate partner violence are more likely to report risk factors for HIV.⁵⁸

3.5 Needs Assessment

The information gained from the 2019 HIV Care Needs Survey represents a statewide comprehensive assessment of the needs of PWH in Florida. Survey questions were designed to better understand the current demographics of PWH in Florida and the HIV medical care, patient care services, jail and prison release services, and housing services that were needed and delivered during the 12 months prior to the time the survey was taken.

To ensure that services provided through the Patient Care Program are appropriate and contribute to improving health outcomes for PWH, the HIV/AIDS Section conducted the 2019 HIV Care Needs Survey throughout the state. The primary focus of the survey was to determine met and unmet service needs for PWH in Florida. Data collected from this survey are intended to help statewide and local planning stakeholders determine the best ways to distribute funds and resources. This survey was launched on

May 28, 2019, and continued to completion on September 6, 2019. The survey was delivered via Survey Gizmo and paper to Floridians living with HIV who sought HIV care services in each of the 14 program areas of the Ryan White Patient Care Program.

Limitations

Using the convenience sampling method to collect input for this type of assessment has its advantages, disadvantages, and limitations. Surveys collected using this method can yield rich qualitative data for review and planning in a comparatively cost-efficient manner. Data are available relatively quickly to match the pace of planning needs and are useful to signal changes or shifts in attitudes, behaviors, and outcomes. Among the disadvantages of collecting assessment data via convenience sampling are the potential for bias in data collection and sampling errors that could introduce inaccuracies. Surveying processes that use the convenience sampling method have limitations. Survey participants were self-selected.

3.5.1 Methodology

Survey questions were grouped into sections that included general demographics, HIV medical care, and patient care, jail and prison release, housing, and prevention services. Questions were related to the past 12 months of service. Distribution of the survey was facilitated by the 14 consortia lead agencies throughout Florida. A sample size for each county was calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. RWHAP Part B lead agencies, in collaboration with RWHAP Part A recipients, worked with local providers, community members, and other stakeholders to obtain the survey responses. The survey was made available in three languages: English, Haitian-Creole, and Spanish. Paper surveys were collected locally and mailed to the HIV/AIDS Section for data entry and analysis.

A total of 4,114 surveys were conducted by the end of the survey period: 3,758 in English, 334 in Spanish, and 22 in Haitian-Creole. Of these, 3,777 were complete, 147 were partial, and 190 were disqualified. Respondents were required to answer the demographic questions about age, gender, race, and county.

This document presents the key findings of the 2019 HIV Care Needs Assessment. Results from this survey will be used to help guide service implementation and resource allocation in Florida's HIV/AIDS Patient Care Program.

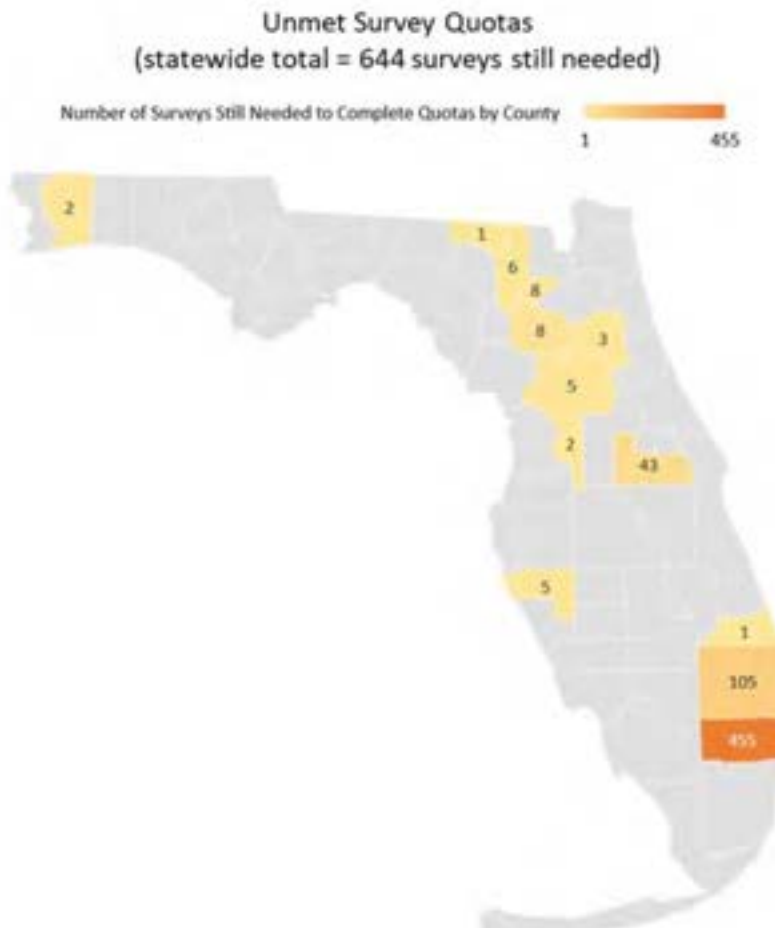
Survey respondents' counties of residence were reported for 66 of Florida's 67 counties. Union County was not surveyed because there are no reported PWH in that county. A total of 3,879 respondents answered the question about residence. Table 7 lists the number of respondents from each county.

TABLE 7: FLORIDA COUNTY OF RESIDENCE

County	Count	Percent	County	Count	Percent
Alachua	20	0.52%	Lake	45	1.16%
Baker	3	0.08%	Lee	76	1.96%
Bay	29	0.75%	Leon	221	5.70%
Bradford	3	0.08%	Levy	5	0.13%
Brevard	244	6.29%	Liberty	4	0.10%
Broward	65	1.68%	Madison	11	0.28%
Calhoun	1	0.03%	Manatee	22	0.57%
Charlotte	24	0.62%	Marion	23	0.59%
Citrus	8	0.21%	Martin	22	0.57%
Clay	16	0.41%	Miami-Dade	765	19.72%
Collier	29	0.75%	Monroe	37	0.95%
Columbia	3	0.08%	Nassau	4	0.10%
DeSoto	14	0.36%	Okaloosa	17	0.44%
Dixie	3	0.08%	Okeechobee	7	0.18%
Duval	230	5.93%	Orange	187	4.82%
Escambia	47	1.21%	Osceola	53	1.37%
Flagler	25	0.64%	Palm Beach	107	2.76%
Franklin	5	0.13%	Pasco	78	2.01%
Gadsden	49	1.26%	Pinellas	319	8.22%
Gilchrist	1	0.03%	Polk	76	1.96%
Glades	2	0.05%	Putnam	3	0.08%
Gulf	1	0.03%	Santa Rosa	5	0.13%
Hamilton	3	0.08%	Sarasota	68	1.75%
Hardee	2	0.05%	Seminole	51	1.31%
Hendry	7	0.18%	St. Johns	12	0.31%
Hernando	37	0.95%	St. Lucie	63	1.62%
Highlands	13	0.34%	Sumter	5	0.13%
Hillsborough	475	12.25%	Suwannee	5	0.13%
Holmes	2	0.05%	Taylor	5	0.13%
Indian River	18	0.46%	Volusia	164	4.23%
Jackson	14	0.36%	Wakulla	9	0.23%
Jefferson	3	0.08%	Walton	5	0.13%
Lafayette	2	0.05%	Washington	7	0.18%
			Total	3,879	

A sample size for each county was calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. As shown in the figure below, the three counties with highest unmet quotas were:

- Broward
- Palm Beach
- Orange

FIGURE 14: UNMET SURVEY QUOTAS BY COUNTY

3.5.2 Approach

The FCPN Needs Assessment Committee has worked diligently since 2019 to develop the 2022 HIV Care Needs Survey and Needs Assessment Toolkit; releasing it in October 2022. The purpose of the toolkit is to familiarize areas statewide with the importance, components, and processes of needs assessment. The toolkit provides the information needed for active involvement in the needs assessment process by individuals with little or no prior experience in community planning or community-based assessments. The needs assessment process is designed to gather data to inform patient care services both locally and statewide with meaningful input from people impacted by HIV. The survey remained open through December 31, 2022. Once results are received and analyzed, this information will be used to update the SCSN.

The 2019 survey questions were grouped into sections that included general demographics, HIV medical care, and patient care, jail and prison release, housing, and prevention services. Questions were related to the past 12 months of service. Distribution of the survey was facilitated by the 14 consortia lead agencies throughout Florida. A sample size for each county was calculated based on the number of

PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. RWHAP Part B lead agencies, in collaboration with RWHAP Part A recipients, worked with local providers, community members, and other stakeholders to obtain the survey responses. The survey was made available in three languages: English, Haitian-Creole, and Spanish. Paper surveys were collected locally and mailed to the HIV/AIDS Section for data entry and analysis.

A total of 4,114 surveys were conducted by the end of the survey period: 3,758 in English, 334 in Spanish, and 22 in Haitian-Creole. Of these, 3,777 were complete, 147 were partial, and 190 were disqualified. Respondents were required to answer the demographic questions about age, gender, race, and county.

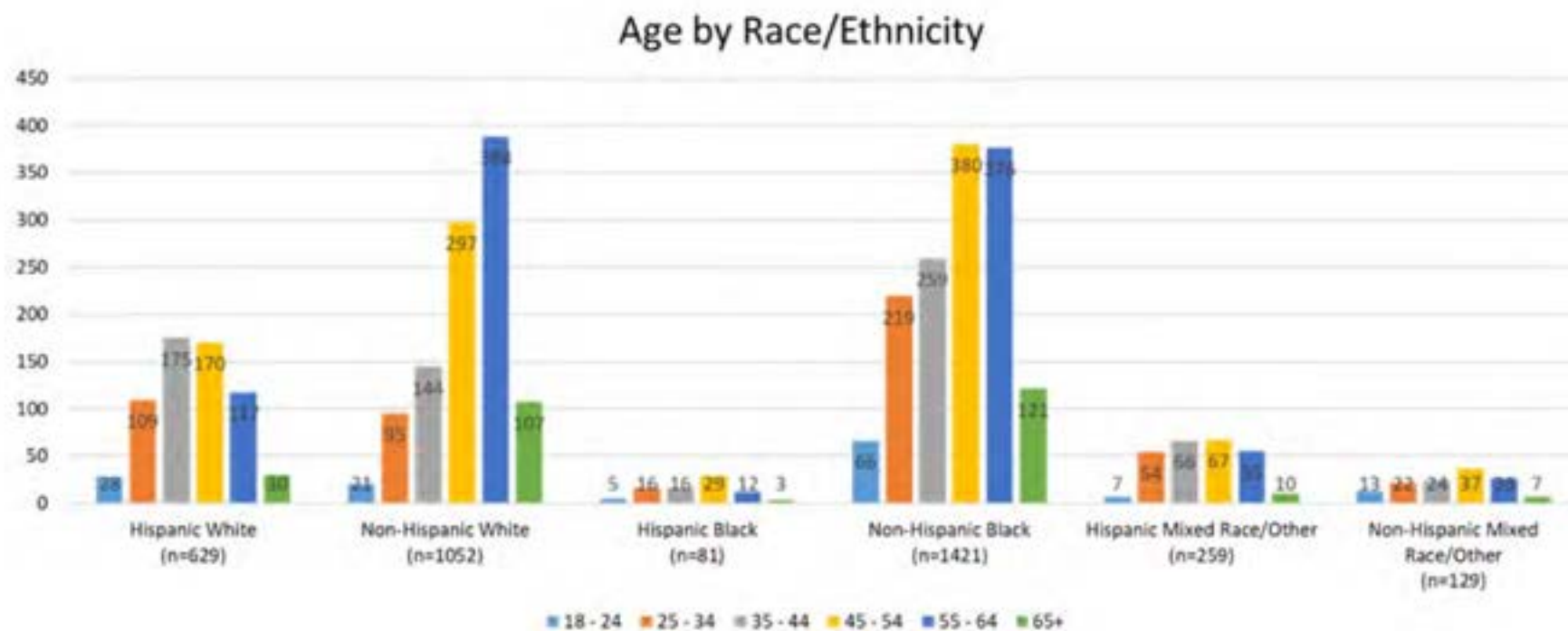
3.5.3 Priorities

The needs assessment process identified the following key priority areas: Demographics, HIV Medical Care, Patient Care Services, Jail and Prison Release Services, and Housing.

Demographics Summary

Appropriate sample sizes for each county were calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. The five counties with the most survey respondents were Miami-Dade, Hillsborough, Pinellas, Brevard, and Duval. Most counties met their quotas, but 13 did not. The three counties with highest unmet quotas were Broward, Palm Beach, and Orange.

Overall, most survey respondents fell into two age groups: 55 to 64 years old and 45 to 54 years old. Stratified by race/ethnicity (see Figure 15), this trend held true for those who identified as non-Hispanic White, non-Hispanic Black, and non-Hispanic multiracial/other. However, for those who identified as Hispanic White, Hispanic Black, and Hispanic multiracial/other, the trend showed that most fell into the 35 to 44 years old and 45 to 54 years old categories as seen in Figure 15.

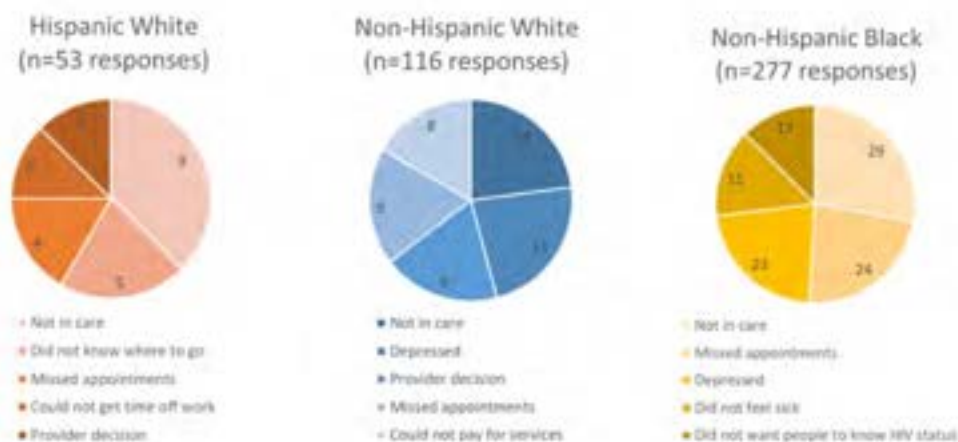
FIGURE 15: HIV CARE NEEDS SURVEY RESPONDENTS (PWH) BY AGE AND RACE/ETHNICITY

Most survey respondents reported working a full-time job for the past 12 months. The second largest group reported not being able to work due to disability. Approximately half of respondents reported that their 2018 household gross income (before taxes) was less than \$15,000 and roughly one-third reported incomes that were between \$15,000 and \$30,000. Stratified by race/ethnicity, most of those categorized as earning less than \$15,000 and those earning between \$15,000 and \$30,000 were non-Hispanic Black. Most of those categorized as earning between \$30,000 and \$50,000, between \$50,000 and \$100,000, and more than \$100,000 were non-Hispanic White.

HIV Medical Care Summary

Most survey respondents reported that they had seen a doctor about their HIV during the past 12 months. When asked about the frequency of HIV-related care, most reported receiving care two or three times during the past 12 months. For respondents who reported that they had not received HIV-related care or had received care fewer than two times in the past year, the most common reasons overall were that they were not in care, were depressed, or missed their appointments, as shown in Figure 16. When stratified by race/ethnicity, the most common reason given by Hispanic White, non-Hispanic White, and non-Hispanic Black persons remained that they were not in care. The second and third most common reasons given by Hispanic White persons were not knowing where to go and missing their appointments, respectively. For non-Hispanic White persons, the second and third most common reasons were that they were depressed and that this was their provider's decision, respectively. For non-Hispanic Black persons, the second and third most common reasons were that they missed their appointments and were depressed, respectively. The total numbers of responses from those who identify as Hispanic Black, Hispanic multiracial/other, and non-Hispanic multiracial/other about reasons for not receiving care were very low (8, 31, and 8, respectively).

FIGURE 16: TOP 5 REASONS RESPONDENTS HAD NOT BEEN IN CARE BY RACE/ETHNICITY



*Hispanic Black, Hispanic Multiracial/Other, and Non-Hispanic Mutliracial/Other not shown due to low number of responses.

The overwhelming majority of survey respondents received HIV-related medical care in the county where they live. For the small number of respondents who received care in a different county from where they live, the most common reasons given were that doctors or services were not available in their county of residence, preference and better doctors in a different county, continuity of care with an established provider, convenience and closer to home, and confidentiality.

Most survey respondents reported that they always take their HIV medications just as their doctor prescribed them. For those who reported that they did not always take their medications as prescribed, the reasons given included that the medication made them feel bad or sick, they could not afford the cost, they were on a medication break as directed by their physician, they did not know where to get medication, and forgetting.

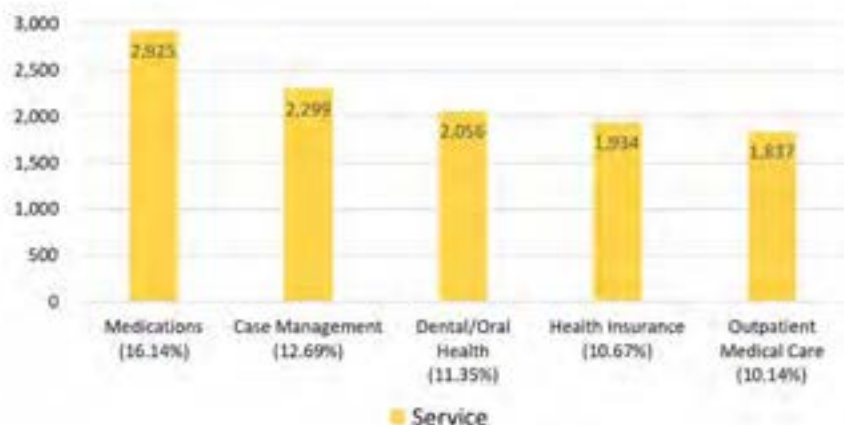
Patient Care Services Summary

Most survey respondents reported that they did get the patient care services they needed during the past 12 months. For those who did not get needed services, the five most common barriers listed were not knowing where to get services, being depressed, not having transportation, not being able to pay for services, and missing appointment(s). When stratified by race/ethnicity, the most common barrier listed for all race/ethnicity categories (except Hispanic Black persons) was not knowing where to get services. The top barrier to care for Hispanic Black persons was depression.

As shown in Figure 17, the top five patient care services deemed by respondents as most important for the state to provide for PWH were (in order of priority):

1. Medications
2. Case management
3. Dental and oral health
4. Health insurance
5. Outpatient medical care

FIGURE 17: TOP FIVE PATIENT CARE SERVICES MOST IMPORTANT TO SURVEY RESPONDENTS

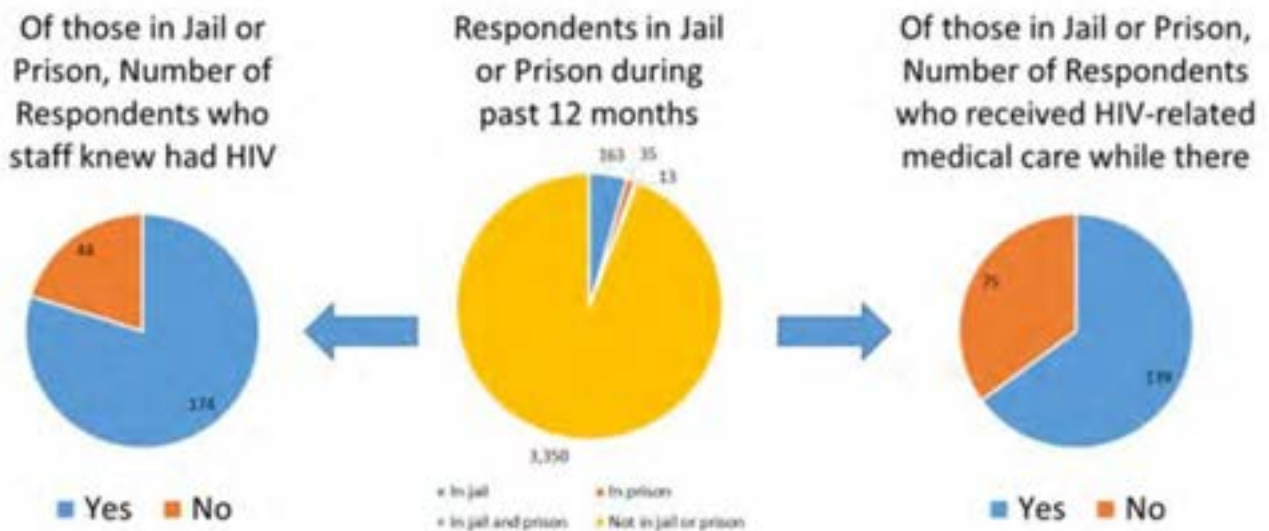


When stratified by race/ethnicity, the top two services reported by respondents as most important remained medications and case management across all race/ethnicity categories, but the priorities for dental and oral health, health insurance, and outpatient medical care were ranked differently (though they remained in the top five).

Jail and Prison Release Services Summary

The overwhelming majority of survey respondents reported that they had not been in jail or prison during the past 12 months as shown in Figure 18. Of the 211 who reported having been incarcerated (5.9% of all respondents), 82.5% reported that the jail or prison staff knew of their HIV status and most (65.9%) reported that they did receive HIV-related medical care. Upon release from jail/prison, 40.3% of respondents reported that they did not receive any HIV-related information or assistance. Of those who did receive care and assistance, 29.4% received a supply of HIV medication to take with them, 24.2% received referral to medical care, 22.3% received referral to case management, and 10.9% received information about finding housing.

FIGURE 18: SURVEY RESPONDENTS IN JAIL AND PRISON DURING THE PAST 12 MONTHS AND WHETHER SERVICES WERE RECEIVED WHILE INCARCERATED



Of the 240 respondents who answered the question about barriers to getting needed HIV services after release from jail or prison, most (59.6%) indicated that this question did not apply to them because they did get needed services. For those who experienced barriers to care, the most frequent barriers reported were:

- No insurance or financial reasons.
- No transportation to services.
- Did not know where to go for services.
- Could not get away from drugs.
- Had trouble finding trustworthy friends.

- Did not want others to know of their HIV status

Housing Summary

Overall, survey responses indicated that most respondents did not experience barriers to HIV-related care due to their current housing situation as shown in Table 8. Of those who did experience housing-related barriers, the top three barriers were not having money to pay rent, being afraid of others knowing their HIV status, and not having enough food to eat. When stratified by race/ethnicity, barriers varied in rank, but the top three barriers from the overall responses consistently remained in the top three across race/ethnicity categories.

TABLE 8: HIV HOUSING SERVICES RESPONDENTS NEEDED OR RECEIVED IN THE PAST 6 MONTHS

	Received Needed Services		Needed Service, But Could Not Get Service		Needed Service, But Did Not Know About Service		Did Not Need Service		Total Responses
	Count	Row %	Count	Row %	Count	Row %	Count	Row %	Count
Help finding an affordable place to live	357	11.26%	345	10.88%	303	9.56%	2,165	68.30%	3,170
Permanent, independent housing	258	8.62%	312	10.42%	266	8.88%	2,158	72.08%	2,994
Temporary short-term housing	141	4.91%	181	6.30%	152	5.29%	2,397	83.49%	2,871
Housing where my child(ren) can live with me	108	3.80%	69	2.43%	98	3.45%	2,567	90.32%	2,842
Nursing home	81	2.88%	48	1.71%	53	1.88%	2,633	93.53%	2,815
Money to pay utilities	281	9.49%	289	9.76%	319	10.78%	2,071	69.97%	2,960
Money to pay rent/mortgage	304	10.20%	319	10.70%	343	11.51%	2,015	67.59%	2,981
Housing for persons living with HIV	174	5.91%	249	8.46%	237	8.05%	2,285	77.59%	2,945
Assisted living facility	99	3.49%	82	2.89%	91	3.20%	2,568	90.42%	2,840
Column Totals	1,803		1,894		1,862		20,859		26,418

	Received Needed Services	Needed Service, But Could Not Get Service	Needed Service, But Did Not Know About Service	Did Not Need Service	Total Responses
% of Overall Total	6.82%	7.17%	7.05%	78.96%	100.00%

Overall, most survey responses indicated that respondents did not need any of the available housing services offered through Florida's HIV/AIDS Patient Care Program. For those who were in need, the services most frequently reported as being received, needed but unable to get, or needed but unaware of where to get (approximately 30% of all the survey responses given for each of the following services) were:

- Help finding an affordable place to live.
- Money to pay rent or mortgage.
- Money to pay utilities.
- Permanent, independent housing.

Between 65% and 70% of respondents in need of these services either could not get them or did not know about them. When stratified by race/ethnicity, non-Hispanic Black persons represented the largest number of responses across the board for all services respondents needed but could not get. This same trend held true for all services respondents needed but did not know about.

Overall, for those who needed services, most survey responses (approximately 60%) indicated that respondents did not experience barriers to getting needed housing services and were able to get them. But a sizeable proportion of responses (nearly 40%) indicated barriers to getting needed housing services. The top three barriers reported were that the respondent:

1. Did not know where to get services.
2. Did not qualify for services.
3. Was put on a waiting list.



Actions Taken

The following recommendations were developed to identify key activities to address needs and barriers of the key priority areas:

Demographics Recommendations

It is of concern that the three counties with the largest unmet survey quotas are also three of the counties that have high prevalence of PWH. Collectively, those counties were 603 surveys below quota. Given that this represents 20.6% of the total number of surveys needed to meet quota, it may present a significant deficit of information that is important to consider regarding allocation of resources for HIV

care and services. Going forward, planning for increased staffing and concentrated efforts ahead of survey implementation may help mitigate unmet quotas in counties with high prevalence of PWH.

If survey results are representative of PWH in Florida, they indicate that most are non-Hispanic Black males between the ages of 45 and 64 who have fulltime employment but are living below the poverty level. This highlights the continued disparities minorities face and the economic disadvantage of populations most affected by HIV. Giving priority to this priority population for outreach, staffing, and resources may be warranted to promote diverse community wellness.

With the development and release of the 2022 HIV Care Needs Survey and Needs Assessment Toolkit in October, Florida hopes to increase the number of surveys completed by PWH.

HIV Prevention

One of the priorities for the Department's HIV/AIDS Section is the development of a comprehensive HIV prevention needs assessment through surveys administered to and through HIP providers to address services provision (PrEP, HIV testing, Test & Treat, harm-reduction needs) for persons at risk for HIV. Other entities to be included in the needs assessment include CHDs and operational syringe services programs (SSPs). The Department hopes to accomplish this in 2023.

Policy Barriers

Currently, Florida laws do not present barriers to HIV prevention or patient care services. Minor limitations exist in state laws allowing for syringe exchange programs and include prohibitions on using state, county, or municipal funds to support the operation of the program and permitting a one-to-one exchange of syringes. Florida is also a Medicaid non-expansion state and this may have implications for HIV-related service coverage levels for persons who are eligible for Medicaid.

HIV Medical Care Recommendations

The top reasons given for not receiving care or receiving less frequent care were missed appointments and not in care. To ensure that all PWH in Florida receive the appropriate frequency of HIV-related care, it may be necessary to determine why they were not in care and why they missed appointments. Depression was another top reason given for not receiving care. This points to the importance of educating care providers to be aware of potential mental health and HIV comorbidities and the possible need to implement a protocol for mental health screening along with HIV care visits. To best address these needs and allocate resources appropriately, detailed attention to the top reasons for not receiving care in race/ethnicity categories may be helpful.

In counties where providers and services for HIV-related care are not available, the magnitude of those affected should be investigated and solutions to this problem should be explored. The desire for confidentiality was reported as a reason for seeking HIV-related care in a county other than the

respondent's county of residence. More efforts are needed to address HIV stigma and normalize HIV prevention and care seeking behaviors.

Because HIV medications, when taken as prescribed, are highly effective in attaining VLs that are undetectable and therefore not transmittable, it is imperative that all PWH receive appropriate medication and take it as directed by their physician. It is encouraging that most survey respondents reported that they always take their medications just as prescribed. However, even though the number of those who reported noncompliance with taking their medications is low (12.9%), other personal or biological issues may hinder persons from achieving sustained viral suppression. Reasons given by respondents for not taking medications as prescribed should be investigated further, and solutions or services should be found to overcome these barriers.

Patient Care Services Recommendations

Although most respondents received patient care services they needed, a large proportion (43.4%) did not. Barriers to care centered mostly around logistics, depression, and personal finances. To address logistics and personal finance barriers, allocating more resources for outreach and public information campaigns providing awareness of available HIV/AIDS services for those with low or no income may be helpful. Regarding depression, again we stress the importance of educating care providers to be aware of potential mental health and HIV comorbidities and the possible need to implement a protocol for mental health screening along with HIV care visits. Stigma may prevent persons with HIV from seeking mental health services. Additionally, partnering and finding more accessible mental health service providers is key.

As seen in Figure 19, of the four patient care services reported as most important to respondents, (1) dental and oral health, (2) medication, (3) case management, and (4) health insurance was also high on the list of needed services that respondents reported they could not get or did not know about. This is an area of concern; further investigation into this issue is warranted.

FIGURE 19: PATIENT CARE SERVICES



Jail and Prison Release Services Recommendations

Based on survey responses, the HIV status of 17.5% of those respondents who were incarcerated was not known to jail or prison staff. In addition, 34.1% of those incarcerated did not receive HIV-related medical care while in jail or prison, and 40.3% did not receive HIV-related information or assistance upon release. These numbers represent care intervention opportunities lost. Improvement for collaboration with jail and prison systems to improve continuity of HIV care and post-release accessibility is needed.

Housing Recommendations

Overall, survey results show that most respondents did not need housing services. This is likely a limitation of the persons who responded to the needs assessment. An opportunity could be to ensure that there is a separate avenue with HOPWA to address this in the future. Most who did need services did not experience barriers to getting these services, nor did they experience barriers to taking care of their HIV that were related to their current housing situation. But for those who needed housing services, most centered around needing help to find housing and help to pay for housing and utilities. Because needed housing services for a sizeable proportion of survey respondents were unmet, with the race/ethnicity category most represented in this proportion being non-Hispanic Black, further investigation focusing on this disparity is warranted.

Lastly, the most frequently reported barriers to getting needed housing services reveal distinctly different issues. The most common barrier was not knowing where to get services, which may indicate that public awareness campaigns for this may be needed. Florida does have a HOPWA campaign (Housing for Better Health-Assistance for Persons with HIV/AIDS in Florida); however, its effectiveness and reach may need to be evaluated. The second most common barrier was that respondents did not qualify for services. This may indicate a disconnect between actual need and the program criteria currently in place to determine need. The third most common barrier to getting housing services was that the respondent was put on the waiting list. Causes for this may include limited housing availability and resources and a need for more staffing to process housing services.

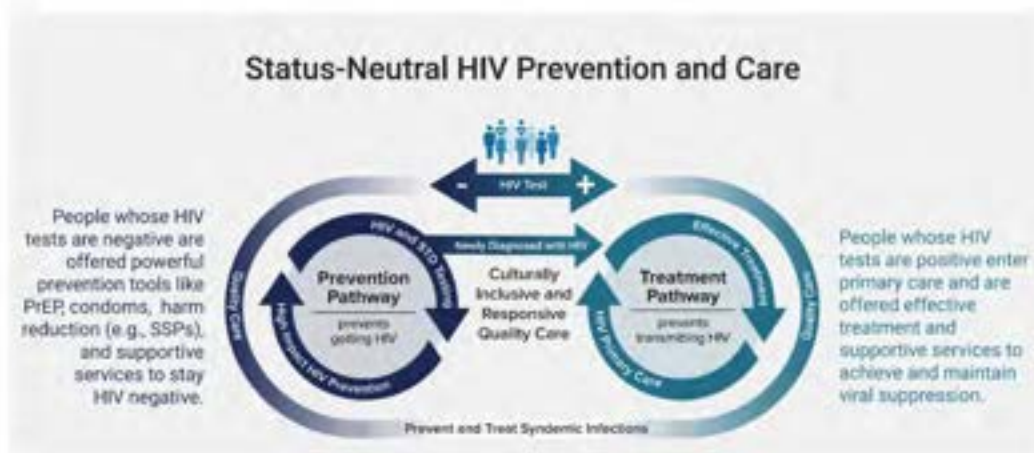
4 Situational Analysis

Florida is one of the most culturally diverse states in the nation with a vast array of residents from a wide variety of ethnic, racial, national, and religious backgrounds. The state has long attracted immigrants, particularly from Cuba, Haiti, Colombia, Venezuela, and Mexico. In fact, almost 21% of Florida's population are foreign-born persons (US Census Data - Quick Facts - Florida, 2021). With this diversity comes a higher incidence of disease burden from those in the emerging racial/ethnic minority populations from rural, socio-economically disadvantaged, and medically underserved backgrounds.

Florida continues to implement the best strategies to build a path to improve HIV prevention and care access, specifically among racial/ethnic minorities and other underserved groups. Specific demographics of racial and ethnic minorities and communities experience more barriers to accessing prevention and care services. For persons who are already diagnosed and living with HIV in Florida, activities centering around access to HIV care, including ART, retention in HIV care, and viral suppression, should be focused on such priority populations, including: Black heterosexual individuals (with added focus on Black WCBA), gay and bisexual males of all races/ethnicities, and transgender individuals of all races/ethnicities.

To further move the needle in reducing new HIV diagnoses in Florida, the Department's HIV/AIDS Section is proposing several high-impact initiatives based on the status-neutral approach to HIV prevention and care. The HIV status-neutral approach to reducing new HIV diagnoses involves initial HIV testing services as the entry point to HIV prevention and care services irrespective of a positive or negative test result. See Figure 20.

FIGURE 20: STATUS-NEUTRAL APPROACH TO HIV PREVENTION AND CARE



Source: <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>

The strategies proposed include:

1. Statewide expansion of routine HIV, HCV and syphilis screening in hospitals, emergency departments and other health care settings.
2. Increasing PrEP and PEP awareness and uptake.
3. Expansion and awareness of rapid antiretroviral therapy (ART) starts, i.e., Test and Treat.
4. Improving stigma, social determinants of health through awareness and education.
5. Improving health outcomes in aging populations with HIV.

To implement HIV prevention and care services based on the status-neutral approach, Florida will employ the initiatives and strategies which align with the EHE pillars below. The information below also highlights the strengths, challenges, and identified needs related to HIV prevention and care in Florida, the subsequent sections describe each of the following areas:

- DIAGNOSE all people with HIV as Early as Possible (Section 4.1)
- TREAT people with HIV rapidly and effectively to reach sustained viral suppression (Section 4.2)
- PREVENT new HIV transmissions by using proven interventions, including PrEP, and SSP (Section 4.3)
- RESPOND quickly to potential HIV outbreaks to get prevention and treatment services to people who need them (Section 4.4)
- Priority populations (Section 4.5)

4.1 DIAGNOSE People with HIV as Early as Possible

Routine HIV, STI, and HCV Testing in Health Care Settings

In July 2015, the Florida Legislature amended Florida’s HIV testing law to remove the need for separate informed consent prior to HIV testing in health care settings. In September 2016, Rule 64D-2.004, Florida Administrative Code (FAC), was adopted to implement the amended HIV testing law. The intent of this amendment was to simplify routine HIV testing in health care settings, improve the identification of new or existing HIV infections, and help to normalize HIV testing as a routine component of primary health care. There was no change in the law regarding non-health care settings. These changes align Florida more closely with the CDC’s HIV Screening Recommendations.⁴⁴

Since 2015, the Department, including CHDs, has developed a collaborative model for routine communicable disease screening with the Gilead Sciences’ Frontlines of Communities in The United States (FOCUS) initiative. The FOCUS program is a public health initiative that enables partners to develop and share best practices in routine blood-borne virus (HIV, HCV, HBV) screening, diagnosis, and linkage to care in accordance with screening guidelines promulgated by CDC, the U.S. Preventive Services Task Force (USPSTF), and state and local public health departments. FOCUS funding supports HIV, HCV, and HBV screening and linkage to the first appointment after diagnosis. FOCUS partners do not use FOCUS awards for activities beyond linkage to the first appointment.

Florida FOCUS partners include FQHCs and large hospital systems. The Department's public-private partnership with Gilead's FOCUS initiative began in 2016 with the establishment of the very first site—Homestead Hospital in Miami-Dade County. A Department DIS or Linkage to Care Coordinator works with each FOCUS emergency department partnership to assist with linkage to care and other services. The partnership with Homestead was expanded to include syphilis screening and the Department supports the cost of these screenings.

Currently, the Florida FOCUS program has 22 partners across the state (see map in Figure 21) and in 2021, institutions that have implemented the FOCUS program conducted 156,288 HIV tests (1.2% positivity), with 86% linked to care. Additionally, 74,910 HCV tests (4.6% HCV Ab positivity) were conducted and 75% linked to care. In 2022, Florida FOCUS projects plan to complete 187,000 HIV tests and 104,500 HCV tests and commits to onboard facilities to also conduct syphilis testing.

There is no monetary relationship between the Department and Gilead Sciences and as the partners age out of their relationship with Gilead, the Department has developed a cost-sharing model to continue to support testing and linkage to care at these sites by assisting with the costs of testing and reagents.

Current efforts to support expansion include the inclusion of this initiative as an objective in the State Health Improvement Plan where, by December 31, 2026, the Department and external partners aim to increase the number of emergency room or acute care hospitals that are conducting opt-out HIV screening, routine HCV screening, and syphilis testing with a smart screen algorithm from 1 (2021) to 15. Figure 21 visualizes 2022 partner reach for the state of Florida.

FIGURE 21: FLORIDA PARTNER REACH IN 2022



Gaps still exist in the implementation of routine HIV, STI, and HCV testing in hospital emergency departments (EDs) and primary health care settings. Accounts of individuals seeking medical care in hospital EDs for symptoms akin to acute HIV infection are frequent, and, oftentimes, persons visit the ED several times before being tested for HIV, diagnosed, and linked to care. Approximately 7 in 10 PWH saw

a health care provider in the 12 months prior to diagnosis and failed to be diagnosed.⁵⁹ Additionally, reimbursement by Medicaid for HIV testing in hospital EDs is a challenge as we move forward with routinizing testing in EDs; in some cases, testing may not be covered unless deemed medically necessary or clinicians may be less likely to bill when they frequently receive rejections.

From June 2019 to April 2020, the University of Miami AIDS Education and Training Center (UM-AETC) performed outreach to health care facilities in the highest HIV incidence areas throughout Miami-Dade and Broward counties to conduct assessments and academic detailing. Facilities included community health centers and primary care and internal medicine clinics. Assessments examined the status of health care facilities in implementing routine HIV testing and PrEP provision in accordance with CDC guidelines and in implementing or extending third-party billing for routine HIV screening. Less than a quarter (20%) of the health care provider practices reported offering routine HIV screening services to all patients ages 13 to 64, regardless of symptoms or demographics. Of the remaining clinics, 28.6% reported that they test patients based on symptoms and demographics and 30% reported testing only those who requested an HIV test. Among barriers to rapid HIV testing, most practices indicated that they never considered rapid HIV testing as a service (30%). Other barriers to providing rapid HIV testing were the perceived need to obtain consent, staff lacking training for administering and billing, the concern that testing would not be reimbursed by payors, and uncertainty about the implementation of in-office rapid testing.

To eliminate these barriers, the Department has done or will do the following:

- Conducted a Routine Screening Expansion Roundtable, which took place May 26, 2022. The purpose of this meeting, hosted by the Lieutenant Governor, was to bring together a wide variety of external stakeholders to discuss how to expand routine opt-out HIV, syphilis, and HCV screenings in EDs and acute care settings and move toward ending these syndemics in Florida.
- Update Chapter 64D-3, FAC, to include the mandatory reporting of all HIV test results. 64D-3 is titled “Control of Communicable Diseases and Conditions which may Significantly Affect Public Health”. Currently, providers and laboratories are required to report only positive HIV test results to the Department.
 1. Improve the reporting and surveillance of stage zero or acute diagnoses to understand the burden of recent transmission for intervention and prevention.
 2. Understand the scope and total HIV testing being conducted in Florida and calculate a state positivity rate that can be used to drive future interventions and prevention efforts.
- Conduct an assessment on current Florida FOCUS partners to understand who is aging out of the program, and when, and use current funding to support testing and linkage to care efforts.
- Work with directly funded RWHAP Part A programs in the six metropolitan areas of the state to collaborate on supporting routine screening efforts in those areas.
- Collaborate with AHCA to develop a Dear Colleague letter from Medicaid to clarify reimbursement support for routine HIV and HCV screening in hospital EDs.

- Explore leveraging Opioid Settlement Funds to help support the expansion of medication-assisted treatment pathways in hospitals.

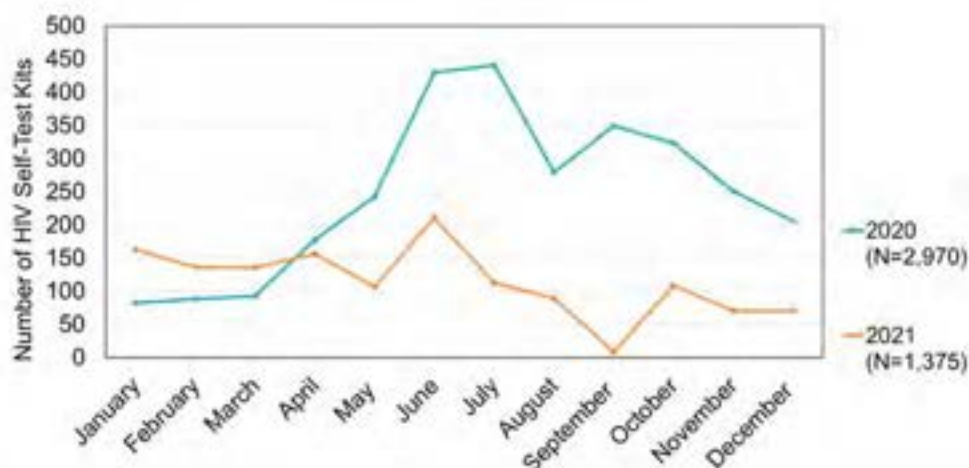
In addition to the FOCUS program, the HIV/AIDS Section also has a contract funded through federal grants with the University of Central Florida HealthARCH program that aims to assess the readiness of health systems in the seven metropolitan counties of high-HIV burden and onboard them to modify their electronic health records and offer routines screening for HIV.

Rapid HIV Testing through Non-Traditional Settings and Modalities

Considering Florida's percentage of PWH unaware of their status (14%), increased access to rapid HIV testing is required. Feedback received through community engagement indicated a need for expanded use of mobile testing units, HIV self-test kits, social and sexual network screening, and testing at non-traditional settings and hours. The Department currently supports more than 1,600 registered HIV testing sites around the state that conduct targeted HIV testing in non-health care settings in areas and communities with high HIV incidence. The Department supports these sites with rapid HIV test kits at no cost to the site. Sites must register with the Department and submit HIV testing data as criteria to receive rapid HIV test kits. In 2021, the Department conducted 73 rapid test trainings and certified 1,032 individuals to perform rapid HIV testing. The Department will continue to conduct rapid HIV testing trainings to certify individuals to perform rapid HIV testing in non-health care settings.

In June 2019, the Department began an HIV self-test kit distribution program to provide rapid HIV self-test kits to individuals, at no cost, and through an online request form (available at [KnowYourHIVStatus.com](https://www.knowyourhivstatus.com)). This program was particularly important as COVID-19 closures and restrictions fueled increases in the demand for alternative options for HIV testing. As shown in Figure 22, monthly requests for HIV self-test kits rose sharply beginning in April 2020 and continued through July 2020. Monthly requests tapered slightly from September through December 2020. In 2021, monthly requests for HIV self-test kits decreased but are still higher than pre-COVID levels. Since the program's inception, more than 4,600 rapid HIV self-test kits have been distributed. The HIV/AIDS Section continues to look for opportunities to collaborate, especially with internal Department partners such as the Bureau of Tobacco Free Florida to advertise the availability of free, in-home testing kits.

FIGURE 22: HIV SELF-TEST KITS DISTRIBUTED THROUGH KNOWYOURHIVSTATUS.COM, FLORIDA, 2020 vs. 2021



Additional funds will be needed to support and sustain the expansion of the in-home and point-of-care HIV testing program. Concerns around linkage to care for persons using HIV self-test kits exist and mechanisms will need to be developed to ensure appropriate follow up and timely linkage to care.

Partner Notification Services

Per section 384.26, F.S., the Department is the only entity authorized to perform HIV and STI partner services and notification, and these activities are carried out by trained DIS. While Florida maintains a mature and robust HIV/STI partner services program, opportunities to strengthen the DIS workforce and update partner notification mechanisms exist. Extensive training needs, high caseloads, and low staff retention not only contribute to high DIS turnover rates, averaging 40% annually over the past five years, but also impact the effectiveness of partner elicitation. Numbers of claimed partners have decreased as numbers of anonymous partners reported through mobile dating applications has increased, creating challenges for intervention. In 2017, the Department piloted the use of mobile dating applications as an added partner notification tool for persons exposed to HIV/STIs, with marginal success. Additional strategies are being explored to allow for HIV partner notification via text messaging or phone calls. Since summer 2022, the Bureau of Communicable Diseases has been working to secure approval to allow for text messaging by the DIS workforce as a tool to initiate confidential first contact with clients and enable DIS to conduct partner services for STI/HIV partner notification.

Florida is unique in that there are now four qualified staff to teach the week-long Passport to Partner Services training. In 2022, the STD Section will enter a contract with the University of South Florida to establish a learning academy and completely revamp the existing core training curriculum for DIS and STD program supervisors.

Billing and Reimbursement

In April 2013, the USPSTF gave routine HIV screening of all adolescents and adults, ages 15 to 65, an “A” rating, aligning the rating with the CDC’s HIV screening guidelines. The “A” rating has further implications given the ACA, which requires or incentivizes new private health plans, Medicare, and Medicaid to provide preventive services rated “A” or “B” at no cost to patients. Challenges exist with reimbursement by Medicaid for routine HIV screening in hospital EDs and some facilities report only being able to reimburse for those tests deemed medically necessary. As the state moves forward with expanding routine HIV screening in hospital EDs, more work is needed to ensure these facilities have the ability to bill and receive reimbursements from Medicaid for these screenings.

Billing third-party insurance was reported as a barrier to billing and reimbursement by almost one-third of providers assessed by UM-AETC and was the most prominent barrier encountered. Most clinics reported staff lack of knowledge regarding billing and coding and corporate decisions to be the greatest barriers to implementing routine HIV screening. Other notable barriers were lack of time and staffing capacity to perform billing, challenges in contracting with third-party payors, and difficulty managing multiple contracts with third-party payors.

Stigma

Stigma around HIV affects health care-seeking behavior. Stigma related to HIV/STI screening can occasionally lead individuals to state they do not possess insurance coverage for the service. Similar confidentiality concerns exist for young people who receive health insurance coverage through their parent or guardian (i.e., explanation of benefits). Fear of disclosure of confidential health information can deter youths and adults from seeking out HIV/STI screening and PrEP services. HIV testing locations that are associated with HIV/AIDS service organizations are also perceived as more stigmatizing, with clients citing additional disclosure concerns. There is a need for integration of HIV testing locations with other health care services and screenings to minimize stigma.

The MMP surveillance system also conducts a self-reported survey to understand the various types of stigmas PWH have experienced, including anticipated, enacted, and internalized HIV-related stigma using a 10-item scale ranging from 0 (no stigma) to 100 (high stigma) that measures four dimensions of HIV stigma: personalized stigma since HIV diagnosis, current disclosure concerns, current negative self-image, and current perceived public attitudes about people living with HIV. Analysis of the 2015–2020 Florida MMP data found that females (n=44) reported experiencing a higher level of stigma compared to males (n=32). Additionally, thirty-nine (n=39) transgender individuals reported experiencing stigma.

Thirty-seven (n=37) Black persons reported experiencing HIV-related stigma, compared to White (n=32) and/or Latino (n=32) survey respondents.

Thirty-eight (n=38) heterosexual people reported experiencing HIV-related stigma, compared to bisexual survey respondents (n=36).

Lastly, it was found that those ages 18–29 experienced a higher level of stigma (n=43) than ages 40–49 (n=36), and ages 30–39 (n=35). It was also found that ages 50 and higher experienced the lowest level of stigma (n=32).

Findings from a Department project with the University of Florida ⁴³ (a Bayesian spatial-temporal analysis of racial disparities in HIV clinical outcomes and a pilot stigma intervention protocol for people living with HIV in Florida) indicate that disparities in immune restoration and viral suppression vary by county. Identification of counties where these disparities are most severe provides useful information for the Department and other decision makers to reduce racial disparities in HIV clinical outcomes by implementing targeted interventions, with the ultimate objective of achieving HIV elimination goals in Florida. Stigma remains a key barrier to care engagement and ultimately achieving viral suppression and immune restoration. The preliminary work in this project outlines the development and validation of an updated measure of stigma, which could be implemented to better monitor stigma and its impacts, and an intervention to improve patient-provider communication about HIV-related stigma. The intervention was generally well received by participants and several potential routes of dissemination were identified.

4.2 TREAT People with HIV Rapidly and Effectively to Reach Sustained Viral Suppression

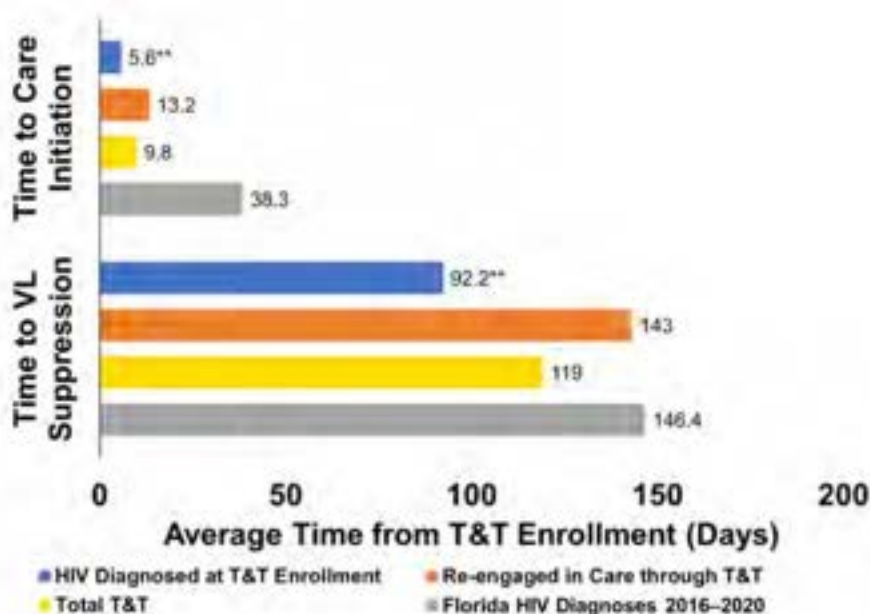
Access and adherence to HIV treatment is important to promote optimal health outcomes for PWH and harnessing the benefits of “treatment as prevention”—when someone takes their HIV medications as prescribed and the amount of HIV in the body is kept at such a low level, they reach viral suppression. Those virally suppressed essentially have no risk of sexually transmitting HIV to others. Treating PWH rapidly after diagnosis will help PWH to achieve and maintain viral suppression, which is part of the current HIV treatment guidelines and is a major pillar in EHE. According to the CDC, approximately 80% of new HIV transmissions occurring annually are from persons who are not receiving HIV-related care and medications. One issue is that the availability of treatments is not evenly accessible or distributed, compounding health disparities and the social determinants of health that fuel further transmission of HIV in the community. This represents a need for expanded access points, hours of operation (to include non-traditional hours and locations) and telehealth capabilities to reach persons with transport or other access issues. Other challenges exist around identifying and re-engaging PWH who are not in care to ensure medical adherence and viral suppression. All areas of the state have dedicated the Department’s linkage staff to not only link persons newly diagnosed with HIV but also identify PWH currently not in care and reengage them into HIV care and treatment.

Test and Treat Program and Rapid Access to ART

Since 2016, Florida has had a robust rapid access to ART program called Test and Treat (T&T). This program offers patients newly diagnosed with HIV, as well as those who have been lost to care and are returning to care, an opportunity to obtain expedited practitioner office visits, labs, and ART, combined with a support system of retention-in-care specialists, to reduce barriers to care engagement. In this

expedited “red-carpet” scenario, PWH have immediate access to a medical provider who can start them on ARV (antiretroviral) medications immediately. T&T has assisted in engaging individuals in care at a much faster rate than those not diagnosed through the program. Since the program’s inception, Florida’s T&T program has enrolled more than 7,374 clients statewide (comprising of 3,342 newly diagnosed individuals and 4,032 previously diagnosed individuals returning to care). Compared to persons diagnosed in Florida who are not enrolled in T&T (see Figure 23), it takes on average 38.3 days to initiate treatment compared to 5.6 days for those newly diagnosed through T&T. Furthermore, the average time to achieve viral suppression is much lower for those who initiate treatment rapidly through T&T—92.2 days compared to 146.4 days for those not engaged in T&T. Wider expansion and adoption of this strategy is needed to impact linkage, retention, and VL suppression rates. Almost all of Florida’s 67 counties have a HRSA-designated Health Professional Shortage Area (areas categorized as rural, partially rural, or non-rural), which represents a need to recruit and train more primary health care and dental service providers. Additionally, needs exist for expanded access points, hours of operation (to include non-traditional hours and locations), and expanded telehealth capabilities to reach persons in rural areas. There is also a need for increased access to treatment for persons diagnosed and living with co-occurring HCV/HIV.

FIGURE 23: TIME FROM T&T ENROLLMENT TO CARE INITIATION AND VL SUPPRESSION, MARCH 2016–DECEMBER 2020, FLORIDA



Below are activities that can help overcome the challenges related to T&T:

- Address gaps in the level of knowledge about the RWHAP system of care among non-RWHAP network health care providers. More education and training are needed for providers on the services available to clients (including ADAP), eligibility requirements, and access points in their service regions.

- Address the need for more training and resources for health care providers related to trauma-informed care (TIC) and intersectionality. Past and current traumatic experiences have an impact on whether a person acquires HIV, is diagnosed, is linked to care, is retained, and maintains viral suppression. Because HIV disproportionately impacts marginalized communities, it is important to consider intersectionality in concert with TIC.
- Intersectionality is a framework for conceptualizing a person, group of people, or social issue as affected by several discriminations and disadvantages; it considers people’s overlapping identities and experiences to better understand the complex prejudices they may face. Examples of social categorizations that inform identity include race/ethnicity, class, gender, sexual orientation, poverty and homelessness, and substance use.

Housing

Many Floridians experience homelessness or unstable housing, which presents a barrier to wellness for PWH as well as those at increased risk for HIV acquisition. Stable housing is closely linked with and is often one of the main determinants affecting HIV health outcomes. Florida’s Council on Homelessness annual report showed that prior to the emergence of the COVID-19 pandemic, homelessness in Florida has declined steadily from 57,551 identified as homeless in January 2010 to 28,328 in January 2020—a 50.8% reduction in homelessness over the last 10 years. In 2021, the Florida Housing Coalition reported Florida having the third-highest homeless population of any state in the nation, with 27,640 people living in homeless shelters and on the streets. It is important to consider the spectrum of housing instability for PWH—traditional definitions of homelessness or unstable housing—but also takes into account situations where individuals and families are residing in temporary residences (e.g., motels), staying with friends or family, or “couch-surfing.” While the federal Fair Housing Act makes it illegal to discriminate against PWH in the provision of housing, consumers frequently cite discrimination, fear of disclosure, and stigma as barriers to safe and affordable housing.³⁵

To meet the housing needs of low-income PWH and their families, the Department administers the HOPWA program. The HOPWA program is a federally-funded initiative through HUD that helps people with HIV/AIDS maintain stable housing and have access to treatment and support services—which can all lead to better health. In Florida, through the State HOPWA Program, 11 regional agencies and 6 cities deliver HOPWA-funded housing services. In addition to the state HOPWA Program, there are 6 non-state funded city HOPWA programs administered locally.

The Department oversees the state HOPWA program and contracts with local community organizations and CHDs as project sponsors to provide HOPWA services in 11 Ryan White Part B consortium geographical areas and six cities throughout the state. Six non-state funded cities redesignate their funds to the state for distribution and fund management by the state HOPWA program. However, the re-designated funds are to be spent in the Eligible Metropolitan Statistical Areas (EMSAs) on housing services in those areas, not the state at large. These cities (counties) include City of Palm Bay (Brevard), City of Cape Coral (Lee), City of Lakeland (Polk), City of Sarasota (Sarasota), City of Port Saint Lucie, (Saint Lucie), and City of Deltona (Volusia).

Additionally, six cities or EMSAs receive and retain management of HOPWA funds they receive directly from HUD; the Department does not manage the HOPWA programs for Jacksonville, Tampa, Orlando, West Palm Beach, Fort Lauderdale, and Miami-Dade. The Florida State HOPWA Program serves those areas of the state that do not directly qualify for HOPWA funding. Between 2020 and 2021, over 2,034 individuals received HOPWA services to ensure they could access and maintain a stable living environment for themselves and their immediate families. An assessment of the state's HOPWA program is needed to identify gaps and barriers in order to make changes to the program in 2023.

With EHE funding received directly through HRSA, RWHAP Part A programs are also exploring ways to leverage funds to assist with paying for housing and rental assistance for persons with HIV.

Patient and Peer Navigation

HIV health navigators (both patient and peers) have a positive impact on the health and well-being of people living with HIV. Patient navigation programs for persons newly diagnosed with HIV or those previously diagnosed and returning to care have consistently proven to be efficacious in ensuring individuals get linked to and are retained in treatment. The lived experiences of peers, “near-peers,” and community health workers are drivers for meeting the diverse needs of newly diagnosed individuals who may be overwhelmed by the thought of entering a health care system as complex as the HIV system of care. In addition, peer navigators act as a support line for persons newly entering or re-entering the care system, providing non-judgmental guidance. There is also a need for expanded patient or peer navigation among persons diagnosed with HCV. Expanded patient navigation is also needed for HIV-negative partners of PWH seeking services. Florida plans to establish and disseminate a statewide peer certification training program.

People with Co-Occurring HIV and Hepatitis C

The current opioid and crystal methamphetamine epidemics are fueling the number of co-infections. It is estimated that 60 to 90% of people who contracted HIV from intravenous drug use also have HCV.³⁶ People living with HCV often have difficulty accessing HCV treatment and related health care. In recent years, there have been improved HCV treatments that can cure HCV in as little as 8 to 12 weeks. ADAP clients living with HCV have access to assistance with HCV treatments. The ADAP formulary was updated in 2017 to include HCV treatments without the need for prior authorizations. Between 2020 and 2021, the ADAP assisted over 650 ADAP clients with access to HCV treatment supported by ADAP. There are opportunities for more uninsured HCV patients to be treated at some free clinics, FQHCs, private clinics, and a limited number of CHDs, but many patients are unaware of where to go when they are first diagnosed.

Expanded Pharmacy Benefits Manager (PBM) for Uninsured or Underinsured ADAP Clients

Clients enrolled in ADAP realize important health benefits. ADAP provides access to U.S. Food and Drug Administration (FDA)-approved medications to low-income individuals with HIV who have limited or no coverage from private insurance, Medicaid, Medicare, or the federally facilitated Marketplace®. About

53% of ADAP clients are uninsured or under-insured and receive medication assistance through the ADAP direct-dispense program. These clients receive assistance with approved ADAP formulary medications directly from the program's contracted pharmacy network. The remaining 47% of ADAP clients obtain access to ADAP formulary medications through supported health insurance plans. These clients are enrolled in the ADAP insurance program and receive assistance with insurance premiums as well as prescription co-pays and deductibles associated with ADAP formulary medications. The ADAP aims to achieve at least 95% of clients who achieve viral suppression regardless of their insurance status. For those in the ADAP insurance program, approximately 97% achieved viral suppression in 2021; however, for those enrolled in the ADAP direct-dispense program, there is a clear disparity with only 89% achieving viral suppression in 2021.

In October 2022, ADAP implemented a PBM network of pharmacies to its uninsured direct-dispense client population. With this initiative, ADAP will increase equity among insured and uninsured clients by providing expanded access to medications through a network of independent pharmacies and commercial chains. The PBM will provide the network of 340B pharmacies and manage the claims using a replenishment model in which direct-dispense clients can access ADAP medications statewide with the main goal of increasing access points and convenience for ADAP clients in Florida. The PBM pharmacy network will ensure access to ADAP formulary medications for enrolled clients served in the direct-dispense in 24 hours. ADAP eligibility files are shared with the contracted PBM entity multiple times throughout the day to ensure newly enrolled clients can access ADAP services during the same day they enroll in the program. The PBM entity will assist clients with their prescriptions by reviewing use data, addressing medication adherence issues, and collaborating with prescribers to resolve incorrect regimens and drug interactions. The PBM entity will also develop and provide training to case managers and health care providers, develop educational materials for providers and clients, and maintain a program information website for providers and clients.

Case Management

Case management plays a critical role in the care coordination of PWH as it assists patients in accessing services, identifying needs, and addressing gaps in services. Case managers also perform important functions such as ensuring rapid access to ART; providing medication samples, where appropriate and feasible; and determining eligibility and enrollment into services. Case manager caseloads are high and continue to increase, impacting the ability to effectively manage complex issues, such as providing medication adherence counseling, helping navigate the health care system, and staying informed and educating PWH on available health care coverage plans. There is a need for additional resources and training to support the case management workforce.

Injectable ART

In May 2021, Florida's ADAP added Cabenuva, the first long-acting injectable antiretroviral to the formulary. Uninsured and insured clients are able to access the medication with coordination between their practitioner's office and a specialty pharmacy. The program provided a series of technical

assistance presentations to providers, staff, and case managers to increase awareness and provide best practices for client adherence. Over 500 ADAP clients have accessed Cabenuva since its addition to the formulary in 2021.

Minority AIDS Initiative (MAI)

As shown in Figure 5 (Section 3.1), Florida continues to experience disparities in HIV diagnoses among adults, despite an annual decrease in the HIV diagnosis rate among Black persons in the past five years. MAI seeks to address the gaps in medical care capacity and increase the accessibility and availability of HIV medical care and related HIV services in minority communities through outreach and education. MAI funds are received from HRSA and are designed to improve linkage and reengagement to comprehensive care and ADAP for low-income racial and ethnic minorities who are living with HIV/AIDS. The Department receives the MAI funding allocation through the state's RWHAP Part B grant and these funds support six community-based providers in Florida counties with the highest HIV incidence. In FY 2021, Florida's funded MAI providers enrolled 1,033 clients, of which 64% were Black and 32% were Hispanic/Latino, a 28% increase from the previous fiscal year which saw 806 clients enrolled, of which 62% were Black and 31% were Hispanic/Latino. Many participants are individuals who had a previous HIV diagnosis but have fallen out of care and have not received care for more than six months. The Department's HIV/AIDS Section will continue to look for ways to strengthen the network of MAI providers with the development and release of the next funding solicitation.

Correctional Settings Initiatives

The Department continues to support treatment and prevention services for incarcerated individuals living with HIV. Persons with HIV in prisons and jails are disproportionately represented compared to the general population. The Department addresses this through the following corrections initiatives: the Pre-Release Planning Program (PRPP), the Peer Education Program (Peer-Ed), and Jail Linkage Programs (JLP). The Department maintains two interagency agreements with the Florida Department of Corrections (FDC) to provide PRPP and Peer-Ed.

JLP is concentrated in the higher populated metropolitan areas in Florida. Fourteen CHDs work to provide services to at-risk inmates and PWH inside the county jails. JLP functions include HIV testing and education in the facility, linkage to care following release from jail, linkage to support services, and follow up with individuals for up to three months following release to ensure medication and treatment adherence. In 2021, approximately 1,755 inmates were tested for HIV, of whom 31 had a positive result.

PRPP provides services to inmates with HIV who are preparing to return to their communities. In 2021, the PRPP provided linkage services to 644 inmates, of whom 305 were linked to care and 160 (52%) kept their appointments upon returning to their community. Recidivism, housing, and transportation are recurring barriers to recently released individuals accessing medical care. In addition, FDC conducts peer education train-the-trainer programs for select inmates at FDC's Central Florida Reception Center and Florida Women's Reception Center (the two largest reception centers in the state). In 2021, 53 inmates completed training to become inmate peer educators and conducted 146 peer-led HIV/STD prevention

and risk-reduction sessions to approximately 5,170 inmates. As a result of the peer education training session, 266 inmates requested an HIV test upon completion.

Expansion of Telehealth

The HIV/AIDS Section began offering telehealth (TH) services in January 2018. The TH program provides on-demand and scheduled PrEP, PEP, same-day or rapid ART and HIV and STD primary care evaluation and treatment visits. The HIV TH service is available to all 67 CHDs. As of May 2021, the Department is averaging over 100 services per month and has provided TH services to 1,604 CHD patients. In 2020, the Department launched a TelePrEP program where patients can access PrEP services through the CHD system via a dedicated telehealth practitioner team. Further credentialing of the HIV TH team of three providers in other CHDs is occurring to allow for these services to be provided by the team. Florida plans to expand and promote the use of telehealth and other new technologies to help alleviate barriers and improve access to HIV prevention and care services.

Insurance Coverage and Affordable Health Care

Florida remains a non-Medicaid expansion state and from 2015 to 2020, an average of 12.7% of people in Florida did not have health insurance coverage (compared to 8.7% for the U.S.).³⁸ The ACA has enabled more individuals to enroll in health insurance but some, particularly those who live just above the federal poverty level (i.e., the working poor), are still unable to afford the cost of coverage. Individuals who fall into this category and need health care are often forced to make difficult choices based on competing life priorities.

As a Part B grant recipient through the RWHAP HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87), the Department administers the ADAP program. Florida ADAP provides FDA-approved medications to low-income PWH between 0 and 100% FPL who have limited or no health coverage from private insurance, Medicaid, or Medicare. ADAP assists with some premiums and with out-of-pocket costs for drugs on the program formulary. Out-of-pocket costs can be deductibles, co-pays, coinsurance, or similar costs for Medicare Part C or D. Health insurance assistance funded through ADAP is part of ADAP, not a separate program. ADAP provides premium assistance for ACA Marketplace® plans for people with HIV whose income is between 75 and 400% of the FPL. The strategy of enrolling these clients in the direct-dispense program is more cost-effective than enrolling them in the insurance program. Clients in the direct-dispense program have access to the RWHAP system of care, which includes access to outpatient ambulatory health services, case management, and other allowable services. ADAP clients enrolled in the direct-dispense program achieved a VL suppression rate of 89%.

In addition, approximately 93% of ADAP clients enrolled in the program for at least six months have undetectable HIV VL, indicating their HIV disease is under control and unlikely to be spread sexually. The ADAP program aims to achieve at least 95% of clients enrolled in the program at least 6 months who achieve viral suppression regardless of their insurance status. For those in the insured program, approximately 98% achieved viral suppression in 2021, however, for those not insured, there is a clear disparity with only 89% achieving viral suppression in 2021. The approach that Florida ADAP takes

constitutes a close working relationship between the ADAP state health office team, Florida’s 67 CHDs, and 3 contracted statewide service providers: CVS Caremark for PBM services for ADAP insured clients, Magellan Rx for PBM services for ADAP uninsured and underinsured clients and Broward Regional Health Planning Council for Insurance Benefits Management (IBM) services for clients seeking enrollment and premium assistance with health insurance coverage. The Department’s ADAP is operationalized at the CHDs, where ADAP staff assist clients with enrollment by ensuring eligibility determinations and re-certifications. ADAP staff at CHDs use the ADAP database, called Provide, to upload client eligibility documentation. Eligibility files are shared with the contracted PBM and IBM providers multiple times throughout the day to ensure newly enrolled clients can access ADAP services during the same day they enroll in the program. Provide also helps ADAP staff keep track of their client caseload; the system helps identify clients who should be enrolled in the direct-dispense or insurance program based on the information presented during their enrollment. CHD ADAP staff also work closely with the provider community and RWHAP case managers to coordinate efforts with clients to promote medication adherence and retention in care.¹⁶

Additional Unmet Needs of Persons with HIV

Further work is needed to address the unmet needs of PWH identified through various mechanisms—including needs assessment surveys and Florida’s MMP project. The MMP is a surveillance system designed to understand the met and unmet needs of PWH. Among those surveyed in Florida from 2015 to 2020, the most common unmet need was access to dental services (24%), followed by shelter or housing services (14%), SNAP or WIC (12%), and meal or food services (9%). Other unmet needs included mental health services (8%) transportation assistance (8%), HIV case management services (8%), HIV peer group support (6%), medicine through ADAP (4%), and patient navigation services (5%).

4.3 PREVENT New HIV Transmissions by Using Proven Interventions, Including PrEP and Syringe Services Programs (SSPs)

Access to PrEP and PEP

The use of ARV medications to prevent HIV transmission in persons at risk for acquiring HIV is an effective prevention tool. Part of CDC’s HIP approach includes PrEP; in 2014, CDC issued clinical PrEP guidelines for health care providers. CDC recommends PrEP as a prevention tool for persons at increased risk for HIV: persons in sero-different relationships, gay and bisexual men who have sexual partners of unknown HIV status, and PWID. As of December 2018, the Department’s CHDs in each of Florida’s 67 counties are providing PrEP services (counseling, medications, follow-up testing) with support from state funding. CHDs provide PrEP primarily through the STI and family planning clinics and medication is provided at no cost to the client (repeatedly) through the state’s supply of medication. Since the launch of the Department’s PrEP drug assistance program in 2018 over 11,319 CHD clients have received PrEP medications. Current challenges to PrEP delivery through the CHDs include clinician

and staffing shortages and limited capacity for clinicians in smaller CHDs (e.g., fewer clinicians performing multiple duties in the clinic).

The Department’s publicly funded PrEP drug assistance program only accounts for a small portion of all PrEP services statewide. Numerous private-sector partners—including private physicians, FQHCs, community health centers, sexual health clinics, community-based organizations, HIP providers—are screening, prescribing, and maintaining people on PrEP throughout Florida. Also, over the past two years, HRSA has funded approximately 22 FQHCs through their EHE Primary Care HIV Prevention funding opportunity for health centers to expand access to medication to prevent HIV (including PrEP and related services), connect people to care, and ensure care services are well coordinated. According to the latest data available on AIDSVu, Florida has seen an increase in the rate of PrEP users per 100,000 population since 2016; as of 2021, the rate was 226 per 100,000. Florida now ranks third among states and jurisdictions with the highest rate of PrEP users, behind Washington D.C. and New York. PrEP data from AIDSVu reflect the number of people prescribed PrEP in a calendar year. AIDSVu uses data from a database that contains anonymized individual-level prescription records collected electronically from U.S. retail pharmacies, traditional pharmacies, specialty mail-order pharmacies, long-term care facilities, and other pharmacies (e.g., in-hospital pharmacies, HMO pharmacies).⁴⁹

Disparities in the uptake of PrEP and PEP still exist among key priority populations (e.g., Black, and Hispanic males and females, and transgender individuals). Taking a sexual history and discussing sexual health with patients should be a routine practice for primary health care providers; however, limited time for office visits and the reluctance of some providers to discuss sex with their patients presents barriers to routinization. There is a need for increased access to PrEP services in non-traditional settings and through innovative practices. PrEP delivery via telehealth (or “TelePrEP”) was recommended by community groups, clients, and providers as a mechanism by which people facing transportation and employment barriers could access PrEP and increase adherence to follow-up testing. Partnerships with retail pharmacies and clinics and through mobile applications may assist in bridging gaps in PrEP and PEP access. In 2020, by leveraging the existing state telehealth practitioner team, the Department launched a TelePrEP program where patients can access PrEP services through the CHD system.

Currently, federal funding requires the implementation of PrEP and PEP services but does not allow states to allocate funding for medications and limitations for covering associated clinical costs exist. While there are patient assistance programs available to offset the cost of medications, medical visits, and lab testing costs still pose a significant barrier to already disproportionately impacted populations. Clients receiving PrEP have reported that returning every three months for follow-up testing is a barrier to remaining adherent; and in rural and semi-rural areas of the state, transportation to follow-up medical appointments can present further challenges. Clients also cited the cost of medical visits and lab tests and not being able to get time off from work for appointments as barriers to PrEP initiation and maintenance. As a result, more clinics and pharmacies have started to offer non-traditional and after-hours services to increase access to PrEP and PEP. In late December 2021, Apretude (cabotegravir extended-release injectable suspension) received FDA approval for HIV PrEP. Injectable PrEP provides a new option to prevent HIV that does not involve taking a daily pill—which for some people presents

challenges. In summer 2022, the Department initiated a pilot project to test the feasibility of delivering Apretude through CHD clinics. Three CHD clinics (Alachua, Hillsborough, and Miami-Dade) were chosen to participate in the pilot project and represent geographic areas with varying HIV incidence.

In 2019, the USPSTF issued a Grade A recommendation for offering PrEP with effective antiretroviral therapy to persons at increased risk of HIV acquisition. Under the ACA, most private insurance plans must cover preventive services with an “A” or “B” recommendation from the USPSTF without copays or deductibles. This means that at least one PrEP option should be available at no cost to qualifying individuals on these plans.

Increased public and private partnerships are needed to fill gaps in access to PEP services. Many CHD clinics have traditional hours, making them ill-suited as delivery points. Access to PEP is needed quickly after exposure to HIV (in 72 hours) to prevent seroconversion. Clients requesting PEP tend to do so more often during evening hours and weekends. Partnerships with retail pharmacies, rape crisis centers, and sexual assault nursing teams in hospital EDs are needed to expand access points to PEP.

Substance Use Disorders, Syringe Service Programs, and Health Care Access

The past-year prevalence of substance use disorders among adults in Florida was 14.8% in 2019–2020, and the prevalence of needing but not receiving treatment for substance use was 7.5%. According to the Florida Association of Managing Entities, 5,117 adults were added to a waitlist for substance use services in FY 2020–2021.⁵⁰

The most recently published prevalence rates for various substances and substance use disorder among young adults (ages 18–25) and adults in Florida are presented in Table 9 below:

TABLE 9: PREVALENCE OF SUBSTANCE USE AND SUBSTANCE USE DISORDER IN THE PAST YEAR, IN FLORIDA BY ADULT AGE GROUP (2019–2020)

	18 and Older	18–25	26 and Older
Marijuana Use	16.6%	32.9%	14.5%
Cocaine Use	1.7%	4.4%	1.4%
Methamphetamine Use	0.6%	0.6%	0.6%
Heroin Use	0.2%	0.1%	0.2%
Prescription Pain Reliever Misuse	3.6%	4.8%	3.4%
Alcohol Use Disorder	9.5%	13.6%	9.0%

According to FDCF, 2020 Florida Youth Substance Abuse Survey State (FYSAS) report, substance use among students in Florida continues to decline. Among middle and high school students in Florida, between 2010 and 2020, the prevalence of lifetime alcohol use decreased from approximately 52% to 35% and the past-30-day prevalence of alcohol use decreased from 29% to 15%. Regarding marijuana use, the prevalence of lifetime and past-30-day marijuana use among middle and high school students also decreased between 2010 and 2020. Lifetime prevalence decreased from approximately 24% to 20% and past 30-day prevalence decreased from 13% to 11%. According to estimates from the 2022 FYSAS, among high schoolers the lifetime prevalence is 2.8% for opioid misuse, 4.1% for stimulant misuse, and 5.7% for opioid and stimulant misuse.⁴⁵

Section 381.0038(4), F.S., or the Infectious Disease Elimination Act (IDEA), was passed by the Florida Legislature in 2016 and in 2019, the Governor signed a bill amending IDEA to allow county commissions to authorize syringe exchange programs in their county by way of county ordinance. The IDEA legislation mandates that SSPs operate a one-to-one exchange; provide or make referrals for HIV and HCV testing; provide access to substance use prevention, education, and treatment; and provide emergency opioid antagonist kits (naloxone kits). A CDC Determination of Need for Florida for SSPs was approved on February 1, 2020. The CDC Determination of Need supports federal funding applications for SSPs and other organizations. In Florida, there are five approved and currently operational SSPs: IDEA Exchange Miami (located in Miami-Dade County) operated by the University of Miami Miller School of Medicine, the SPOT (in Broward County) operated by Care Resource, the Rebel Recovery SSP (in Palm Beach County) implemented by Rebel Recovery FL, IDEA Exchange Tampa (in Hillsborough County) implemented by Tampa General Hospital and the University of South Florida, and IDEA Orlando (in Orange County) implemented by Hope and Help. An SSP in Pinellas County will be opening their doors in 2022.

Apart from federal funds, grants and donations are the only authorized funding sources for SSP operations in Florida. The five currently operating SSPs receive funding for harm-reduction supplies and services from private grants, donations, and foundations. FDCF donates naloxone nasal spray kits to the SSPs. All sites report that the biggest barrier to effective implementation and operation of their program is funding for harm-reduction supplies. Current funding is inadequate to support the foundational operation of the exchanges, with one site reporting continuous supply shortages that have led to the SSP closing on certain days of the week at a time when the program was experiencing rapid growth.

Since the inception of FDCF's Overdose Prevention Program, the five operational SSPs have distributed over 30,000 naloxone kits and reported 5,602 reversals or rescues. About 29% of all reversals reported to FDCF are through the SSPs. Supplying SSPs with naloxone kits therefore remains a top priority. As other harm-reduction organizations, recovery community organizations, and peer networks, expand and evolve in ways that engage and maintain relationships with the hardest to reach, most at risk individuals in their communities, they should also receive priority support for naloxone distribution. Additionally, in March 2022, the Florida Harm Reduction Collective (FLHRC) established a mail-based naloxone distribution program. The FLHRC comprises of recovery community organizations, overdose prevention programs, SSPs, CBOs, and other stakeholders working to decrease the harms of drug use and eliminate

the stigma associated with harm-reduction. Since March 2022, FLHRC has distributed 1,482 naloxone kits and received 104 reports of overdose reversals through their mail-based naloxone distribution efforts.

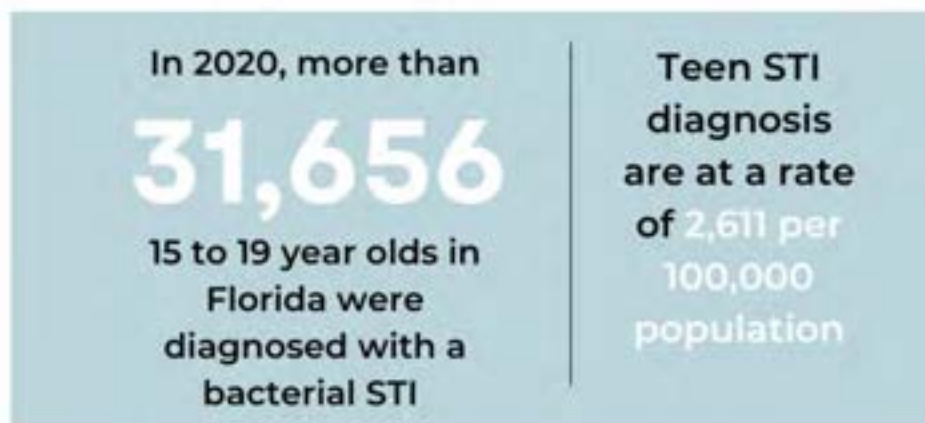
Florida's overdose epidemic continues to pose a considerable challenge that the Department addresses through surveillance, prevention, education, and policy efforts. The Florida Overdose Data to Action (OD2A) program has a direct connection to the State Health Improvement Plan and the Department's Strategic Plan. The Department also recently launched an initiative to make naloxone kits available at all 67 CHDs. In 2021, as part of the nationwide opioid litigation undertaken by more than a dozen states, Florida was able to secure more than \$1 billion in settlement funds which will be used to support prevention, treatment, and recovery related services.

The Department supports the IDEA Exchange Miami to provide training and technical assistance to new SSPs, as well as education to local communities on the evidence behind SSPs in the prevention of HIV, HCV, and overdose. Another project, supported by the congenital syphilis grant routinely screens women who inject drugs for HIV and syphilis to reduce the likelihood of babies born with congenital syphilis and link women to treatment and care. Lastly, we will create tangible and measurable steps in addressing viral hepatitis statewide by developing a robust hepatitis elimination plan. We will focus on priority populations disproportionately affected by hepatitis A, B, and C through improving access to prevention, diagnosis, and treatment and increasing vaccination among those priority populations. Also, we will increase access to medication-assisted therapies and linkage to HCV treatment among PWID.

During FY 2021–2022, FDCF deployed HIV Early Intervention Services set-aside funding from the SAMHSA Substance Abuse Prevention and Treatment Block Grant to conduct 18,313 HIV tests across 47 treatment provider sites. A total of 163 tests were positive for HIV.

Comprehensive Health Education and Interventions for Youth

In 2020, more than 31,656 persons between 15 and 19 years of age in Florida were diagnosed with a bacterial STI (syphilis, chlamydia, gonorrhea), for a rate of 2,611 per 100,000 population as shown in Figure 24. These numbers are down slightly from previous years due to the lack of testing and access to testing during the COVID-19 crisis. The presence of an STI increases a person's risk of acquiring HIV. The teen birth rate in Florida has decreased by 59.7%, from 37.2 per 1,000 population in 2009 to 15.0 per 1,000 population in 2020. Of the 4,708 HIV diagnoses in Florida in 2021, 13% (634) were among 13 to 24-year-olds, of whom 53% were Black, 33% were Hispanic/Latino, 12% were White, and 2% were multiracial/other. Most youth diagnoses were attributed to sexual contact, with only 2% attributed to other risks. Of the 2,678 young PWH in Florida in 2021, 67% had a suppressed viral load (versus 69% for all PWH in Florida).

FIGURE 24: TEEN STI RATES

Section 1003.42(2)(n), F.S., requires comprehensive health education that incorporates disease prevention and includes language on the benefits of sexual abstinence and the consequences of teenage pregnancy. Additionally, section 1003.46, F.S., allows school boards to include additional instruction regarding HIV/AIDS. Such instruction may include information about “means used to control the spread of [AIDS].” As outlined in section 1003.42, F.S., parents may submit a written request to the school principal to exempt their child from “the teaching of reproductive health or any disease, including HIV/AIDS, its symptoms, development, and treatment.” Specific content in any subject matter is determined by local school district policy, which gives districts the latitude to determine the type of education program that is implemented. Florida plans to look for alternative settings in which to provide HIV education to youth such as recreation centers, after-school programs, faith-based programs, youth coalitions, and juvenile justice facilities.

Perinatal HIV Prevention Efforts

Perinatal transmission of HIV is when HIV is passed from a woman with HIV to her child during pregnancy, childbirth, or breastfeeding. The use of HIV medicines and other strategies have helped to lower the rate of perinatal transmission of HIV to 1% or less in the US and Europe.³⁷ In Florida, the Department is actively managing the following perinatal HIV initiatives:

- Targeted Outreach for Pregnant Women Act (TOPWA)** – Section 381.0045, F.S., also known as the “Targeted Outreach for Pregnant Women Act of 1998” provides a state funding appropriation for programs to provide outreach and linkage services to pregnant women who may not seek proper prenatal care, who suffer from substance-use disorders, or who are living with HIV or are at increased risk for HIV acquisition. TOPWA providers serve pregnant women who are HIV negative and those living with HIV to ensure they are linked to and receive adequate prenatal care and adhere to medical treatment to prevent perinatal transmission. There are seven funded TOPWA programs in Florida and they provided services to 1,772 clients in 2021. Black females represented 45% of enrollees, Hispanic females represented 44%, and White females represented 7%. Females living with HIV made up just under 8% of TOPWA enrollments.

- **Fetal Infant Mortality Review (FIMR)/HIV Prevention Methodology** – The Department is developing a FIMR/HIV Prevention Methodology in conjunction with a Community Action Team. These efforts are part of a larger effort the Department is undertaking to reduce communicable diseases in WCBA to include congenital syphilis, HBV, and HCV.
- **Baby Rxpress** – The Department’s Baby Rxpress program provides a six-week course of ARV medication to newborns with HIV exposure, lowering the risk of mother-to-child HIV transmission to less than 1%. In 2020, Baby Rxpress filled 344 prescriptions for ARV medications for 256 newborns with HIV exposure at a cost of \$13,556.00, or just under \$53 per baby. Baby Rxpress maintains over 85 participating pharmacies across the state. Participating partners include Empath Health Pharmacy, Health Matters Pharmacy, Walgreens Co., Jackson Pharmacy (three specialty locations), Scripts Pharmacy, and Jackson Drugs.

HIV High-Impact Prevention (HIP) Provider Network

In early 2019, the Department made awards for HIP Request for Applications (RFA) 18-001. HIP RFA 18-001 was released in fall 2018 and provided non-profit organizations an opportunity to apply for funding provided by the Department through the state’s integrated HIV prevention and surveillance grant. A total of \$10 million from this grant was allocated and 44 awards were made to organizations throughout the state that serve Florida’s priority populations. Three-year contracts were executed beginning January 1, 2019, and ending on December 31, 2021, with the option for up to three, one-year renewals. These awards have the ability to be continued through December 31, 2024.

Funded HIP providers deliver a wide array of services, depending on the category of funding and includes, but are not limited to, routine and prioritized testing; integrated STI screening, linkage and reengagement to prevention and care services; interventions for PWH and persons at increased risk of acquiring HIV; PrEP and PEP services; condom distribution; outreach, education, and community engagement; social media and marketing; and essential support services.

In 2021, a total of 12,281 PWH received risk-reduction interventions through contracted HIP providers. Of the PWH receiving risk-reduction interventions, 39.5% identified as MSM, 29% identified as heterosexual males, 28.7% identified as heterosexual females, and 2.8% identified as transgender. Interventions for PWH include Partnership for Health, CLEAR, ARTAS, Healthy Relationships, Connect, Peer Support, and personalized risk-reduction counseling.

Forty-one of the 44 funded HIP providers deliver PrEP screening and referrals and 16 of the providers are able to prescribe for PrEP onsite. In 2021, approximately 42,138 clients of HIP providers were found to be eligible for PrEP services, and, of those, 24,562 were referred for PrEP services and 1,211 were prescribed PrEP.

Risk-reduction interventions for HIV-negative persons at increased risk for acquiring HIV are also delivered by contracted HIP providers. In 2021, a total of 16,235 HIV-negative persons received risk reduction interventions through contracted HIP providers and of those, 43% identified as heterosexual

females, 38% identified as heterosexual males, 18% identified as MSM, and 1% identified as transgender. Interventions for persons with a negative or unknown HIV status include VOICES, CLEAR, Social Network Strategy, Mpowerment, Popular Opinion Leader, Personalized Cognitive Counseling, RESPECT, Community PROMISE, HIV and STD educational sessions, and personalized risk reduction counseling services.

HIP providers are also required to screen clients and refer them to essential support services to assist with housing, transportation, mental health, substance use disorder, and other barriers to care. In 2021, HIP providers screened 51,306 clients for essential support services; 21,224 were referred to services and 2,032 were linked to essential support services.

HIV Minority Media Campaign

In 1999, the Department established a statewide minority media campaign for HIV prevention, as required by section 381.046, F.S. This campaign was most recently rebranded in 2017 with the theme “Protect Yourself.” In 2020, the campaign evolved to include the stories and testimonials of real individuals from Florida impacted by HIV. Figure 25 provides an example of how the Protect Yourself campaign images were used.

FIGURE 25: PROTECT YOURSELF CAMPAIGN IMAGE



The Protect Yourself campaign is implemented across all industry standard platforms including broadcast radio and television, digital and mobile advertising, out-of-home advertising (billboards, bus stops), a dedicated website, social media, and public outreach events. The Department works with local areas to supplement media buys as applicable. The Department updates the campaign annually with input from local and statewide advisory and work groups. During COVID-19, the HIV media campaign was instrumental in getting out social media messaging and website content to populations at risk for or living with HIV. More recently, the HIV media campaign was used to quickly disseminate information and messaging for HIV priority populations related to hepatitis A, meningococcal disease, and Mpox virus. Moving forward, the Department plans to broaden the scope of the campaign to address syndemics (STIs, viral hepatitis).

As previously discussed in Section 2.5, the Department announced its endorsement of the Prevention Access Campaign’s U=U in June 2020. In becoming a U=U partner, the Department joined nearly 1,000 organizations around the world supporting the science-backed message that PWH who use antiretroviral

therapy and have an undetectable viral load in their blood have effectively no risk of sexually transmitting HIV.

4.4 RESPOND Quickly to Potential HIV Outbreaks to Get Needed Prevention and Treatment Services to People Who Need Them

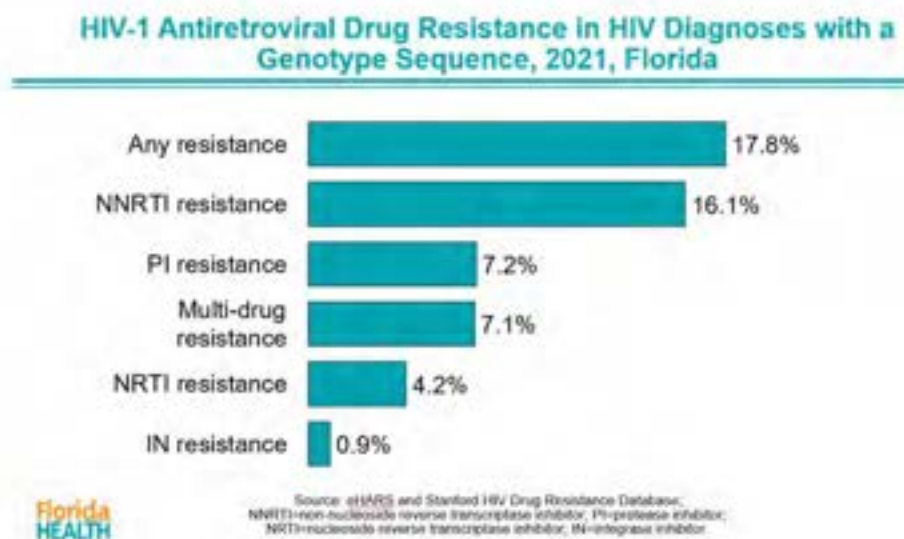
Cluster Detection and Response Plan

The Department is actively conducting surveillance and investigation for HIV clusters. The Department routinely conducts monthly analysis to detect rapidly growing molecular clusters and time-space clusters of public health significance. Additionally, a state level cluster review committee is convened monthly to review cluster data, discuss challenges, and brainstorm strategies to improve the statewide response. Since fall 2021, the state health office has established routine communication with CHDs experiencing clusters to coordinate and guide local responses to investigate and respond to clusters. Florida's updated HIV Cluster Detection and Response plans were submitted to CDC in fall of 2021 and will be updated in 2023. The Department's Bureau of Communicable Diseases plans to engage community stakeholders in further development of the cluster detection and response plan and will accomplish this through the FCPN and associated workgroups, RWHAP partners, and other stakeholders.

Increase Receipt of Genotype Test Results

As the number of analyzable HIV-1 genotype sequences reported to the state has decreased and the number of physicians ordering those tests has also decreased, the Department will enhance physician capacity to order genotype testing for those newly diagnosed or those not on ART returning to care. Figure 26 breaks out resistance type with a genotype sequence.

FIGURE 26: HIV-1 ANTIRETROVIRAL DRUG RESISTANCE IN HIV DIAGNOSES WITH A GENOTYPE SEQUENCE 2021, FLORIDA



The Department is engaging laboratories to improve the completeness and timeliness of electronic laboratory reporting of all reportable HIV lab results including genotype consensus sequences used in transmission network analyses. To increase the receipt of genotypes test results, the Department and its partners are:

- Developing a protocol with the Department’s Bureau of Public Health Laboratories to facilitate access to HIV genotype testing.
- Engaging and educating providers on current HRSA recommendations to order baseline genotypes for newly diagnosed and those returning to care and increase understanding of clinical and epidemiological importance of these tests.
- Educating providers and laboratories on statutory reporting requirements for HIV.
- Educating provider population on response and genotype testing.
- Creating a health care provider letter demonstrating the importance of genotype testing.
- Collaborating with the University of Florida to conduct focus groups on molecular surveillance.
- Conducting laboratory survey on current types and volume of HIV testing in Florida.
- Conducting provider survey on current test ordering strategies.
- Creating of a laboratory report card for laboratories and providers to facilitate improvements.

Data to Care (D2C)

HIV is a reportable disease where routinely collected surveillance data are used as a strategic tool to trigger HIP activities. The D2C initiative is a HIP activity that relies on the use of surveillance data to generate lists of persons living with HIV not in care in Florida. Linkage services are offered to those not receiving treatment by connecting them with HIV care. Florida is a high-morbidity state that has implemented a statewide D2C program since 2015, with the goal of reaching individuals who were not linked to HIV care in one month of diagnosis or if not virally suppressed and part of an HIV transmission cluster and network. In partnership with the six RWHAP Part A programs located in the seven EHE counties and through funding received by Georgetown University, the Department is embarking on a data sharing effort to improve linkage to HIV care for persons out of care in those jurisdictions. Enhancing and expanding on the prioritization of D2C activities by focusing on priority populations that need linkage to care, for example, homeless persons, non-White minorities, non-U.S. born, and persons who inject drugs are populations with the highest rate (>21%) of being out of care (no care in the past 12 months) in 2021, compared to the state (20%). Furthermore, males with IDU, Black men, and persons aged 13 to 39 are populations with the lowest percentage of viral suppression rates (<68%) in 2021, compared to the state (69%). The Department is also increasing linkage-to-care staff training to promote diverse community wellness.

Education and Outreach

As part of the ongoing efforts to respond to HIV transmission clusters and outbreaks, the Department collaborates to provide education, outreach, and community engagement with Floridians at risk for HIV or currently living with HIV, informing them of available HIV prevention and treatment options and

other resources in their area. The Department will complete the following activities to improve awareness of HIV-related services and cluster detection and response actions:

- Generate an annual surveillance summary detailing the community-level response to transmission networks in areas of high HIV burden.
- Create and develop education materials to improve awareness and reduce anxiety surrounding HIV transmission network response activities citing standard public health practice.

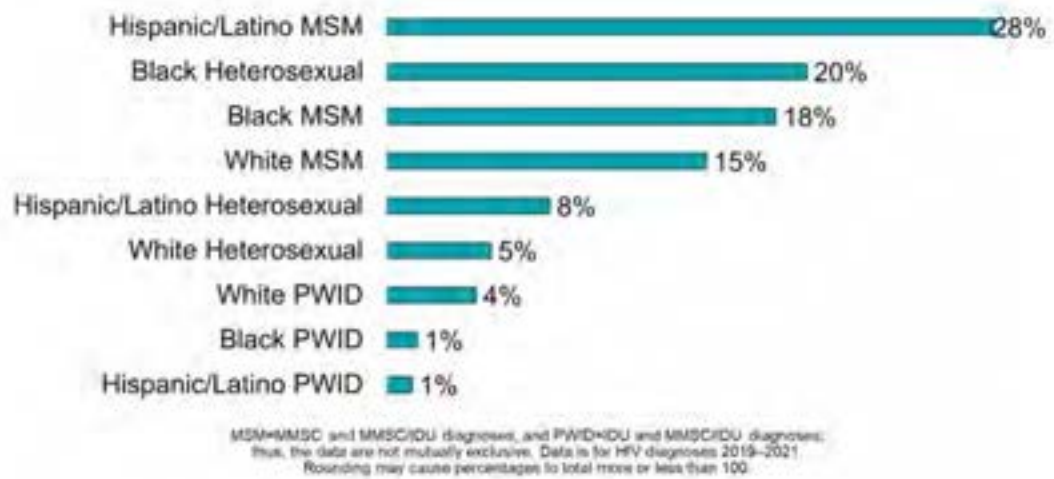
Additionally, several of the RWHAP Part A jurisdictions receiving EHE funding from HRSA have purchased mobile medical units to improve their ability to take services and education to populations and communities.

HIV Criminalization

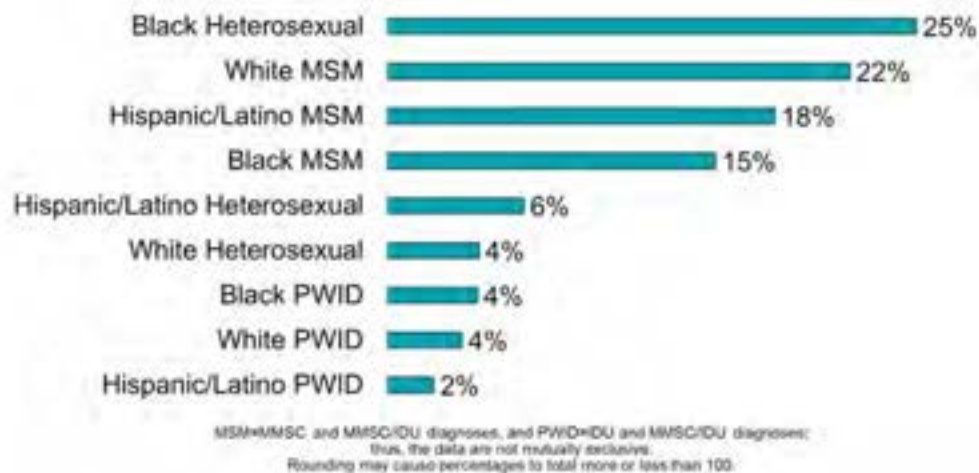
While molecular HIV surveillance (MHS) cannot determine the directionality of disease transmission, it remains a public and community concern that MHS data could be used in criminal transmission prosecutions. An often-required aspect of criminal prosecutions is the “intent to transmit” disease, which cannot be presumed through molecular surveillance or epidemiologic data. However, the ability to use these data in a criminal prosecution poses a threat to community buy-in of routine public health surveillance practices and the use of these data for improving HIV detection and prevention efforts.⁵⁴ In October 2022, the President’s Advisory Council on HIV/AIDS convened and developed recommendations related to MHS such as: local adaptations of MHS must be responsive to the needs in a given jurisdiction based on reviews of state and local HIV criminalization laws; establishment of community advisory boards focused on MHS and cluster detection and response; and plain language notifications be available to PWH about the types of surveillance being conducted and safeguards in place to protect access to and usage of those data. Education to the community at-large is needed on the recent advancements in biomedical interventions, since PWH on medication and virally suppressed (i.e., U=U) have effectively no risk of transmitting the virus to others through sex.

4.5 Priority Populations

Priority populations for primary HIV prevention are derived from the average proportion of each of the race and mode of exposure groups diagnosed with HIV in the last three years (2019–2021). This information is used to address those at the highest risk of acquiring HIV and with the greatest need for primary prevention services (i.e., services directed toward people who have a negative or unknown HIV status). As shown in Figure 27, the top five priority populations are Hispanic/Latino MSM (28% of new diagnoses over the past three years), Black heterosexuals (20%), Black MSM (18%), White MSM (15%), and Hispanic/Latino heterosexuals (8%).

FIGURE 27: PRIORITY POPULATIONS FOR PRIMARY HIV PREVENTION, FLORIDA, 2021

Priority populations for secondary prevention for PWH represent the proportion of each of the race and mode of exposure groups to the total PWH. Secondary HIV prevention activities are directed toward people with HIV, with the intention of preventing transmission to those who are HIV negative. This information is used to prevent HIV transmission through services provided to PWH in these affected demographic groups. As shown in Figure 28, for 2021, the top priority groups include Black heterosexuals (25%), White MSM (22%), Hispanic/Latino MSM (18%), Black MSM (15%), and Hispanic/Latino heterosexuals (6%). Efforts to reduce the transmission of HIV include improving viral suppression among Black males and females and among WCBA (aged 15 to 44).

FIGURE 28: PRIORITY POPULATIONS FOR SECONDARY HIV PREVENTION FOR PWH, FLORIDA, 2021

There were 120,502 persons with an HIV diagnosis living in Florida through 2021 which is estimated to represent only 86% of persons with HIV—the remainder of whom are unaware of their status (approximately 14%, based on the current CDC methodology used to calculate percentage unaware). Persons living with HIV but unaware of their status also need to be prioritized and underscore the

importance of implementing a status-neutral approach to HIV prevention and care. Routine screening is needed to diagnose persons with HIV who are unaware of their status and rapidly link them to care and treatment to achieve viral suppression.

The full Epidemiological Profile for HIV in Florida, 2021, will be provided as a separate attachment. It was developed in accordance with the Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2022–2026 issued by the CDC and HRSA in June 2021. This document provides a comprehensive data overview of HIV, STDs, and HCV in Florida. The full Epidemiological Profile for HIV in Florida, 2021, will also be used to address CDC-PS18-1802 grant requirements.

5 2022–2026 Goals and Objectives

In January 2021, HHS released the HIV National Strategic Plan: A Roadmap to End the Epidemic 2021–2025 which creates a collective vision for HIV service delivery across the nation. IPC Plans created for every jurisdiction address four goals:

- Prevent new HIV infections.
- Improve HIV-related health outcomes for people with HIV.
- Reduce HIV-related disparities.
- Achieve integrated, coordinated efforts that address the HIV Epidemic among all partners and stakeholders.

Objectives have been identified for each of the four goals, and the details of such are outlined in the subsequent section.

Table 10 outlines the goals and objectives for how Florida will address the strategies to diagnose, treat, prevent, and respond to HIV; the goals and objectives align with the NHAS. Actionable activities have been identified to address each of the goals and objectives, along with other pertinent information to inform a plan of action. Those additional details are described in Appendix 9.1 Strategy and Activity Table.

TABLE 10: GOALS AND OBJECTIVES

Goal	Objective
Goal 1: Prevent New HIV Infections	Objective 1.1. Increase awareness of HIV.
	Objective 1.2. Increase knowledge of HIV status.
	Objective 1.3: Expand and improve implementation of effective prevention Interventions.
	Objective 1.4 Increase capacity of health care delivery systems, public health, and health workforce to prevent and diagnose HIV.
Goal 2: Improve HIV-Related Health Outcome of PWH	Objective 2.1. Link people to care rapidly after diagnosis and provide low-barrier access to HIV treatment.
	Objective 2.2: Identify, engage, or reengage people with HIV who are not in care or not virally suppressed.
	Objective 2.3: Increase retention and adherence to treatment to achieve and maintain long-term viral suppression.

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Goal	Objective
	Objective 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV.
	Objective 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors.
	Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure.
Goal 3: Reduce HIV-related Disparities	Objective 3.1. Reduce HIV-related stigma and discrimination.
	Objective 3.2. Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum.
	Objective 3.3. Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV.
	Objective 3.4: Address social determinants of health and co-occurring conditions that exacerbate HIV-related disparities.
	Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations.
	Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust.
Goal 4: Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic Among All Partners and Interested Parties	Objective 4.1. Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and institutional factors including stigma, discrimination, and violence.
	Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and CBOs, the private sector, academic partners, and the community.
	Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data.
	Objective 4.4: Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.

6 2022–2026 Integrated Planning Implementation, Monitoring, and Jurisdictional Follow Up

To break down the approach for Integrated Planning Implementation, Monitoring and Jurisdictional follow up, the subsequent sections will detail how best to ensure the success of IPC Plan goals and objectives through the following five key phases:

- Implementation (Section 6.1)
- Monitoring (Section 6.2)
- Evaluation (Section 6.3)
- Improvement (Section 6.4)
- Reporting and Dissemination (Section 6.5)

6.1 Implementation

The Department will continue to coordinate and collaborate with internal and external partners and stakeholders to meet the objectives of the IPC Plan. The Department's RWHAP Part B; RWHAP Part A, C, D, and F programs; PWH; and other members of the FCPN-associated committees, workgroups, and advisory groups (e.g., FL Gay Men's HIV Workgroup, Community HIV Advisory Group, Florida Black Leaders Group, CQM Committee); EHE-funded jurisdictions and directly-funded providers; HIV prevention and care providers; state and local agency administrators; and persons at increased risk for HIV will be included in each step of the IPC Plan implementation, monitoring and evaluation. Through this coordinated implementation approach, the Department and partners can explore opportunities to better leverage funding streams supporting Florida's HIV prevention, care, and treatment services (e.g., CDC and HRSA funding to state and local entities). Implementation progress of the IPC Plan will also be used to identify where more resources (e.g., funding, staffing) may be needed to ensure IPC Plan objectives are met.

6.2 Monitoring

The goal of the monitoring and evaluation plan is to assess successful implementation of the unified IPC Plan as measured by:

- Completion of stated strategies and activities.
- Annual progress toward the target measurements of stated goals, objectives, and benchmarks.

Data are used to direct efforts to ensure the program achieves the intended results and to help identify additional operational and process improvement opportunities.

Through biannual meetings and monthly committee calls, the Department's HIV/AIDS Section and the FCPN will actively participate in regular monitoring of strategies and activities set forth in the unified IPC

Plan. The Department, in collaboration with the FCPN Coordination of Efforts Committee, will establish mechanisms and time frames the state will use to monitor, evaluate, and update the IPC Plan, as necessary. This committee leads efforts to ensure data indicators for plan activities are being tracked and that progress is communicated with appropriate programs and partners to meet plan objectives. Data on performance indicators will be collected and disseminated through a status report to statewide partners. Local planning body feedback will also be collected and shared by FCPN representatives for each respective area. The Department currently uses an electronic dashboard tool to collect EHE-related activity information and consideration is being given to using this tool to collect activity-related information for the IPC Plan. Regular FCPN meetings are the principal mechanism for updating planning bodies and stakeholders on the progress of plan implementation as well as soliciting and using feedback from stakeholders for ongoing plan improvements. A standing agenda item to review IPC activity progress will be added to the state's FCPN meetings. After each FCPN meeting, a summary report is provided to all attendees and shared with community partners; this mechanism will be used to share information on the IPC Plan's progress toward completing activities and achieving objectives.

The IPC Plan will receive a detailed annual review by the Department HIV/AIDS Section leadership. As part of the annual review, the section will use surveillance and program data to assess health outcomes along the HIV Care Continuum that impact the quality of the HIV service delivery system. This will allow for adjustments to be made in response to changing conditions, and information from the review will be provided to FCPN for feedback.

The Department's HIV/AIDS Section, with the engagement of stakeholders, will review the strategic plan using identified measures and indicators to analyze, assess, and evaluate outcomes and determine whether modifications to the IPC Plan are necessary. The diverse range of perspectives—knowledge, values, needs, and abilities—of stakeholders will be applied through a participatory planning and evaluation process. The collaborative approach, structured and arranged to interweave state and local community partnerships with shared discretion and responsibilities, will help to achieve the IPC Plan objectives more effectively than each program could on its own. This approach will align with, support, and advance the goals of the IPC initiative, the NHAS, and the Department, as well as meet CDC and HRSA requirements. As the state of Florida moves forward in ending the epidemic, regularly scheduled events to inform all stakeholders and researchers of relevant data and evidence for improving or, more precisely, monitoring and evaluating the implementation and impact of the IPC Plan is essential. These opportunities will ensure that plan implementers are working with the best available evidence to work toward ending the epidemic.

6.3 Evaluation

Meaningful measures and indicators will be used to monitor both operational performance and progress on objectives, strategies, and activities in the strategic plan. Data are used to make program decisions and direct efforts to ensure the state achieves the intended results and also to help identify additional operational and process improvement opportunities.

The IPC Plan will receive a detailed annual review by HIV/AIDS Section leadership subsequent to Florida's legislative session and the Department's budget planning process. As part of the annual review, the section will use surveillance and program data to assess health outcomes along the HIV Care Continuum which impact the quality of the HIV service delivery system. This will allow for adjustments to be made in response to changing conditions and information from the review will be provided for input and feedback to the FCPN.

Strategic planning, the process generating the statewide IPC Plan, helps focus resources on vital objectives chosen to move the Patient Care and Prevention programs toward fulfillment of the NHAS goals. The IPC Plan identifies key objectives that Florida will pursue in the next five years, along with strategies and activities that will guide and facilitate the necessary actions required to achieve the desired outcomes. Plan objectives each have a corresponding measure for ongoing monitoring. Using meaningful measures and data indicators will ensure Department HIV/AIDS Section leadership, RWHAP Part A partners and the FCPN planning body members are able to manage and track efforts toward the intended results, while identifying improvement opportunities over the course of the five-year period.

Evaluation ensures the strategies and activities are making changes that positively affect outcomes of the IPC Plan objectives. Evaluation that focuses on project outputs, provides accountability for public resources relating to specific actions. It establishes the empirical basis needed for the ongoing cycle of collaborative planning and the actions that need to be accomplished. The evaluation component is an extension of the integrated Plan, Do, Study, Act cycle which is a continuous process. The IPC Plan must be flexible to allow for adjustments as there are changes to external or internal conditions; yet a meaningful evaluation must be integrated in the planning process and include a review and analysis of the intended outcome. The HIV/AIDS Section, with the engagement of stakeholders, will review the strategic plan using meaningful performance measures and indicators to analyze, assess and evaluate outcomes and determine whether modifications to the IPC Plan are necessary. Through participatory evaluation and diverse range of perspectives, knowledge, values, needs, and abilities of stakeholders will be applied to the planning and evaluation process.

6.4 Improvement

Through routine (biannual) monitoring and communication of progress in achieving the goals and objectives outlined in the IPC Plan, the state will identify areas in need of improvement and make necessary adjustments to the IPC Plan. Revisions will be made on an annual basis and items for proposed revision will be reviewed with RWHAP Part A jurisdictions, members of the FCPN and associated workgroups and advisory bodies, and other key stakeholders, voted on, and implemented. The collaborative approach—structured and arranged to interweave state and community partnerships with shared discretion and responsibilities—will help to achieve the IPC Plan objectives more effectively than each program could on its own. This approach will align, support, and advance the goals of the NHAS, the Department, as well as meet CDC and HRSA requirements, to ensure improvement in the access to and quality of HIV prevention and care services throughout Florida.

6.5 Reporting and Dissemination

Summarized annual data are uploaded to the Department's HIV/AIDS Section web page (<http://floridaaids.org/>) and are also available on an internal SharePoint site for internal use at the state and CHD level. Annual data releases include a comprehensive epidemiological profile for the state and for each partnership area, a state slide set presented annually to FCPN and RWHAP partners, and other annual data products. The epidemiological (epi) profiles are an expanded Excel workbook with multiple tabs containing 5-year trend analyses of HIV (demographics, diagnosis, AIDS, deaths, and continuum of care), STIs, HBV, HCV, and TB.

Various factsheets are generated to portray epidemiology and disease highlights for a demographic population. These fact sheets highlight summary data for priority population groups and are updated annually, shared with community stakeholders, and uploaded to the Department's external web and internal SharePoint sites. Integrated slide sets and epidemiological profile tables are generated to support stakeholder engagement and planning. The Department's HIV/AIDS Section has generated compressive slides sets and epi profiles specifically for each of the 14 partnership areas each year since the 1990s. These slide sets and epi profiles are shared with the RWHAP Part A entities, community stakeholders, field surveillance staff, and others who may request these data. These data are frequently used as tools for program planning and evaluation.

Data Sharing and Use

De-identified HIV, viral hepatitis, STD, and TB data are routinely shared via ad-hoc requests to surveillance programs with outside entities including, but not limited to, academic institutions, community partners, RWHAP Parts, internal agency partners and collaborators, and the public.

Each of these programs provide annual data which are uploaded into FLHealth CHARTS (<https://www.flhealthcharts.gov/charts/CommunicableDiseases/default.aspx>). In addition, FL Health CHARTS is updating the FLHealth CHARTS website (a web-based platform that provides easy access to health indicator data at the community and statewide level for the state of Florida from a multitude of sources) with a new dashboard (at the county level) that will incorporate a multitude of HIV/AIDS indicators including, but not limited to, demographic and socio-economic indicators, partner services data, testing and treatment facilities, PrEP, and other data not previously included on FL Health CHARTS. By ensuring all these data and information are made readily accessible and user friendly, the new dashboard will help local and state planning bodies develop more effective and efficient programs and corresponding activities and monitor progress of IPC strategies and activities.

Along with HIV data, the Department also summarizes data from MMP and NHBS surveillance along with the Department's PrEP, Test and Treat, and HIV counseling and testing data. Data from the needs assessments are also shared in reports sent out to FCPN membership.

7 Letter of Concurrence

For the purpose of this plan, the FCPN membership served as the designated entity to certify concurrence with the content, strategies and activities included in the IPC Plan. The FCPN membership held the concurrence session on October 19, 2022, to officially adopt Florida’s Statewide Integrated HIV Prevention and Care Plan, 2022–2026. Moving forward, all updates to concurrence will be completed through the state’s integrated HIV planning process and with the FCPN.

The concurrence process included:

- Several virtual IPC Planning sessions that reflected the progression of the statewide IPC Plan to ensure that members of the planning body and other community stakeholders had an opportunity to provide input into the development of goals, objectives, strategies, and activities proposed in the IPC Plan.
- Opportunities for FCPN members and community stakeholders to submit their feedback to the state health office representatives with a response to their inquiries and recommendations.
- An opportunity for the FCPN to vote to accept the IPC Plan for submission to HRSA and CDC.

FIGURE 29: LETTER OF CONCURRENCE

F C P N

Florida Comprehensive Planning Network

Dear Colleague:

The Statewide Florida Comprehensive Planning Network (FCPN) concurs with the following submission by the Florida Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HMAIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SC5N) for calendar year (CY) 2022–2026.

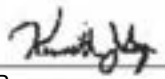
Members of FCPN include PWH and representatives across the state representing patient care and prevention groups, local planning bodies, CEOs, academic institutions, local and regional clinics, city, and county governments, RWHA Program recipients, the transgender community, advocacy groups, substance use and social service providers and behavioral science groups.

After a year of collaboration with our planning body members, federal/state/local partners, and community stakeholders, this plan reflects Florida's commitment to eliminating new HIV transmissions and reducing HIV related deaths in our state. FCPN members and guests helped to develop and prioritize the proposed strategies and activities for inclusion into the plan during the Summer 2022 meeting. FCPN members and guests reviewed and made suggestions to the first draft of the plan during the Fall 2022 in-person/virtual meeting. Comments and suggestions from FCPN members were then incorporated into the final draft of the plan.

The FCPN has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV.

The planning body concurs that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance.

Astute Co-Chairs of the FCPN, the signatures below confirm the concurrence of the planning body with the Integrated HIV Prevention and Care Plan 2022-2026.

 _____ Ken Bargar FCPN Community Co-Chair	1/5/23 _____ Date
 _____ Daniel Wall FCPN Community Co-Chair	1/5/23 _____ Date

Florida Comprehensive Planning Network
c/o The AIDS Institute
17 Davis Blvd., Ste. 403
Tampa, FL 33606

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9 Appendix

9.1 Strategy and Activity Table

The table below provides details on the activities suggested to address each strategy. Strategies are categorized by the goal and objective that they fall in.

9.1.1 Goal 1: Prevent New HIV Infections

9.1.1.1 Objective 1.1. Increase awareness of HIV

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

TABLE 11: STRATEGIES AND ACTIVITIES

Strategy 1.1.1		Develop and implement campaigns and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.			
Data Indicators		• Number of campaigns developed • Number of publicly funded HIV tests • Number of areas engaging with law enforcement • Stigma measure to be developed • Additional specific, quantifiable measures for each activity (TBD)			
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth			
Timeframe		Critical Partners		Activities	
By 12/31/2026		• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Case managers • Health educators • Peer workers • Community health workers • Linkage Coordinators • Faith-based Organizations		• Develop stigma toolkit and campaign and localized stigma task forces. • Engage with law enforcement around HIV awareness and stigma, and HIV information in their curriculum for youth intervention programs. • Increase culturally competent sexual health education outside of schools. • Increase the use of digital media resources to include messaging on dating apps (e.g., Grindr) and social media apps (e.g., TikTok). • Solicit and execute agreement with new media vendor to deliver HIV media services statewide and to add campaign material to increase awareness of HIV testing, PrEP, treatment, prevention, and stigma awareness among priority groups.	
Planning Areas					
Statewide					

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.1.2		Increase awareness of HIV among people, communities, and the health workforce in geographically disproportionately affected areas.	
Data Indicators		• Number of publicly funded HIV tests • Number of BRTA/FRTA partnerships • Number of outreach and education efforts to specific priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth; sex workers and human trafficking victims	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Case managers • Health educators • Peer workers	• Increase targeted outreach and education efforts specific to specialized groups, (e.g., FQHCs, local gang taskforces, and other geographically disproportionate communities). • Increase the number of BRTA and FRTA initiatives and partners statewide to increase HIV awareness and reach in communities. • Offer in-person learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators (as a result of increased HIV 101 train the trainer opportunities). • Provide HIV education and information to school district stakeholders to encourage buy-in and adoption of culturally competent sexual health education curriculum. • Develop education materials that are both age appropriate and language appropriate.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.1.3	Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders.	
Data Indicators	• Number of campaigns with integrated messaging addressing syndemics • Number of new or non-traditional partnerships established to deliver education around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth; individuals with dual diagnoses	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance use treatment settings • Mobile units • STD clinics • SSPs • Drug treatment programs • Case managers • Health educators • Peer workers • Community health workers	• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV messaging in messaging related to other communicable disease areas. • Increase awareness and collaboration with existing SSP to incorporate viral hepatitis, STIs, mental health and substance use disorder messaging in campaigns. • Collaborate with non-traditional and new partners to deliver HIV, STI, viral hepatitis, substance use disorder and mental health messaging across multiple platforms (e.g., radio, print, digital, social media, out-of-home, venue/event-based). Ensure all messaging is culturally and linguistically appropriate. • Identify and engage with other organizations and coalitions that have existing campaigns for STIs, viral hepatitis, substance use, mental health, behavioral health, etc. to encourage these groups to include HIV prevention and care messages in their efforts. • Partner with SAMHSA funding recipients update or create messaging related to the nexus between HIV/STIs and HCV, substance use, and/or mental health. • Collaborate with other local EMAs, RWHAP providers (e.g., Part C clinics), and FQHCs to incorporate additional HIV messaging into existing activities and/or campaigns.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

9.1.1.2 Objective 1.2. Increase knowledge of HIV Status

Strategy 1.2.1		Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.	
Data Indicators		• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Develop messaging that normalizes routine HIV testing and reduces stigma surrounding HIV testing. Utilize peers and popular opinion leaders to increase testing in communities. • Ensure providers are kept up to date through education and communication. • Implement routine HIV and STIs screening in health care settings and priority testing in non-health care settings. Expand routine HIV testing to include additional medical settings (e.g., EDs, urgent care facilities, OB/GYN, and primary care providers). • Increase opportunities for HIV testing and address barriers to testing in traditional and non-traditional settings. • Increase testing accessibility through increased partnerships with outside-the-box providers, such as non-traditional medical settings, civic groups, local papers, event planners, FBOs, population-based care providers, and others. Ensure testing is where people are.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.2.2	Develop new and expand implementation of effective, evidence-based or evidence informed models for HIV testing that improve convenience and access.	
Data Indicators	• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs	• Assess current HIV testing laws for opportunities to consider increasing testing requirements in additional circumstances. • Decrease barriers to testing by increasing testing beyond traditional venues and work hours and normalizing knowing your status. • Identify barriers to testing and care from people with lived experience and develop improvements to delivery. • Provide easy access to home test kits, including through self-serve vending machines and as add-ons to other self-tests (such as COVID, pregnancy); improve reporting structures to increase self-test linkage. • Routinize HIV testing as part of the standard of care during an annual physical as well as during other health or wellness visit appointments or opportunities.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.2.3		Incorporate a status neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.	
Data Indicators		• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Develop and provide status-neutral resources around testing, treatment, prevention, and other services. • Educate private providers about status neutral HIV prevention and care services. • Ensure strong linkage to PrEP and PEP infrastructure that exists. • Increase the use of combined testing and vaccination efforts as a means of destigmatizing HIV prevention and testing services. • Support and expand the use of a “no wrong door” approach for HIV prevention and care services in a variety of organizations.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.2.4		Provide partner services to people diagnosed with HIV or other STIs and sexual or needle sharing partners.	
Data Indicators		• Number of people receiving HIV partner services interviews • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Increase collaboration with needle exchange/harm-reduction programs. • Increase partner services capacity, whether by increasing funding for DIS positions, allowing additional Department staff to provide partner services, or allowing non-Department organizations to provide partner services. • Provide partner services during non-traditional hours and via telehealth to reduce barriers. • Reduce barriers around partner disclosure and referral. • Use partner services to provide negative partners access to PrEP, educational materials, and other preventative resources and services.	
Planning Areas			
Statewide			

9.1.1.3 Objective 1.3: Expand and Improve Implementation of Effective Prevention Interventions

Strategy 1.3.1		Engage people at risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.	
Data Indicators		• Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Number of people receiving prescriptions for PrEP • Number of primary care visits (AHCA report) • Number of FQHC visits for priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs • AHCA (Medicaid/Medicare)	• Create local Prevention Interventions Taskforces to work collaboratively to raise awareness (e.g., utilizing non-health care events), share resources, and provide referrals. • Incorporate additional public health professionals in care settings • Increase academic detailing in Primary Care, Urgent Care, and Emergency Department settings to raise awareness for prevention interventions. • Increase the number of community mobilization initiatives and partnerships in communities, (e.g., FRTA and BRTA). • Partner with additional social service organizations, (e.g., domestic violence care providers, human trafficking organizations, United Way, YMCA, Boys and Girls club, and others) to expand HIV testing, prevention, and care services.	
Planning Areas			
Statewide			

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Strategy 1.3.2	Scale-up treatment as prevention/U=U by diagnosing all people with HIV, as early as possible and engaging them in care and treatment to achieve and maintain viral suppression.	
Data Indicators	• Number of publicly funded HIV tests • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Use existing planning bodies to work collaboratively to expand and increase rapid ART access programs. • Increase viral suppression rates by increasing the use of peers in programs and using messaging that focuses on living a healthy life. • Review programs with low VL suppression to identify areas for technical assistance and increase the number of trained evidence-based Intervention (EBI) providers in those programs to assist in navigation services and other interventions to reduce community VL. • Scale up of injectable ARV programs (i.e., PrEP and HIV treatment).
Planning Areas		
Statewide		

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Strategy 1.3.3		Make HIV prevention, including condoms, PrEP, PEP, SSPs easier to access and support continued use.	
Data Indicators		• Number of condoms distributed statewide • Number of people receiving prescriptions for PrEP • Number of people receiving PEP • Number of operational SSPs • Additional specific, quantifiable measures for each activity (TBD)	
		Priority Populations PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Use existing planning bodies to work collaboratively to raise awareness and share resources on PrEP, PEP, condoms, and SSP, in order to provide referrals and increase accessibility of services. • Increase the number of PrEP providers through academic detailing and education. • Encourage that SSPs (including clean-needle distribution and exchange) are placed in proximity of known overdose events or deaths. • Increase awareness and promote the use of the Provider PrEP hotline.	
Planning Areas			
Statewide			

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Strategy 1.3.4		Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.	
Data Indicators		• Number of cultural humility trainings performed • Number of engagement activities with local and state civic, community and spiritual leaders • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Embrace the adoption of assessing quality of life instead of limiting approach to focusing on health outcomes only. • Engage with local and state civic, political, community, and spiritual leaders to increase awareness of HIV and populations living with and affected by HIV. • Increase cultural humility trainings and other linguistically appropriate trainings for delivering HIV prevention services. • Partner with the Florida Department of Education (FDOE) to open conversations on how to evaluate outcomes of current health education programs for success. • Provide HIV messaging in English, Spanish, and Haitian-Creole.	
Planning Areas			
Statewide			

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Strategy 1.3.5	Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.	
Data Indicators	• Number of partnerships with HIV-related research entities • Number of HIV research sharing events and opportunities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Academia • SSPs	• Expand frameworks for evaluation of EBIs through collaborative efforts and partnerships. • Expand the use of economic modeling to optimize public health strategies and interventions (e.g., PrEP 2-1-1) in additional jurisdictions. • Strengthen partnerships with HIV-related research entities (e.g., Florida Consortium for HIV Research [FCHAR]) to increase knowledge sharing and build expertise. Encourage attendance at Florida HIV Community, Providers & Researchers Conference.
Planning Areas		
Statewide		

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Strategy 1.3.6	Expand implementation research to successfully adapt EBIs to local environments to maximize potential for uptake and sustainability.	
Data Indicators	• Number of partnerships with HIV-related research entities • Number of HIV research sharing events/opportunities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Academia • SSPs	• Adapt interventions frameworks to be more inclusive of all communities. • Conduct listening sessions with those currently implementing interventions and those participating in interventions to uncover best practices and lessons learned. • Increase collaboration with state and national entities, subject matter experts (SMEs) and CBA and TA providers to share information and findings that may lead to innovation and strategies.
Planning Areas		
Statewide		

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9.1.1.4 Objective 1.4 Increase capacity of health care delivery systems, public health, and health workforce to prevent and diagnose HIV

Strategy 1.4.1	Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.		
Data Indicators	• Number of cultural humility trainings performed • Number of public health workforce trainings on PrEP and PEP, mental health, and substance use and misuse • Number of partnerships with rural health networks • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Community-based organizations, health care delivery systems, public health, and health workforce		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Drug treatment programs • Correctional health settings • SSPs • Case managers • Health educators • Peer workers • Linkage coordinators	• Collaborate with local, state, and national training partners to increase and expand training cultural humility trainings. • Collaborate with local, state, and national training partners to provide additional training for the public health workforce and front-line staff on PrEP and PEP prescribing, mental health, and substance use and misuse. • Expand awareness and use of the Collaborative Pharmacy Practice Agreement which gives pharmacists authority to provide specific patient care services, including PrEP. • Expand partnerships with rural health networks. • Explore opportunities to incentivize the expansion of the health care workforce and health care facilities. • Identify language barriers and use stigma-free language for vulnerable populations.	
Planning Areas			
Statewide			

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Strategy 1.4.2		Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.	
Data Indicators		• Number of cultural humility trainings performed • Number of HIV testing providers in rural areas • Number of partnerships with rural health networks • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Community-based organizations, health care delivery systems, public health, and health workforce	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Drug treatment programs • SSPs • Case managers • Health educators • Peer workers • Linkage coordinators	• Determine areas that lack providers and find ways to incentivize organizations to serve as HIV CBOs. • Encourage HIV testing as a workplace activity. • Engage community hubs and community leaders to broaden their social services by provided HIV testing. • Use all available training resources (local and national) to create a diverse testing force across the state in both traditional and non-traditional settings.	
Planning Areas			
Statewide			

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Strategy 1.4.3	Increase inclusion of paraprofessionals and SMEs on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.	
Data Indicators	• Number of partnerships with private entities • Assessment of ART barriers conducted • Number of peer navigators or near-peers • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Case managers • Health educators • Linkage coordinators • Peer and near-peer workers • CHWs	• Assess barriers to antiretroviral therapy (HIV treatment or PrEP) in communities • Develop a community-based workforce that is able to provide more services in a single visit • Find creative ways to combat critical workforce attrition • Increase the number of peer navigators providing services. • Leverage partnerships with private entities to increase access to prevention services. • Develop pathways which promote career growth for paraprofessionals.
Planning Areas		
Statewide		

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Strategy 1.4.4	Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV.	
Data Indicators	• Number of academic institutions receiving education and outreach • Number of local providers, peer navigators and near-peers that reflect priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Case managers • Health educators • Linkage coordinators • Peer workers, Near Peers • CHWs	• Increase the number of local care providers, peer navigators, and SMEs of color in order to reflect the burden of the epidemic in a county. • Increase the number of inclusive sexual health services being offered by providing training on sexual orientation and gender identity. • Provide education and outreach to academic institutions (e.g., public health programs, nursing, other paramedical programs) to encourage integration of testing and prevention training into curriculum to increase the number of certified testers. • Require HIV education and training of school personnel. • Require HIV education in clinical licensure. • Establish best practices for responsible parties to hire and retain employees that reflect the epidemic.
Planning Areas		
Statewide		

Goal 2: Improve HIV-Related Health Outcomes of Persons with HIV (PWH)

9.1.2.1 Objective 2.1. Link people to care rapidly after diagnosis and provide low-barrier access to HIV treatment

Strategy 2.1.1	Increase linkage to HIV medical care in 30-days of diagnosis, as early as the same day.	
Data Indicators	• Number of new HIV diagnoses • Number of PWH engaged in care through T&T • Number of PWH engaged in care through telehealth • Number of PWH linked to same-day treatment (rapid ART) • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners	• Facilitate the ability of peers, medical providers, and eligibility staff to link clients to care and access rapid ART medications. • Collaborate with local partners and providers across multiple platforms to incorporate more T&T facilities that will offer rapid access to ART and PrEP and PEP medications. • Increase awareness with local providers to incorporate messaging on T&T and rapid ART protocols. • Support the use of incentives such as food and transportation vouchers and phones to assist with linkage to care activities.
Planning Areas		
Statewide		

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Strategy 2.1.2	Provide same-day initiation or rapid start (within 7 days) of ART for those who are able to take it.	
Data Indicators	• Number of new HIV diagnoses • Number of PWH engaged in care through T&T • Number of PWH engaged in care through telehealth • Number of PWH linked to same-day treatment (rapid ART) • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local Part A and EHE programs	• Establish youth ambassadors and advocates; collaborate with academic institutions (e.g., Scale It Up Florida). • Expand routine HIV and STI testing to include additional medical settings (e.g., pediatricians, primary care, and student health centers). • Increase targeted outreach and education efforts specific to specialized youth and teen groups. • Increase the number of culturally competent sexual health education in educational, recreational, and faith-based organizations, facilities, and groups.
Planning Areas		
Statewide		

9.1.2.2 Objective 2.2: Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

Strategy 2.2.1	Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.	
Data Indicators	• Number of new HIV diagnoses • Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners	• Collaborate with local partners and providers across more platforms to incorporate more T&T facilities that will offer rapid ART and PrEP and PEP medications. • Develop a single-point eligibility data system that will support all RWHAP partners to assist with linkage and retention services. • Execute cooperative agreements and data sharing agreements with local providers, jails, and prisons to link and refer clients to care who are soon to be released from an institution. • Support data sharing efforts and educate peers, DIS, medical providers, pharmacists, and eligibility and outreach staff on how to assist in linking clients to care and accessing rapid ART medications.
Planning Areas		
Statewide		

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Strategy 2.2.2		Identify and address barriers for people who have never engaged in care or who have fallen out of care.	
Data Indicators		• Number of new HIV diagnoses • Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners		• Expand opportunities to increase awareness and education of local providers on how to incorporate messaging and services for mental health, substance use, homelessness, and other wrap-around services. • Expand routine HIV/STI testing, and substance use counseling to additional settings such as homeless shelters, urgent care centers, substance use treatment centers. • Expand RWHAP drug formularies to include more treatment drugs for comorbidities. • Expand the use of mobile units to assist with linkage and reengagement efforts. • Support the use of peers to assist with linkage, reengagement, and retention efforts.
Planning Areas			
Statewide			

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9.1.2.3 Objective 2.3: Increase retention and adherence to treatment to achieve and maintain long-term viral suppression.

Strategy 2.3.1		Support the transition of health care systems, organizations, and clients to become more health literate in the provision of HIV prevention, care, and treatment services.	
Data Indicators		• Number of in-person and virtual learning opportunities for staff providing prevention, care, and treatment services • Number of plain language processes and materials developed to assist clients who are newly diagnosed or returning to care • Number of peers and near-peers providing linkage, reengagement, or retention efforts • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Persons living with diagnosed HIV, health care systems, community-based organizations	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local Part A and EHE programs		• Develop plain language processes and materials to assist clients who are newly diagnosed or returning to care. • Offer in person and virtual learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators and clients (as a result of increased HIV 101 train the trainer opportunities). • Support the use of peers and near-peers to assist with linkage, reengagement, and retention efforts.
Planning Areas			
Statewide			

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Strategy 2.3.2		Develop and implement effective, evidence based or evidence-informed interventions and supportive services that improve retention in care.	
Data Indicators		• Number of peers, near-peers, and/or CHWs providing retention support • Number of peer programs implemented • Number of provider educational opportunities around syndemics • PWH reengaged through D2C • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Peers and near-peers • CHWs • Linkage coordinators • Local RWHAP Part A and EHE partners		• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) into primary care practice. • Expand the use of peers, linkage coordinators and CHWs to implement the ARTAS intervention strategies and adherence measures. • Identify and integrate best practices for peer programs from similar states and jurisdictions. • Review EBIs for effectiveness by using validated tools to predict engagement. Ensure EBIs include target audience. Establish rapid response protocols. • Streamline clinical protocols to eliminate client burden by reducing the frequency of CD4/VL labs, providing 3–6 months of medications at one time, and offering telehealth clinical and case management services.
Planning Areas			
Statewide			

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Strategy 2.3.3	Develop and implement effective, evidence-based, or evidence-informed interventions such as HIV telemedicine, accessible pharmacy services, CHWs and peer navigators, and others, that improve convenience and access, facilitate adherence, and increase achievement and maintenance of viral suppression.	
Data Indicators	• Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Number of peers, near-peers, and CHWs providing linkage and retention support • PWH reengaged through D2C • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, health care systems, academic institutions, community-based organizations	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Pharmacies • Peers and near-peers • Case managers • CHWs • Linkage coordinators • SSPs • Local RWHAP Part A and EHE partners	• Allow 3–6 months of ART medications to be dispensed at one time. • Create funding opportunities for community-based providers to support recruitment and retention of staff. • Develop a single-point eligibility data system integrated with multi-data systems that will support all RWHAP parts. Implement a centralized eligibility determination system for all RWHAP Parts. • Expand access to health insurance coverage to eligible clients. • Provide training to health workers and peers that will support or increase adherence measures.
Planning Areas		
Statewide		

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Strategy 2.3.4	Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence and durable viral suppression.	
Data Indicators	• Number of collaborations with academic institutions engaged in HIV research • Number of updates to providers on ongoing or recruiting efforts on clinical trials • Number of FQHCs and other community health settings engaged in research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, health care systems, academic institutions, community-based organizations	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Encourage persons living with HIV to participate in the research by making research findings easier to understand. • Engage and collaborate with local colleges and universities to increase research opportunities at the local level. • Engage local organizations such as FQHCs to assist with research and interventions. • Provide paid incentives to encourage persons living with HIV, students, or researchers to get involved in the research. • Provide updates to providers on ongoing or recruiting efforts on clinical trials.
Planning Areas		
Statewide		

9.1.2.4 Objective 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

Strategy 2.4.1	Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.		
Data Indicators	• Number of cultural humility trainings performed • Number of public health workforce trainings on PrEP and PEP, mental health, and substance use or misuse • Number of PWH engaged in care through telehealth • Number of peers, near-peers, and CHWs providing linkage and retention support • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, and health workforce		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Pharmacies • Peers and near-peers • Case managers • Linkage coordinators • CHWs • SSPs • Local RWHAP Part A and EHE partners	• Collaborate with the AETC to assist with training efforts. • Establish a statewide conference for medical providers. • Expand telehealth to increase capacity for services and use mobile units to increase outreach efforts. • Increase culturally competent HIV trainings to local providers. • Increase targeted outreach and education efforts specific to specialized providers.	
Planning Areas			
Statewide			

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Strategy 2.4.2		Increase the diversity of the workforce of providers who deliver HIV and supporting services.	
Data Indicators	Priority Populations	• Number of public health workforce trainings on basic HIV education • Number of peers, near-peers, and/or community health workers providing linkage and retention support • Number of provider educational opportunities around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, and health workforce	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Peers and near-peers • Case managers • CHWs • SSPs • Local RWHAP Part A and EHE partners		• Facilitate the ability of peers, medical providers, and eligibility staff to link clients to care and access rapid ART medications. • Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) into primary care practice. • Increase providers of color in communities. • Offer in-person and virtual learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators (as a result of increased HIV 101 train the trainer opportunities). • Modify contractual language in HIV contracts to encourage staffing reflects the local demographics of the HIV population.
Planning Areas			
Statewide			

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Strategy 2.4.3	Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.	
Data Indicators	• Number of peer navigators or near-peers • Number of public health workforce trainings on basic HIV education • Number of peers, near-peers, and CHWs providing screening and adherence support • Number of provider educational opportunities around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Peers and near-peers • Case managers • CHWs • SSPs • Certified addiction professionals and counselors • Local RWHAP Part A and EHE partners	• Collaborate with social service organizations on screening and management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions. • Identify support staff who can be trained to provide support services in a range of industries (i.e., medical COE). • Develop and implement a statewide peer certification program. • Increase training and inclusion opportunities for CHWs. • Collaborate with other social service providers to increase screening and management of HIV, STI, viral hepatitis, and mental and substance abuse. • Expand collaborations with school health services to provide support to the younger population. • Identify and promote trainings for paraprofessionals regarding social determinants of health and the syndemics facing Florida.
Planning Areas		
Statewide		

9.1.2.5 Objective 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

Strategy 2.5.1	Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.		
Data Indicators	• Number of partnerships with organizations that serve PWH aged 50+ • Assessment of barriers to care for PWH aged 50+ • Number of educational opportunities for PWH aged 50+ • Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Broaden the scope of partnerships to include established entities who serve PWH over the age of 50 providing primary, specialty and pharmacy services. • Utilize statewide advisory groups to identify barriers in models of care for PWH who are aging. • Collaborate with existing service providers (e.g., Eldersource, Department of Elder Affairs, Visiting Angels) that work with the elderly to integrate in HIV prevention, care, and support services. • Increase HIV and aging education in senior centers, assisted living facilities, retirement communities, and others. • Collaborate with geriatric care providers to educate on risk of aging PWH. Also educate them on risk for older patients who may be at risk of acquiring HIV, e.g., how to talk to and engage older adults in sexual health conversations.	
Planning Areas			
Statewide			

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Strategy 2.5.2	Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.		
Data Indicators	• Number of partnerships with organizations which address psychosocial and behavioral health for PWH aged 50+ and long-term survivors. • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Local RWHAP Part A and EHE partners	• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) and behavioral health into primary care practice. • Increase provider knowledge on the aging HIV population and the effects on dementia. • Expand partner networks to include organizations already addressing psychosocial and behavioral health for persons with HIV aged 50+ and long-term survivors. • Engage national aging institutions to advise on establishing the most effective program design to address psycho-social and behavioral needs of the aging population including substance use and mental health treatment. • Review existing research and evidence-based practices from mainstream non-HIV oriented care providers and integrate into HIV-oriented care. • Establish Long Term Survivor Empowerment Teams which can foster individual virtual or in-person mental health sessions assessing the needs of patients and ensuring their needs are met accordingly. • Reach out to existing elder services providers to learn more about what they offer and what's working and ask how HIV prevention and support could be added into their efforts.	
Planning Areas			
Statewide			

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Strategy 2.5.3	Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.		
Data Indicators	• Number of partnerships with organizations which address psychosocial and behavioral health for PWH aged 50+ and long-term survivors. • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Local RWHAP Part A and EHE partners	• Collaborate with local Area Agencies on Aging. • Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) and behavioral health into primary care practice. • Establish a long-term survivor peer empowerment team (statewide).	
Planning Areas			
Statewide			

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Strategy 2.5.4	Promote research, cross-agency collaborations, and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.	
Data Indicators	• Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities provided by HIV long-term survivor groups • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Academy of HIV Medicine • Area Agencies on Aging • Association of Nurses in AIDS Care • Local RWHAP Part A and EHE partners	• Create housing opportunities for the aging HIV population. • Expand funding to allow medical and support care for comorbidities. • Integrate cross-agency collaborations to include access to all client-level data to all RWHAP parts. • Provide education around HIV and aging to local partners and service organizations • Provide HIV education to the Florida Insurance Commission's office to promote less insurance burdens on HIV care. • Collaborate with HIV long-term survivor's groups to provide education to various stakeholder groups.
Planning Areas		
Statewide		

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Strategy 2.5.5	Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.	
Data Indicators	• Number RWHAP programs offering geriatric case management services • Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities provided by HIV long-term survivor groups • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Assisted living and skilled nursing facilities • Local RWHAP Part A and EHE partners	• Expand RWHAP services to offer geriatric case management and offer partner prevention services. • Explore opportunities to educate local and state legislators on the important role medical marijuana plays in the management of HIV disease. • Increase awareness with local providers to incorporate messaging on T&T and rapid ART protocols, HIV stigma and care, and aging HIV population. • Increase provider knowledge on aging HIV population, including persons with perinatally-acquired HIV • Revise service delivery models to address healthy aging and address comorbidities.
Planning Areas		
Statewide		

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9.1.2.6 Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure.

Strategy 2.6.1		Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.	
Data Indicators		• Number RWHAP programs offering geriatric case management services • Number of collaborations with service providers that specialize in services for the aging population • Number of collaborations with academic institutions focusing on HIV therapies and HIV cure research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners		• Collaborate with academic institutions to explore opportunities for research around HIV therapies and an HIV cure. • Explore ways to leverage RWHAP Part A funding to support services for aging PWH. • Provide HIV education to the Florida Insurance Commission's office to promote less insurance burdens on HIV care.
Planning Areas			
Statewide			

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Strategy 2.6.2	Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ARV-free remission, reduce, and eliminate viral reservoirs, and achieve HIV cure.	
Data Indicators	• Percent of ADAP clients using injectable ART • Number of collaborations with academic institutions focusing on HIV therapies and HIV cure research • Number of collaborations with academic institutions engaged in clinical research and ART clinical trials • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Engage with medical providers and insurance companies to on ways to reduce the burden of medication interruption. • Collaborate with academic partners and institutions on clinical research and ART clinical trials. • Collaborate with academic partners and institutions to explore opportunities for research around HIV therapies and an HIV cure. • Increase access to ART injection medications through ADAP and other payer sources.
Planning Areas		
Statewide		

**Goal 3: Reduce HIV-related Disparities and Health Inequities****9.1.3.1 Objective 3.1. Reduce HIV-related stigma and discrimination**

Strategy 3.1.1	Strengthen enforcement of civil rights laws (including language access services and disability rights), reform state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, and sexism.	
Data Indicators	• Number of educational and skills building opportunities for PWH • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Advocates • Local and state law enforcement • First responders • Department of Justice and U.S. Immigration and Customs Enforcement satellite offices • Correctional facilities • HIV Justice Coalitions • RWHAP partners	• Educate local and state law enforcement agencies on culturally competent HIV basics, civil rights, and trauma informed care. • Educate local and state legislators, political and civic. Leaders and organizations, and policy makers on basic HIV transmission, prevention, and care; include HIV data specific to local areas. • Support education and skill building opportunities for PWH to promote understanding of civil rights and engagement in policy making.
Planning Areas		
Statewide		

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Strategy 3.1.2	Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or at risk for HIV.	
Data Indicators	• Number of continuing education opportunities and trainings for health care professionals and front-line staff • Number of HIV stigma materials developed and/or disseminated • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • State and local law enforcement • First responders • RWHAP partners	• Develop and/or identify and disseminate HIV stigma materials and resources for health care professionals and front-line staff. • Identify and disseminate continuing education opportunities and training for health care professionals and front-line staff on HIV stigma; include working with the AETC and Area Health Education Centers. • Work with professional organizations to encourage the adoption of HIV stigma training as part of professional standards for health care professionals and front-line staff.
Planning Areas		
Statewide		

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Strategy 3.1.3	Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.	
Data Indicators	• Number of outreach and education opportunities to recruit peers • Number of community and faith-based leaders engaged in trainings that address HIV stigma and misconceptions • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Conduct outreach and education campaigns to train and employ peers to provide education, navigation, and support services. • Create opportunities and invite marginalized individuals to speak and join virtually (and anonymously) to present their perspectives, educate, and stay protected. • Engage community- and faith-based leaders at local and state levels to develop and host culturally tailored trainings that address stigma and HIV misconceptions. • Support local areas to develop general education and social media campaigns and materials to de-stigmatize HIV and those living with or affected by HIV.
Planning Areas		
Statewide		

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Strategy 3.1.4	Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.	
Data Indicators	• Number of new diagnoses in communities and priority populations at increased risk for HIV • Number of mobile medical units providing services to priority populations • Number of ongoing and new initiatives for priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Identify or develop information to educate potential funders and philanthropic organizations to increase awareness of HIV-impacted populations and communities. • Support ongoing and new initiatives and programs specifically focused on priority populations. • Use HIV data to target HIV and STI education and outreach to high-priority populations and ZIP codes which reflect the residents and effectively represent the community. • Use mobile medical units and street outreach to bring services and resources to communities and populations where the need is greatest.
Planning Areas		
Statewide		

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Strategy 3.1.5		Create funding opportunities that specifically address social determinants of health (SDOH) as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.	
Data Indicators	Priority Populations	• Number of funding opportunities which support programs that address SDOH in Black, Hispanic and other racial/ethnic communities • Number of educational opportunities which address SDOH • Additional specific, quantifiable measures for each activity (TBD)	
		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Tribal organizations • RWHAP partners		• Approach private corporations and other entities for sponsorship and educational opportunities to address SDOH. • Develop mini grants and create other opportunities to support programs that address SDOH in Black, Hispanic/Latino, and other racial/ethnic communities. • Explore opportunities to expand the use of MAI funding and assess outcomes.
Planning Areas			
Statewide			

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9.1.3.2 Objective 3.2. Reduce disparities in new HIV diagnoses, in knowledge of status, and along the HIV care continuum

Strategy 3.2.1		Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.	
Data Indicators		• Number of materials developed and disseminated which highlight HIV-related disparities • Number of HIV data dashboards available • Number of educational opportunities and listening sessions for impacted communities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Develop and expand the use of easy-to-read materials (e.g., infographics, one pagers) to help audiences of varying types (general public, clients, providers) to highlight HIV-related disparities. • Expand the use of data dashboards and provide education to relevant groups on how to access and use the information to increase awareness of HIV-related disparities. • Focus efforts to educate and gather information from populations and communities impacted by disparities. Include client perspectives and needs in addition to quantitative data.	
Planning Areas			
Statewide			

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Strategy 3.2.2	Develop new and scale up effective, evidence-based, or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.	
Data Indicators	• Number of collaborations with academic institutions and other partners (outside of HIV) • Number of funding opportunities which focus on improving health outcomes in priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community-HIV Advisory Group • RWHAP partners	• Collaborate with academic institutions and other partners (outside of HIV) to develop EBIs focused on priority populations and geographic areas impacted by disparities; other partners include mental health, substance use, SAMHSA providers, local homeless coalitions, and others.). • Develop funding mechanisms to support the development or scale up of interventions to improve health outcomes (e.g., mini-grants, RFAs, purchase orders). • Support opportunities at local and state levels to develop or scale up EBIs, including developing internship programs to engage young professionals. • Use local economic modeling to determine those interventions for scale up (e.g., interventions that have the greatest potential to reduce HIV in communities and populations experiencing disparities).
Planning Areas		
Statewide		

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9.1.3.3 Objective 3.3. Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

Strategy 3.3.1		Create and promote public leadership opportunities for people with or at risk for HIV.	
Data Indicators		• Number of people with or at risk for HIV on planning bodies and other advisory groups • Establishment of peer navigator certification program • Number of training and mentorship opportunities for PWH to build leadership and advocacy skills • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • Community-HIV Advisory Group • SSPs • Academia • RWHAP partners	• Develop and support opportunities for people living with or affected by HIV to serve in leadership roles at state and local levels (e.g., HIV Speaker's Bureau). • Establish a statewide peer navigator and educator certification program. • Increase and expand education, training, and mentorship opportunities for PWH to build skills for engaging in a variety of leadership and advocacy roles (social, political, civic, spiritual). • Create an inventory of chairs and co-chairs for local area advisory and planning groups	
Planning Areas			
Statewide			

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Strategy 3.3.2	Work with communities to reframe HIV services and HIV-related messaging so they do not stigmatize people or behaviors.	
Data Indicators	• Number of HIV-related materials reviewed by the state’s educational material review panel • Number of engagement activities conducted with priority populations and local leaders to develop HIV-related messaging • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community-HIV Advisory Group • Educational material review panel • RWHAP partners	• Engage with priority populations and local leaders/influencers to develop HIV-related messaging that does not stigmatize. • Ensure the intentional use of people-first and inclusive language in HIV service delivery, educational materials, and informational campaigns (review existing and incorporate into new products). • Expand the use the state’s health education review panel (i.e., Carlos Alvarez Educational Material Review Panel) to ensure HIV-related messaging and materials are culturally and linguistically appropriate and use people-first language.
Planning Areas		
Statewide		

9.1.3.4 Objective 3.4: Address social determinants of health and co-occurring conditions that exacerbate HIV-related disparities

Strategy 3.4.1		Develop whole-person systems of care that address co-occurring conditions for people with HIV or at risk for HIV.	
Data Indicators		• Number of syphilis diagnoses in communities and priority populations at risk for STIs • Number of HCV diagnoses in communities and priority populations at increased risk for HCV, including PWID • STI, HCV, and TB co-infection rates among persons diagnosed with HIV • Number of new diagnoses in communities and priority populations at increased risk for HIV • Viral suppression percentages in communities and priority populations at increased risk for HIV • Additional specific, quantifiable measures for each activity (TBD)	
		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP (all parts) and EHE partners		• Expand local partnerships and collaborate with local providers to address and alleviate barriers to accessing care. • Identify opportunities to centralize eligibility, enrollment services, and health care services for PWH (e.g., HOPWA, RW, ADAP). • Incorporate other health screenings and services into HIV care. • Pilot health care models and interventions for people at risk for or living with HIV who have co-occurring conditions e.g., SUD and mental health conditions.
Planning Areas			
Statewide			

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Strategy 3.4.2		Adopt policies that reduce cost, payment, and coverage barriers to improve the delivery and receipt of services for people with or at risk for HIV.	
Data Indicators		• Number of HIV service providers offering after hours and weekend services for HIV clients • Number of training and cross-training opportunities for medical case managers, RWHAP Part B, HOPWA, and CBOs • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP Part A and EHE partners • RWHAP Part B • Health care and related policy and advocacy orgs. • Insurance providers • Pharmaceutical industry partners	• Centralize eligibility processes and cross-train medical case managers, RWHAP Part B, HOPWA and CBOs. • Streamline clinical practices, reduce annual number of visits, CDH, PVC tests. Three or 6-month ART prescriptions. • Explore cost-effective programs that reduce cost, payment, and coverage barriers to improve the delivery and receipt of services for people with or at risk for HIV and use their findings for adopting related policies. • Create consistencies in the RWHAP system of care (Part A, Part B) to eliminate barriers to HIV care (e.g., longer time in between recertification, reciprocal eligibility). • Explore the incorporation of afterhours and weekend services for HIV clients to assist with retention in and adherence to care. • Engage in discussions with Florida Office of Insurance Regulation, Medicaid/Medicare (ACHA), and other entities to identify policies that create barriers for delivery of HIV services for people with or at risk for HIV.	
Planning Areas			
Statewide			

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Strategy 3.4.3		Improve screening and linkage to services for people with or at risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.	
Data Indicators		• Number of educational opportunities for providers specializing in co-occurring conditions • Number of partnerships with agencies implementing routine screening and linkage services • Number of mobile units offering HIV/STI screening, treatment, and prevention services during non-traditional hours • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Mobile units • Drug treatment programs • SSPs • Academia • RWHAP and EHE partners	• Educate providers specializing in co-occurring conditions. • Expand collaboration with FQHCs (and FQHC look-alikes) at state level to improve screening. • Expand partnerships with agencies to expand routine screening and linkage to care services for persons newly diagnosed with HIV or for persons previously diagnosed who are returning to care. • Address challenges and barriers to screening and linkage to services for people with or at risk for HIV who are diagnosed with and are receiving services for co-occurring conditions. • For those at risk, educate non-HIV providers to conduct sexual health and substance use risk assessments routinely. Work with medical certification boards to ensure ongoing education and compliance. • Increase the use of mobile units offering HIV and STI screening, treatment, and prevention services beyond traditional testing hours. • Explore opportunities to modify electronic medical records to increase routine screening and facilitate information sharing	
Planning Areas			
Statewide			

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Strategy 3.4.4	Develop and implement effective, evidence-based- or evidence-informed interventions that address social determinants of health among people with or at risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.	
Data Indicators	• Number of mobile units providing outreach services to priority populations • Number of educational materials identified and disseminated on client rights and health literacy • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Peers and near-peers • CHWs • RWHAP (all parts) and EHE partners • Local and state law enforcement • Housing coalitions • Health care and related policy and advocacy orgs. • Transportation agencies	• Expand the use of mobile outreach units and telehealth technology to address SDOH and provide linkage referrals. • Explore opportunities to use peers and CHWs as mentors outside of the health care system. • Identify and disseminate information and trainings for clients on their rights, grievance policies, customer feedback, and health literacy.
Planning Areas		
Statewide		

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Strategy 3.4.5	Develop new and scale up effective, evidence-based/informed interventions to improve health outcomes and QOL for people across lifespan including youth and people over 50 w/ or at risk for HIV, and long-term survivors.	
Data Indicators	• Establishment of telehealth provider network • Number of cultural humility trainings for providers • Number of non-traditional HIV/STI testing and treatment sites • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons aged 50+; youth; long-term survivors	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Elder services agencies	• Develop a telehealth provider network. • Expand access to HIV/STI testing and treatment outside of public health; include public-private partnerships. • Identify and disseminate trainings that include cultural humility trainings for providers. • Identify best practices for consortia to find and identify EBIs. • Promote long-term survivor groups and the Florida Gay Men's HIV Workgroup.
Planning Areas		
Statewide		

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Strategy 3.4.6	Develop new and scale up effective, evidence-based/informed interventions that address intersecting factors of HIV, trauma and violence, and gender especially among cis- and transgender women and gay and bisexual men.	
Data Indicators	• Number of trainings identified and disseminated on TIC • Number of training opportunities for evidence-based interventions addressing mental health • Number of training opportunities to educate the HIV, STD, hepatitis/substance use, and mental health workforce on intersecting issues • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Correctional settings • RWHAP and EHE partners • Correctional settings • Advocacy groups	• Create opportunities to support providers and agencies implementing EBIs that address trauma and violence. • Identify and disseminate provider trainings on trauma informed care (TIC). • Identify and develop training-of-trainers for TIC to ensure all RWHAP are using a TIC approach. • Provide training opportunities for existing EBIs in the mental health practice. • Identify existing effective, EBIs that address intersecting factors of HIV, trauma and violence, and gender. • Recruit staff with lived experience that reflect the PWH they are trying to serve. • Educate the HIV, STD, hepatitis, substance use, and mental health workforce on the intersecting issues. Ensure diverse organizations are involved in the development of new cross-sectional interventions. Seek out or directly provide funds to support collaborative efforts.
Planning Areas		
Statewide		

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- 9.1.3.5 Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations.

Strategy 3.5.1		Promote the expansion of existing programs and initiatives designed to increase the numbers of racial/ethnic minority research and health professionals.	
Data Indicators		• Number of trainings for HBCUs around HIV prevention, care, and treatment • Number of partnerships established with HBCUs • Development of inventory of SPNS projects and opportunities for replication • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Racial/ethnic minority research and health professionals	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations		• Create a state-funded program to fill federal gaps. • Cross-train CHWs. • Increase promotion of the HIV field in academic institutions (e.g., MPH programs, Schools of Medicine, Pharmacy, Nursing, and Social Work) through career fairs and supporting certifications and training programs. • Provide training and opportunities for partnership with HBCUs around HIV prevention, care, and treatment. • Develop an inventory of SPNS and support funding opportunities to replicate effective programs.
Planning Areas			
Statewide			

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Strategy 3.5.2	Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.	
Data Indicators	• Number of organizations identified that have mentorship programs • Number of training opportunities identified for PWH to build leadership and advocacy skills • Number of professional groups and associations engaged • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations	• Identify and support the use of mentorship programs for individuals from diverse backgrounds • Elevate voices of people living with HIV through increased advocacy and training. Encourage their participation through support groups. Ensure people who represent the population are in positions to assist with peer support services. • Support implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals. • Identify organizations that have existing mentoring programs and disseminate the information with other agencies to coordinate efforts. • Reach out to professional groups that emphasize memberships of color like the National Association for Black Social Workers, HBCUs, sororities and fraternities, civic organizations, and others.
Planning Areas		
Statewide		

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Strategy 3.5.3		Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.	
Data Indicators		• Number of opportunities to collaborate with the Florida Center for HIV/AIDS Research • Number of research study opportunities shared with community partners and planning bodies • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWI and persons who use drugs	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations	• Develop professional articles for publication. • Identify opportunities to collaborate with the FCHAR. • Provide information on and encourage community participation in legitimate research studies and grants. • Recruit youth and young adults to participate in local and state HIV planning bodies and advisory workgroups. • Support the use of community opinion leaders and social networking strategies. • Amplify and encourage efforts to share research output with participants.	
Planning Areas			
Statewide			

9.1.3.6 Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust.

Strategy 3.6.1			Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
Data Indicators	• Number of educational and community sharing opportunities to share information and address misinformation • Number of anti-stigma campaigns and materials developed to dispel HIV myths • Assessment of common myths and misconceptions held in and among priority populations • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Peers and near-peers • CHWs • Academia • Media partners • Digital content providers • RWHAP and EHE partners	• Assess common myths and misconceptions in and among priority populations and identify strategies to combat misinformation. • Promote the use of community sharing experiences and educational opportunities (e.g., community forums, celebrations, observance days). • Ensure messaging is succinct, culturally appropriate, consistent with HIV treatment guidelines, and delivered by persons credible to diverse populations across the state. • Develop and disseminate anti-stigma campaigns which focus on dispelling myths and misconceptions about HIV. • Expand the use of community gatekeepers and social network strategies to deliver HIV information through culturally appropriate methods. • Use existing workgroups to assist with developing and testing strategies to promote accurate creation, dissemination, and uptake of information and to counter misinformation.	
Planning Areas			
Statewide			

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Strategy 3.6.2		Increase diversity and cultural competence in health communication research, training, and policy.	
Data Indicators		• Number of collaborations with HBCU medical colleges and other schools of health • Number and type of training opportunities for cultural humility in health communication research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Professional and policy organizations and associations	• Create opportunities for advancement among diverse candidates. • Identify ways to create more targeted messaging for specific populations of PWH and consistently use language that is both people-first and inclusive. • Work with HBCU medical colleges such as Pharmacy, Social Work, Nursing, Medical Schools, and others. • Provide training opportunities for diversity and cultural competence in health communication research, training, and policy (e.g., conferences, webinars, lunch-and-learns). • Train and hire PWH who are qualified for roles in HIV leadership, research, training, peer support, and others. • Work with statewide advisory groups and SMEs to identify ways in which diversity and cultural humility can be incorporated into health communication trainings.	
Planning Areas			
Statewide			

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Strategy 3.6.3		Expand community engagement in health communication initiatives and research.	
Data Indicators	Priority Populations	• Number and type of engagements with CBOs, social service agencies and community resource centers • Assessment of populations that may not be receiving accurate health information • Number of collaborations with academic institutions to solicit feedback on health communication initiatives and research • Additional specific, quantifiable measures for each activity (TBD)	
		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community gatekeepers • RWHAP and EHE partners	• Identify ways to engage priority populations and communities in HIV media and messaging initiatives and research. • Increase engagement with CBOs, community resource centers, and social service agencies to help develop new health communication initiatives; activities could include townhall meetings, focus groups, health fairs, community celebrations, cultural events, and others. • Assess populations that may not be receiving accurate health communications, recruit leaders from those populations and train them to disseminate communications (through staffing agreement). • Engage with academic institutions (e.g., HBCUs) to solicit feedback on health communication initiatives and research. • Amplify and encourage efforts to share research output with participants.	
Statewide			

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Strategy 3.6.4	Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.	
Data Indicators	• Number and type of needs assessments conducted • Number of educational opportunities for providers, peers, and staff on health literacy identified and disseminated • Number and type of health literacy resources identified and developed for clients • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • AETC • Community gatekeepers • CHWs • Peers and near-peers	• Explore ways in which to incorporate critical analysis and health communication skills into HIV programs and services to increase client skills needed for health literacy and advocacy. • Ensure that needs assessments are conducted regularly, including questions related to provider communication skills and HIV-related messaging, in order to better respond to community needs and identify areas for improvement. • Identify and disseminate educational opportunities for providers, peers, and staff on health literacy, and encourage providers to screen clients for health literacy in order to be able to ensure the successful transfer of health information and health communication. • Identify and develop health literacy resources for clients that are new to care in order to help orient them to ways they can become more knowledgeable about their health and actively participate in their plan of care. • Increase provider and staff knowledge for strategies to identify and address misinformation and for strategies that increase the sharing of accurate health information.
Planning Areas		
Statewide		

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Strategy 3.6.5			Expand effective communication strategies between providers and clients to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.
Data Indicators			• Number of local leaders, influencers, and gatekeepers recruited to assist with communication initiatives • Number of CHWs and peers • Number of education and training opportunities on leading with empathy, active listening, patient experience, and on TIC • Additional specific, quantifiable measures for each activity (TBD)
Priority Populations			HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • AETC • Community gatekeepers • CHWs • Peers and near-peers		• Identify best practices for effective communication strategies between providers and clients to address medical mistrust. • Recruit local leaders, influencers, and gatekeepers to assist with communication initiatives designed to build trust. • Use CHWs and peers help to bridge communication gaps between clients and providers. • Offer education and training on leading with empathy, active listening, patient experience, and TIC to promote understanding amongst clients and providers to build trust in the client to provider relationship. • Research best practices in effective communication and explore the creation of a health communication resource compendium. • Increase the reach of messaging and media by engaging with community leaders and expanding partnerships to include organizations and agencies of all size. • Offer third-party encryption messaging to strengthen consumer trust.
Planning Areas Statewide			



Goal 4: Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic Among All Partners and Interested Parties

9.1.4.1 Objective 4.1. Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and/or institutional factors including stigma, discrimination, and violence

Strategy 4.1.1	Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness/housing instability, STIs, viral hepatitis, and substance abuse/mental health disorders.	
Data Indicators	• Development of community of practice to share expertise and collaborate on focus areas • Number of trainings identified and disseminated related to human trafficking, domestic violence, and sexual assault • Number of partnerships with mobile providers • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • Housing coalitions • HOPWA providers • State and local law enforcement	• Develop a Community of Practice program (HUD, Homeless Coalition, FDOE, FDC) to learn, share expertise, and collaborate on focus areas. • Expand marketing and advertising campaigns of internal and external partners to promote and increase awareness of resources and services. • Identify and disseminate trainings and technical assistance on human trafficking, domestic and intimate partner violence and sexual assault for health care staff. • Increase partnerships with mobile service providers. • Leverage social media and outreach to disseminate program results and lesson learned.
Planning Areas		
Statewide		

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Strategy 4.1.2		Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.	
Data Indicators		• Number of reciprocal agreements established with local community partners • Number of HIV service providers using a no-wrong-door approach to screening and linkage services • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Health care providers • RWHAP and EHE partners	• Adopt a no-wrong-door approach focused on streamlining referral processes and linkage to care. A no-wrong-door approach provides individuals with or links them to appropriate services regardless of where they enter the system of care. This principle commits all service agencies to respond to the individual's stated and assessed needs with appropriate treatment or supportive linkage with programs capable of meeting the client's needs. • Establish local referral networking system to increase access to care through assignment of health care navigators. • Establish reciprocal agreements with local community partners.	
Planning Areas			
Statewide			

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Strategy 4.1.3	Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.	
Data Indicators	• Number of local information sessions conducted with stakeholders to identify barriers to service delivery • Analysis of data from the state’s HIV/AIDS hotline • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health and human rights advocates • HIV/AIDS policy experts • Health care providers • STD clinics • RWHAP and EHE partners • Local planning bodies	• Analyze and explore ways to use data from the state HIV/AIDS hotline to assess barriers. • Access statewide resources to identify gaps in service and funding opportunities to combat programmatic barriers. • Conduct local information sessions/workshops with stakeholders to analyze data and identify problematic areas as it relates to the delivery of service. • Create incident reporting system to identify individuals in need of assistance (e.g., assault, discrimination, housing). • Engage with local and state legislators to educate and inform on workforce capacity and impacts of staffing shortages.
Planning Areas		
Statewide		

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Strategy 4.1.4		Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, and local partners.	
Data Indicators	Priority Populations	• Development of collaborative forum to share and learn about OD2A programs • Number of local health care facilities participating in local community health needs assessments • Additional specific, quantifiable measures for each activity (TBD)	
		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • FDCF • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings and providers • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners • Local planning bodies		• Ensure the Community Health Improvement Plan and Community Health Assessment is inclusive of internal and external partners. • Create a collaborative forum to share and learn about (OD2A programs across multi-agencies (e.g., faith-based organizations, CBOs, providers, the Department, FDCF). • Ensure the State Health Improvement Plan process and planning is inclusive of external groups and partners. • Establish a role or function in existing local planning bodies to conduct research into opioid initiatives and networks. • Invite local health care facilities to participate in local community health needs assessments.
Statewide			

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Strategy 4.1.5	Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.	
Data Indicators	• Number of opportunities to education state and local legislators on harm-reduction practices • Number of local planning bodies supporting or participating in opioid initiatives • Number and type of naloxone access points • Number of naloxone training courses identified and disseminated • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • State and local law enforcement • Local planning bodies • RWHAP and EHE partners	• Educate local and state legislators on the use of fentanyl test strips and alignment with harm-reduction practices. • Establish a role or function in existing local planning bodies across multiple agencies (CHD, community, state, FCPN, OD2A project opioid providers) to support and/participate in opioid initiatives or the development of an opioid initiative. • Implement Naloxone Training Course and Training Program (CDC) • Increase the number of access points for naloxone (statewide). • Integrate OD2A into RWHAP service delivery system at local levels.
Planning Areas		
Statewide		

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9.1.4.2 Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and CBOs, the private sector, academic partners, and the community

Strategy 4.2.1		Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.	
Data Indicators		• Development of interactive locator for mobile service providers • Number of public-private partnerships established at local levels • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHP and EHE partners • Digital resource providers (e.g., AIDSVu)		• Develop a mapping tool/interactive map locator/pin map of mobile units. • Develop regular partnership meetings with internal and external service providers at the local level. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Identify best practices and interventions from other jurisdictions that address similar priority populations. • Increase the use of outreach and education to reach priority populations and geographies.
Planning Areas			
Statewide			

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Strategy 4.2.2	Enhance collaboration among local, state, tribal, territorial, national, and federal partners, and the community to address policy barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.	
Data Indicators	• Development of centralized information platform to collect integrated HIV planning information • Number of and type of materials developed and disseminated in three languages (i.e., English, Spanish and Haitian-Creole) • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health and human rights advocates • HIV/AIDS policy experts • Health care providers • PWH engaged in services • Tribal organizations • Minority leadership programs • RWHAP and EHE partners	• Appoint community liaisons among local, state, tribal, territorial, national, and federal partners to assess and address barriers and social determinants via policy change and enhanced communication. • Create a centralized information platform to house local, county, state, consortium planning body meeting information, and proposed activities, and projects. • Create opportunities to bring a wide variety of partners and stakeholders together to increase cross-collaboration. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Incorporate three-language formula in marketing and advertising materials to overcome social barriers in disproportionate communities.
Planning Areas		
Statewide		

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Strategy 4.2.3		Coordinate across partners to quickly detect and respond to HIV outbreaks.	
Data Indicators		- Number and geographic location of HIV transmission clusters identified - Number of intersectional teams developed at local levels for outbreak response - Number of mobile units using HIV transmission cluster data to direct positioning - Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities	
By 12/31/2026	- The Department - Community- and faith-based organizations - Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites - Behavioral health care and substance abuse settings - Drug treatment programs - SSPs - Academia - Health care providers - RWHAP and EHE partners	- Create a centralized system for outbreak detection, reporting, and notification (e.g., meningitis, Mpox, HIV, STD, viral hepatitis). - Develop intersectional teams and protocols that include Department DIS, RWHAP programs, funded EHE providers, case managers, local medical and support services providers to share information and rapidly identify and link individuals diagnosed with HIV to care and treatment. - Establish response planning teams across multi-agencies and multi-sectors of the community (e.g., faith-based organizations, CBOs, providers, the Department) to track HIV outbreaks and provide rapid access to HIV treatment and care. - Use HIV transmission cluster data to direct the positioning of mobile units to respond to clusters of active transmission.	
Planning Areas			
Statewide			

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Strategy 4.2.4	Support collaborations between CBOs, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.	
Data Indicators	• Inventory of multi-agency collaborations at local levels • Number of partnerships with non-traditional sites to provide HIV awareness, prevention, or linkage services • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Educational institutions • Health care providers • Housing providers • RWHAP and EHE partners	• Advocate for the revision of MOAs and contracts to include specific standards, wrap-around services (e.g., housing, mental health services, and participation in planning). • Assess and review state and national collaborative frameworks to identify and adopt approaches that enhance current and future public-private partnerships that help scale up best practices and advances in HIV prevention and treatment. • Educate local and state legislators on the state's priority populations and geographies. • Form partnerships with non-traditional sites (e.g., gas stations, sporting events, public restrooms, rest stops) for the extension of providing HIV prevention and treatment services or awareness. • Identify best practices for increasing collaborations among CBOs, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.
Planning Areas		
Statewide		

9.1.4.3 Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

Strategy 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.		
Data Indicators	• Development of centralized dashboard to share aggregate HIV-related data • Number of data sharing agreements developed with RWHAP partners • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Create centralized system or dashboard to share aggregate HIV-related data (e.g., testing, treatment, surveillance) internally and externally that can be readily used to understand local area disease burden, obtain information for grant requirements and using data for action and response. • Design a data system and process for improving data sharing amongst all RWHAP Parts, Florida ADAP, and service providers to improve client-level data sharing and HRSA RSR reporting requirements. • Develop a process to improve and simplify the sharing of HIV-related data both internally and externally to the Department to improve service provision. • Develop a process to increase working with external partners such as VA, private providers, Medicare, and others to improve data sharing at state and local levels. • Ensure that forms and policies around release of information and methods for release (e.g., text, email, phone) are continuously updated and shared with providers.
Planning Areas Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.3.2	Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator’s Health IT Certification Program, and health information exchange networks, to improve HIV prevention efforts and care outcomes.	
Data Indicators	• Evaluation of digital resources and clinical decision support tools • Development of reciprocal client-informed consent and release of information • Number of local areas with electronic referral systems • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners • Community HIV Advisory Group • AHCA • Correctional settings	• Assess the ability to create a Health Information Exchange (HIE) and master client index among HIV service providers and link the current Florida HIE to data in the HIV/AIDS Section to improve linkage to care efforts. • Create a reciprocal (e.g., across agencies and all RWHAP parts) client-informed consent and release of information to acknowledge that data may be shared to improve service provision and linkage to care needs. • Develop a process and system to initiate and track electronic referrals to HIV-related prevention, treatment services and other ancillary services. Consult with the AIMS workgroup to review current resources. • Evaluate and promote the use of digital resources and clinical decision support tools. • Identify ways to improve data collection efforts for HIV prevention efforts (e.g., HIV self-test kit information).
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.3.3			Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy supportive manner.
Data Indicators	• Development of client-centered training module around public health data collection and uses of patient information for public health • Development of reciprocal client-informed consent and release of information • Number and type of information shared around use of patient portals to facilitate client access to medical information • Assessment of information sharing methods best suited for rural communities and other areas with limited internet access • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Create a client-centered training module around public health data collection and uses of patient information for public health purposes to assist with alleviating fears about misuse and privacy concerns. • Provide guidance and supportive information to encourage the use of patient portals from providers and laboratories to ensure that clients have direct access to their medical information. • Ensure health communication and messaging from provider to client is private, secure, and accessible, and occurs through a HIPAA-compliant platform or channel. • Explore the incorporation of a centralized patient portal or health information application. • Encourage providers currently using patient portals to offer additional client-centered education on patient portal functionality and utilization. • Explore the increase of in-app or in-portal patient health education opportunities. • Assess methods to increase information sharing and patient health education opportunities for people living in rural communities or other areas with limited internet access.	
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

9.1.4.4 Objective 4.4: Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.

Strategy 4.4.1	Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, CBOs, allied health professionals, people with HIV and their advocates, the private sector, and other partners.	
Data Indicators	• Number and type of public-private partnerships established and maintained • Development of statewide conference on HIV • Number of non-traditional partners participating in local HIV awareness events • Number of HIV prevention and treatment sites using ARV starter packs • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Review and assess state and national collaborative frameworks to identify and adopt approaches that enhance current and future public-private partnerships that help scale up best practices and advances in HIV prevention and treatment. • Conduct an annual statewide conference on HIV and invite a wide range of traditional and non-traditional partners to participate and attend and share best practices. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Identify public-private partnership EBIs to scale up the use of ARV starter packs.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.4.2	Expand opportunities and mechanisms for information sharing and peer technical assistance in and across jurisdictions to move effective interventions into practice more swiftly.	
Data Indicators	• Development of centralized information repository on best practices programs and interventions for addressing the HIV epidemic • Number and type of information sharing mechanisms used in local areas • Number of multi-agency collaboratives supporting data and information sharing • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Create a centralized information repository to house and disseminate information on best practices, meeting information, and other information that will assist with addressing the HIV epidemic. • Develop local e-newsletters or other mechanisms to disseminate information quarterly on available resources and EBIs being used in the state. • Identify and establish local area collaborative coalitions across multi-agencies and multi-sectors of the community (e.g., faith-based organizations, CBOs, providers, the Department and others) to support data and information sharing and identify best practices that address the HIV epidemic. • Identify state and local subject matter experts and create a state specific technical assistance network.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.4.3			Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing persons of all ages living with HIV.
Data Indicators	• Development of centralized information repository on best practices programs and interventions for addressing the HIV epidemic • Number and type of information sharing mechanisms used in local areas • Number of multi-agency collaboratives supporting data and information sharing • Additional specific, quantifiable measures for each activity (TBD)		
	Priority Populations		
PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers			
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Health care providers • Academia • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community-HIV Advisory Group	• Adopt a collaborative implementation science approach to evaluate, design, and implement strategies that improve health-related outcomes and promote the dissemination and replication of successful interventions and best practices locally. • Create a centralized online platform to collect and respond to complaints, challenges and general inquiries from service providers, clients, stakeholders, and the public. • Foster new and existing community, private, and cross-sector partnerships through strengthened communication and by supporting increased collaborative opportunities or Memorandums of Understanding centered on sharing information, discussing strategies, and providing education. • Increase partnerships and collaboration to provide age-appropriate sexual health resources, education, and support services for young people. • Conduct an annual statewide conference on HIV and invite a wide range of traditional and non-traditional partners to participate and attend and share best practices.	
Planning Areas			
Statewide			

9.2 Partnership Area Interview Questionnaires



9.3 Partnership Area Resource Inventories



9.4 Epidemiologic Profile

The full Epidemiologic Profile of HIV in Florida, 2017–2021 will be made available separately.

9.5 Other Supporting Documentation



9.6 Glossary

Acquired Immunodeficiency Syndrome (AIDS): A condition that exists when a person has tested positive for HIV and has one or more of 26 listed opportunistic illnesses/infections and/or a T-cell count of 200 or less per micro-liter of blood.

Business Responds to AIDS (BRTA): Modeled after the CDC initiative by the same name, developed initially in 1992, BRTA programs support targeted HIV prevention efforts through partnerships with local businesses. BRTA programs mobilize businesses and labor organizations to respond to HIV/AIDS in the workplace and the community with subtle, noninvasive approaches to raise awareness, promote services, and break down stigma. BRTA activities involve the use of promotional and incentive items that businesses can use to generate conversations around HIV/AIDS with their customers.

Community-Based Organization: A non-profit organization with a 501(c)(3) designation.

Community Engagement: The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address affecting the well-being of those people.

Community Health Worker: Trusted, knowledgeable frontline health personnel who typically come from the communities they serve. CHWs bridge cultural and linguistic barriers, expand access to coverage and care, and improve health outcomes.

Counseling, Testing and Linkage: Provision of counseling, testing and direct assistance in getting a client enrolled into the health and social service system.

Culturally Appropriate: Conforming to a culture's acceptable expressions and standards of behavior and thought. Interventions and educational materials are more likely to be culturally appropriate when representatives of the intended target audience are involved in planning, developing, and pilot testing them.

Epidemic: The occurrence of cases of an illness, specific health-related behavior, or other health-related events in a community or region in excess of normal expectancy.

Ethnicity: The cultural characteristics that connect a particular group or groups of people to each other, such as people of Hispanic or Latino origin.

Faith-Based Organization: A non-governmental agency owned by religiously affiliated entities such as (1) individual churches, mosques, synagogues, temples, or other places of worship or (2) a network or coalition of churches, mosques, synagogues, temples, or other places of worship.

Faith Responds to AIDS (FRTA): Built on the same framework as BRTA, FRTA is a Florida adaptation of the BRTA initiative but for faith-based organizations. FRTA programs are faith-based initiatives that mobilize churches and other faith-based institutions to raise awareness and reduce stigma around HIV/AIDS. FRTA programs are particularly effective at reaching minority communities. FRTA activities involve the use of promotional and incentive items that faith-based organizations can use to generate conversations around HIV/AIDS with their members.

Females: Individuals of the sex that produces large and generally immobile gametes (ova or eggs).

High-Impact Prevention (HIP): Using combinations of scientifically proven, cost-effective and scalable interventions targeted towards the highest risk populations in the right geographic areas to reduce new HIV infections.

HIV Mode of Exposure: Specific behaviors or actions that expose people to HIV and can potentially lead to HIV acquisition. Examples include unprotected anal or vaginal sex with a person living with HIV, injecting drugs with non-sterile, shared drug injection equipment, and male-to-male sexual contact.

Human Immunodeficiency Virus (HIV): The retrovirus virus can lead to AIDS, if not treated. The virus occurs in two types—HIV-1 and HIV-2. Both types are transmitted through direct contact (e.g., through sexual intercourse or sharing injection drug equipment) with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-positive mother to her child during pregnancy, birth, or breastfeeding.

Incidence: The occurrence of new cases of disease or injury in a population over a specified period of time.

Integrated Prevention and Care Plan: A plan based on the Integrated HIV Prevention and Care Plan Guidance that requires a collaborative process between CDC and HRSA to identify and address: statewide goals for HIV prevention and care; emphasize the populations and communities most affected by the epidemic; highlight areas of need, service gaps, and barriers; identify health disparities and social determinants of HIV-related health; outline activities for implementing goals; and, identify factors for measuring success in achieving goals.

Intervention: A specific activity (or set of related activities) intended to reduce the risk of HIV transmission or acquisition. Interventions may be either biomedical or behavioral and have distinct process and outcome objectives and protocols outlining the steps for implementation.

Linkage: Actively assisting clients with accessing needed services through a time-limited professional relationship. The active assistance typically lasts a few days to a few weeks and includes a follow-up component to assess whether linkage has occurred. Linkage services can include assessment, supportive counseling, education, advocacy, and accompanying clients to initial appointments.

Males: Individuals of the sex that produces small, mobile gametes (sperm).

Men who have Sex with Men (MSM): Men who report sexual contact with other men and men who report sexual contact with both men and women (i.e., bisexual contact), whether or not they identify as gay.

National HIV/AIDS Strategy for the United States: A comprehensive plan focused on reducing HIV incidence, increasing access to care and optimizing health outcomes, and reducing HIV-related health disparities.

Navigation Services: Patient navigation assistance is the process of helping a person obtain timely and appropriate medical or social services, taking into account provider preferences,

insurance status, scheduling issues, and other factors that may complicate access or utilization of services.

Navigator: Patient navigators are peers, volunteers, and/or staff members of clinics, health departments, and community-based organizations. Patient navigators may be lay persons, paraprofessionals, or medical professionals (e.g., RNs, LPNs).

Partner Services: A systematic approach to notifying sex and needle-sharing partners of PWH of their possible exposure to HIV so they can be offered HIV testing and learn their status or, if already diagnosed, prevent transmission to others. Partner Services helps partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

Peers (or Near-Peers): Specially trained individuals from the community who may or may not be living with HIV/AIDS, but ultimately have lived experience.

Perinatal: Occurring during the period around birth (5 months before and 1 month after)

Post-Exposure Prophylaxis (PEP): The provision of antiretroviral medications to prevent transmission of HIV following an occupational or non-occupational exposure. Non-occupational post-exposure prophylaxis is referred to as nPEP.

Pre-Exposure Prophylaxis (PrEP): Antiretroviral medication taken to prevention acquiring HIV.

Prevalence: The number of people with a specific disease or condition in a given population at a specific time.

Race: A person's self-reported classification of the biological heritage with which they most closely identify.

Rapid HIV Test: A point-of-care HIV screening test used in both clinical and non-clinical settings, usually with blood from a finger stick or with oral fluid.

Ryan White Treatment Modernization Act: The name given to the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act when it was reauthorized in 2006. This is the primary federal legislation that addresses the needs of persons in the United States living with HIV/AIDS and their families. The original CARE Act was enacted in 1990.

Seroprevalence: The overall occurrence of a disease or condition within a defined population at one time, as measured by blood tests.

Sex: Either of the two main biological categories (male and female) into which humans and most other living things are divided on the basis of their reproductive functions.

Social Determinants: The economic and social conditions that influence the health of persons, communities, and jurisdictions and include conditions for early childhood development; education, employment, and work; food security; health services; housing; income; and social exclusion.

Surveillance: The ongoing and systematic collection, analysis, and interpretation of data about occurrences of a disease or health condition.

Syndemic: The aggregation of two or more concurrent or sequential epidemics or disease clusters in a population with biological interactions, which exacerbate the prognosis and burden of disease.

Transgender: A person who does not identify with their sex at birth and may undergo gender transitionary care including hormone therapy and/or surgical procedures. This is also recognized as gender dysphoria.



2022-2026

STATE OF FLORIDA

Integrated HIV Prevention and Care Plan

EXHIBIT I

FY 2025 Standards of Care and Service Delivery Guidelines

**Dallas Planning Area
Dallas Eligible Metropolitan Area
Dallas and Sherman-Denison HIV
Services Delivery Areas
Ending the HIV Epidemic**

March 1, 2025 – February 28, 2026

Prepared by the Ryan White Planning Council
of the Dallas Area in Collaboration with the
Ryan White Grants Management Division of
Dallas County Health & Human Services

Updated 9/1/2024 **Approved by P&P 10/16/24**

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Table of Acronyms and Abbreviations

AA	Administrative Agency
Ab	Antibody
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ADA	American Disabilities Act
ADAP	AIDS Drug Assistance Program
AIDS	Acquired Immune Deficiency Syndrome
aPTT	Activated Partial Thromboplastin Time
TCT	Take Charge Texas Database
ART	Antiretroviral Therapy
ASAM	American Society of Addiction Medicine
ASI	Addiction Severity Index
ASL	American Sign Language
BIA	Bethesda Inhibitor Assay
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
BUN	Blood Urea Nitrogen
CARE/HIPP	Health Insurance Premium Payment
CBC	Complete Blood Count
CCR5	C-C chemokine receptor type 5
CD4	Cluster of Differentiation 4
CEU	Continuing Education Unit
CLAS	National Standards for Culturally and Linguistically Appropriate Services
CLIA	Clinical Laboratory Improvement Amendments
CNS	Clinical Nurse Assistant
COBRA	Consolidated Omnibus Budget Reconciliation Act
COVID-19	Coronavirus Disease 2019
CT	Chlamydia
DADS	Texas Department of Aging and Disability Services
DCHHS	Dallas County Health and Human Services
DHHS	Texas Office for Deaf and Hard of Hearing Services
DIS	Disease Intervention Specialist
DO	Doctor of Osteopathic Medicine
DPA	Dallas Planning Area
DSHS	Texas Department of State Health Services
DSW	Doctor of Social Work
EdD	Doctor of Education
EFA	Emergency Financial Assistance
eGFR	Estimated Glomerular Filtration Rate
EHE	Ending the HIV Epidemic
EIA	Enzyme Immunoassay
ePHI	Electronic Personal Health Information
EIS	Early Intervention Services

EMA	Eligible Metropolitan Area
FDA	U.S. Food and Drug Administration
FPL	Federal Poverty Level
GC	Gonorrhea
HAB	HIV/AIDS Bureau
HAV	Hepatitis A Virus
HBsAb	Hepatitis B Surface Antibody
HBV	Hepatitis B Virus
HCO₃	Bicarbonate
HCV	Hepatitis C Virus
HDL	High-density lipoprotein
HHS	U. S. Department of Health and Human Services
HIA	Health Insurance Premium and Cost-Sharing Assistance
HIV	Human Immunodeficiency Virus
HLA-B*5701	Human Leukocyte Antigen major histocompatibility complex, class I, B
HOPWA	Housing Opportunities for Persons with AIDS
HRA	High High-Resolution Anoscopy
HRSA	Health Resources and Services Administration
HSDA	HIV Service Delivery Area
IgG	Immunoglobulin G
IGRA	Interferon Gamma Release Assay
LDL	Low-density lipoprotein
LPAP	Local Pharmaceutical Assistance Program
LTBI	Latent Tuberculosis Infection
LVN	Licensed Vocational Nurse
MA	Master of Art
MA	Medical Assistant
MAC	Mycobacterium avium complex
MCM	Medical Case Manager/ Medical Case Management
MD	Doctor of Medicine
MEd	Master of Education
mL	milliliter
mm³	cubic millimeter
MMR	Measles, Mumps, and Rubella
MMSE	Mini Mini-Mental State Examination
MNT	Medical Nutrition Therapy
MS	Master of Science
MSW	Master of Social Work
NAAT	Nucleic Acid Amplification Test
NMCM	Non-Medical Case Management
NMS	National Monitoring Standards
NP	Nurse Practitioner
nPEP	Non-occupational post-exposure prophylaxis
OAHS	Outpatient/Ambulatory Health Services
OBRA	Omnibus Budget Reconciliation Act
PA	Physician Assistant
Pap	Papanicolaou (test)

PAPS	Pharmaceutical Patient Assistance Programs
PCN	Policy Clarification Notice
PCP	Pneumocystis pneumonia
PCV13	Pneumococcal Conjugate Vaccine
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
PHQ-2	Patient Health Questionnaire
PLWH	People Living with HIV
PPV23	Pneumococcal Polysaccharide Vaccine
PrEP	Pre-exposure prophylaxis
PT/INR	Prothrombin and International Normalized Ratio
QTF	QuantiFERON TB Test
RD	Registered Dietician
RN	Registered Nurse
RNA	Ribonucleic Acid
RWHAP	Ryan White HIV/AIDS Program
RWPC	Ryan White Planning Council
SAMISS	Substance Abuse and Mental Illness Symptoms Screener
SDI	State Disability Insurance
SNAP	Supplemental Nutrition Assistance Program
SSDI	Social Security Disability Insurance
SSI	Supplemental Security Income
STDs	Sexually Transmitted Diseases
STIs	Sexually Transmitted Infections
TAC	Texas Administrative Code
TANF	Temporary Aid to Needy Families
TB	Tuberculosis
Td	Tetanus and Diphtheria
Tdap	Tetanus, Diphtheria, and Pertussis
THMP	Texas HIV Medication Program
TMB	Texas Medical Board
TST	Tuberculin Skin Test
USPSTF	United States Preventive Services Task Force
VA	Veteran's Administration Benefits
VTCA	Vernon's Texas Code Annotated
VZV	Varicella-Zoster Virus
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children
μL	microliter

INTRODUCTION

This document provides guidance for care and service delivery, billing, and documentation requirements for organizations receiving Ryan White Parts A, B, State Services, and Ending the HIV Epidemic (EHE) funding in the Dallas Eligible Metropolitan Area (EMA) and the Dallas and Sherman-Denison HIV Service Delivery Areas (HSDA). The guidelines in this document are effective March 1, 2025, through February 29, 2026, and are not to be applied retroactively. Descriptions of the core medical and support services, the [How Best to Meet the Priority](#) document, and the [Service Category Eligibility Based on Federal Poverty Level Guidelines](#) document were developed and approved by the Ryan White Planning Council of the Dallas Area (RWPC) for service delivery in the Dallas EMA and the Dallas and Sherman-Denison HSDAs, known collectively as the Dallas Planning Area (DPA).

DEFINITIONS

Activities May Include:

A list of specific activities that are reimbursable under this service category. This list **is not** comprehensive; it was developed and approved by the RWPC.

Activities Must Include:

A list of specific reimbursable activities that must be included in the delivery of this service category; developed and approved by the RWPC.

Activities May Not Include:

A list of specific activities that are not reimbursable under this service category; developed and approved by the RWPC.

Unallowable Costs Include (per the Health Resources and Services Administration (HRSA)):

- Direct payments to clients
- Clothing
- Employment and employment-readiness services, except in limited, specified instances (e.g., Non-medical case management services or rehabilitation services)
- Funeral and burial expenses
- Property taxes
- Pre-exposure prophylaxis (PrEP)
- Non-occupational post-exposure prophylaxis (nPEP)
- Materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual
- International travel
- The purchase or improvement of land
- The purchase, construction, or permanent improvement of any building or other facility

Unit of Service:

The increment of service delivery used for reimbursement requests, documentation, and Take Charge Texas (TCT) entry. It was developed and approved by the Ryan White Grants Management Division of Dallas County Health and Human Services (the Administrative Agency (AA)).

Billing Limitations:

Additional restrictions or limits on the type or amount of service(s) eligible for reimbursement under applicable service categories developed and approved by the RWPC and the Ryan White Grants Management Division of Dallas County Health and Human Services.

How Best to Meet the Priority:

Special instructions developed and approved by the RWPC. These recommendations are ancillary to the services described in this document. They **may not be eligible** for reimbursement through Ryan White, Housing Opportunities for Persons with AIDS (HOPWA), or State Services grants. **Note:** Backup documentation must be submitted for all service units for which reimbursement is requested.

STATE AIDS DRUG ASSISTANCE PROGRAM TREATMENTS

HRSA Description: The AIDS Drug Assistance Program (ADAP) is a state-administered program authorized under Part B of the Ryan White HIV/AIDS Program (RWHAP) to provide U.S. Food and Drug Administration (FDA)-approved medications to low-income clients living with HIV who have limited or no coverage from private insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of antiretroviral therapy (ART). RWHAP ADAP recipients must conduct a cost-effectiveness analysis to ensure that purchasing health insurance is cost-effective compared to the cost of medications in the aggregate. Eligible ADAP clients must be living with HIV and meet the state's income and other eligibility criteria. Please refer to the [Texas HIV Medication Program \(THMP\) webpage for more information](#).

Activities include those determined by the state. ADAP funds may not be used for Local AIDS Pharmaceutical Assistance Program (LPAP) support. LPAP funds are not emergency financial assistance for medications. Allocations for State ADAP are administered through Part B funds and cannot be allocated with Part A or Minority AIDS Initiative (MAI) funds.¹

¹ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. AIDS Drug Assistance Program Treatments. [Page 8](#)

UNIVERSAL STANDARDS OF CARE

The Universal Standards listed below apply to all service categories funded under the RWHAP Part A, B, State Services, and Ending the HIV Epidemic programs for direct care service providers. These standards also apply to services funded in the Dallas EMA/HSDA. These Universal Standards are taken directly from [HRSA's Ryan White HIV/AIDS Program \(RWHAP\) National Monitoring Standards for RWHAP Part A Recipients](#), which includes the Part B HIV/AIDS Bureau (HAB) National Monitoring Standards and expanded to include the Texas Department of State Health Services (DSHS) program requirements for all Ryan White Part B and State Service subrecipients. HRSA/HAB "expects recipients to monitor fiscal and programmatic compliance with all contracts and other agreements for HIV services in the [EMA and] State/Territory" and to report on "ongoing progress" of implementation of the National Monitoring Standards (NMS).

STANDARD OF CARE FOR LICENSURE OR ASSURANCES

- I.** All service providers that receive Dallas County Health and Human Services (DCHHS) pass-through funds from local, state, or federal sources must comply with existing local, state, or federal laws and regulations governing the need for a criminal history check of prospective staff or volunteers. If the provider employs an individual in a staff or volunteer capacity despite discovering a history of prior criminal activity, DCHHS will assume no responsibility for the service provider's decision or any adverse consequences resulting from the employment.
- II.** All service providers shall ensure that each staff member signs a confidentiality agreement annually, affirming individual responsibility for keeping client information and data confidential, and shall maintain original signed confidentiality and Assurances documentation in staff personnel files.
- III.** All service providers shall ensure that each staff member signs Assurances annually, acknowledging that they have reviewed security policies and procedures relevant to their position and shall maintain original signed confidentiality and Assurances documentation in staff personnel files.

STANDARD OF CARE FOR STAFF AND VOLUNTEER TRAINING PROGRAMS

The service provider shall provide to its staff and volunteers the following training programs or opportunities, receipt of which shall be documented in individual staff/volunteer files:

- I.** Initial in-service orientation and training for new staff and volunteers, including agency policies and standard precautions, and periodic development training for all staff and volunteers as required to ensure the continued, safe delivery of high-quality services;

- II. Training on the laws and regulations regarding the privacy and confidentiality of client information;
- III. The opportunity for licensed/credentialed staff to take relevant outside courses to both improve their skills and, if required, earn continuing education units (CEUs) sufficient to maintain licensure and certification;
- IV. Annual cultural sensitivity/competency training complying with the [*National Standards for Culturally and Linguistically Appropriate Services*](#) (CLAS) to serve youth, transgender, African-American, Latinx, undocumented, and underserved populations.
- V. Written procedures on reporting requirements for suspected sexual child abuse reporting, as required by the State if the agency receives funds through grants provided by DSHS.
- VI. All service provider staff requiring access to local, state, or federal client information systems must complete confidentiality and security training annually before being granted access.

STANDARD OF CARE FOR KNOWLEDGE, SKILLS, AND EXPERIENCE

The staff and volunteers:

- I. Shall possess knowledge of HIV/AIDS; the effects of HIV/AIDS-related illnesses and comorbidities on clients; the psychosocial effects of HIV/AIDS on clients and their families/significant others; and current strategies for management of HIV/AIDS;
- II. Those who interact with clients or contacts shall possess the needed communication skills and experience in dealing with a wide variety of people and;
- III. Are culturally sensitive and promote equity in working with persons affected by the HIV epidemic, such as those who are underserved or part of a disproportionately affected population.

STANDARD OF CARE FOR CLIENT RIGHTS AND CONFIDENTIALITY

The service provider:

- I. Shall provide an orientation for clients, during which the clients are made aware of their rights, obligations, services available to them, and realistic expectations of service (exceptions: Health Education/Risk Reduction and Outreach Services categories);
- II. Shall develop the following instruments in both English and Spanish, distributing a copy to each client and posting a copy in a conspicuous place within the facility, as indicated below (exceptions: Health

Education/Risk Reduction and Outreach Services categories):

- a. A client "Bill of Rights" (distributed to each client) which takes into account state and federal laws protecting client rights (including a nondiscrimination statement covering age, gender, race, color, religion (or lack thereof), national origin, sexual orientation, gender identity or expression, disability, political affiliation, and inability to pay), and a written grievance procedure (distributed and posted in a conspicuous place), including Assurances that neither the agency nor any of its staff will retaliate against clients for filing a grievance;
- b. A written policy regarding clients' entitlement to confidentiality (distributed to each client);
- c. An "authorization form to disclose client information." This form must be specific to the individual(s) and service provider(s) to whom the client authorizes the disclosure of information. The form must specify what information will be disclosed, including the expiration date, and is to be signed by the client before disclosing any information. A copy of the signed authorization form shall be retained in each client's record. If a service provider's standards allow for 'verbal approval' (in urgent situations only), verbal approval will be sufficient so long as the individual obtaining the verbal approval signs the authorization form and a witness's signature to attest to the client giving verbal approval. The authorization form with both signatures should be retained in each client's record.
- d. Written policies and procedures are in place to describe how the agency determines, documents, and reports suspected instances of child abuse in accordance with [Chapter 261 of the Texas Family Code](#);
- e. Written policies and procedures are in place to require documented training of all staff regarding every aspect of suspected sexual child abuse screening and reporting;
- f. Written emergency procedures (building evacuation map and emergency procedures to be followed by staff and clients in the event of a fire, bomb threat, severe weather, loss of power, or pandemic) must all be posted; written policy regarding chemical spills or possible biological exposure (i.e., suspected anthrax or smallpox) event need not be posted, but must be in place;
- g. Application and eligibility assessment process, including written, clearly defined eligibility criteria consistent with HRSA written policy (Policy Clarification Notices (PCN) [#13-03](#), [#16-02](#), and [#21-02](#)), ranking criteria for eligible applicants when waiting lists exist, and a written policy regarding the transfer, discharge, or termination of services (distribute); and
- h. Shall maintain client files (written or electronic) in a locked and secured area.
- i. Written policies ensuring respect for client and staff gender identity and expression, which are a person's gender-related identity, appearance, or behavior, whether or not related to what is traditionally associated with the person's physical characteristics or sex assigned at birth. Gender identity may be supported by a medical history of treatment and care related to the identity, consistent

assertion, or any other affirmation that the identity is sincerely held, part of a person's core identity, and not being asserted for an improper purpose.

STANDARD FOR ACCESS, CARE, AND PROVIDER CONTINUITY

The service provider:

- I.** Shall, except where grant funds may be specifically restricted (e.g., MAI funds), provide its services to eligible persons regardless of age, gender, race, color, religion (or lack thereof), national origin, sexual orientation, gender identity or expression, disability, political affiliation, or inability to pay, to the extent resources allow;
- II.** Shall provide culturally sensitive and promote equity services for clients, and shall address linguistic barriers, either directly (by employing bilingual staff, utilizing adaptive equipment for sensory-impaired individuals, etc.) or indirectly through referral (exception: Health Education/Risk Reduction service category);
- III.** Shall provide access to its facility for disabled persons;
- IV.** Shall abide by the general principles for substance abuse/drug screening and disruptive behavior, as approved by the Ryan White Planning Council of the Dallas Area on August 11, 1999 (refer to Appendices [E](#) and [G](#), Texas DSHS HIV/STD Policies [530.002](#) and [530.003](#)).
- V.** Shall provide access to its system of care for persons with HIV/AIDS twenty-four (24) hours/day (i.e., at a minimum, clients who call during non-operating hours will receive guidance via a pre-recorded message) and shall provide information regarding mechanisms to address urgent and emergency needs of the client. Shall have a process in place to respond to clients after hours where phone lines are monitored by staff trained in crisis/escalation, and the client will receive a call back the next business day with a plan to address the urgent need (only applicable to Mental Health Services and Substance Abuse Services categories).
- VI.** Shall develop, maintain, and enforce a security policy regarding how electronic client data are accessed, edited, and deleted, ensuring maximum client security and confidentiality.
- VII.** Shall maintain a safe environment within its facilities to provide services. This includes adopting a written policy to refuse services to anyone who is being verbally abusive of staff or others, is threatening physical abuse to staff or others, is in possession of illegal substances, drug paraphernalia, or weapons on agency property, or is otherwise acting in an unacceptable manner, until, in the judgment of the agency, the individual ceases such behavior. The service provider shall also explore all available alternative options for service provision to such individuals, including referral to a more appropriate service provider.
- VIII.** HRSA RWHAP funds are intended to support only the HIV-related needs of eligible individuals. To be an HRSA RWHAP allowable cost, HRSA RWHAP recipients and subrecipients must be able to make an explicit connection between any service supported with HRSA RWHAP funds and the HIV care and treatment of an incarcerated person and must adhere to established HIV clinical practice standards consistent with U.S.

Department of Health and Human Services Clinical Guidelines for the Treatment of HIV. See HRSA HAB [Policy Clarification Notice #16-02, Ryan White HIV/AIDS Services: Eligible Individuals and Allowable Use of Funds](#).

- IX. Shall provide gender-affirming care and treatment services as described in the [HHS Guidelines for Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#) refer across HRSA RWHAP core medical and support service categories as outlined in [PCN#16-02 Ryan White HIV/AIDS Program Services: Eligible Individual and Allowable Uses of Funds](#)
- X. Where listed as an allowable activity under these standards, the option to utilize telehealth, telemedicine, or virtual visits instead of in-person services will be the client's decision, rather than the provider's requirement, unless CDC guidelines are issued that require the provider to implement social distancing due to a public health emergency.

PROVIDER RIGHTS FOR SERVICE DELIVERY IN THE DALLAS PLANNING AREA

Service providers reviewing this expectation should be able to identify unacceptable client behavior and respond accordingly with reasonable confidence that the actions taken on their behalf regarding a client were appropriate. Part of the AA's mission is to provide a wide array of services to persons living with HIV (PLWH) and other sexually transmitted diseases (STDs). That mission is achieved through contracts with various service providers who deliver those services.

The AA is responsible for ensuring each service provider understands their rights when addressing client behaviors that may be questionable or disruptive in providing Ryan White programs and services. The service provider will, therefore, be able to ensure that services are offered in a manner free from disruption. In addition, the RWPC of the Dallas Planning Area also has certain expectations of how those services are to be delivered to clients and how client rights are to be respected. On the authority vested by the [Civil Rights Code, Title 42, Chapter 21; Rehabilitation Act of 1973, Sect. 794; Age Discrimination Act of 1975; Public Law 88-352; Title VI](#) and [Part 80 of 45 CFR; 25 TAC §§98.41-98.44](#).

DEFINITIONS AS APPLIED TO THIS EXPECTATION

Contractor: a legal entity under contract with the Administrative Agency to provide goods or services to people living with or affected by HIV, AIDS, or STDs or to implement goals supporting the mission of the RWPC of the Dallas Planning Area.

Service Provider: a person, agency, or facility approved by the Administrative Agency that has entered into a contract with the Administrative Agency or a Texas DSHS contractor to deliver state or federal HIV programs to clients.

Service Program: Health, medical, and social services offered to PLWH by a service provider on behalf of the Administrative Agency.

PLANNING COUNCIL EXPECTATIONS FOR THE SERVICE PROVIDER/CLIENT RELATIONSHIP

The RWPC of the Dallas Planning Area expects service providers to maintain client relations of the highest possible quality by adhering to the following principles:

- I.** Treat each client with respect and consideration while recognizing the client's dignity and individuality.
- II.** Communicate the need for treatment, care, or services to promote equity in a culturally appropriate, culturally sensitive, and equitable manner.
- III.** Allow the client to select comprehensive outpatient health and psychosocial support services or refuse any service without fear of reprisal.
- IV.** Inform the client about treatment or service options, emphasize that it is the client's right to choose an option, and advise the client of several alternatives when multiple service providers are available for the same service.
- V.** Assure that service planning, medical treatment, and counseling plans are determined in cooperation with the client.
- VI.** Maintain a climate free of physical or mental abuse or exploitation in the office or other service delivery settings.
- VII.** Enforce local, state, or federal laws and regulations (such as no smoking or maintaining a drug-free environment) required to conduct business.
- VIII.** Review any decision to modify, suspend, or terminate services.
- IX.** Re-evaluate any modification, suspension, or termination of services to determine if the client's situation has changed (refer to [Texas DSHS HIV/STD Policy 530.003](#)).
- X.** Give clients an avenue to formally complain about treatment or services and inform them of the service provider's decision to deny an application, modify, suspend, or terminate client benefits. Service providers should create a mechanism to receive an appropriate and fair review of the complaint and ensure no reprisal against the client for filing the complaint or grievance.

CONFIDENTIALITY

According to state and federal laws, the service provider must maintain confidentiality regarding all information. The right to confidentiality begins the moment the client applies for services, when the service provider first conducts an evaluation, or when counseling begins.

EQUAL ACCESS TO PROGRAMS AND SERVICES

The service provider must consider client eligibility regardless of age, gender, gender identity, gender expression, sexual orientation, marital status, ethnic origin, race, developmental and physical challenge, or religious practice. Conversely, the client has a right to refuse any recommended services.

IMPARTIAL TREATMENT

Service providers must allow clients to apply for any service or program. Clients must be given fair, impartial treatment in receiving and processing the application and receiving services.

FILING A COMPLAINT OR GRIEVANCE

Contractors must have a written client complaint procedure in place to meet the minimum requirements for managing client complaints. All clients have a right to file a complaint or grievance regarding inappropriate service provider behavior, actions, or perceptions of discrimination. The complaint may be filed per the service provider's grievance procedures. When all other sources with the service provider's grievance process have been exhausted, the client may file the complaint or grievance with the Administrative Agency representative for the DPA by calling 214-819-1849.

In the case of a complaint related to the delivery of clinical services, the client may file a complaint directly to the State of Texas licensing board without filing a complaint locally if the client so chooses.

SERVICE PROVIDER RIGHTS WHEN DEALING WITH A CLIENT

Each service provider must develop written procedures for clients who may be disruptive, uncooperative, or engaging in illegal behavior that is dangerous to themselves or others. The service provider must ensure that staff and clients are consistently informed about the procedures used in every situation. Service providers are expected to use good judgment and attempt to resolve these situations fairly without undue limitation or denial of services to the client.

MODIFYING, SUSPENDING OR TERMINATING CLIENT SERVICES

The service provider is responsible for providing a work environment free from undue disruption, turmoil, or interference. Whenever possible, the service provider should take steps to serve clients to support a healthy work environment. During service provision, clients may behave disruptively, abusively, or threateningly toward staff or other clients. When this type of behavior occurs, the service provider may take the following progressive actions:

- I.** Modify all or part of the services provided to the client.
- II.** Suspend all or part of the services provided to the client.
- III.** Terminate all or part of the services provided to the client.

Depending on the severity of the client's behavior, such as threatening the life of staff or other clients, the service provider may skip one or more of the above steps and take appropriate action. Refer to [Texas DSHS HIV/STD Policy 530.003](#) for information on dealing with clients who threaten to harm themselves or others.

MODIFYING CLIENT SERVICES

The service provider may modify all or part of the services provided to the client when the client is disruptive or uncooperative. Modification may include, but is not limited to:

- I.** Rescheduling the client's appointment for a time later that day or in the near future,
- II.** arranging client services by telephone and
- III.** Mailing food vouchers, bus passes, etc.

SUSPENDING CLIENT SERVICES

Suspension is the temporary withdrawal of a service provided to a client by a service provider. It may be necessary for the service provider to suspend all or part of the services provided to the client for a specific period. This period should be delineated in the service provider's policy and should only be an option when alternative service delivery methods have not produced appropriate client behavior (i.e., the client is repeatedly disruptive or abusive towards staff or other clients). These cases should be directed to the Administrative Agency. Indefinite suspensions are discouraged.

TERMINATING CLIENT SERVICES

The service provider may choose to terminate all or part of the services provided to the client when alternative services delivery methods are not appropriate to the situation (i.e., the client threatens injury or homicide to a staff member or another client, etc.) or when modification or suspension of services has not produced appropriate client behavior. Clinical service providers (e.g., physicians, advanced practitioners, and registered nurses) who terminate services should follow professional practice standards concerning how client services are terminated. Professional organizations and licensing bodies can guide clinical service providers in managing these situations.

DENYING, SUSPENDING, OR TERMINATING A CLIENT'S SERVICE DUE TO SUBSTANCE MISUSE

The service provider may not deny, suspend, or terminate any service funded through HRSA/DSHS if the client is suspected of substance misuse or refuses to accept treatment for substance misuse. Exceptions to this may occur in the course of delivering medical care when a client's active substance misuse contraindicates the prescription of certain medications and treatments. The treating clinician must evaluate these professional decisions on a case-by-case basis.

NOTIFICATION OF THE DECISION TO MODIFY, SUSPEND, OR TERMINATE CLIENT SERVICES

The decision to modify, suspend, or terminate services must promptly and appropriately be communicated to the client. Notice of service termination may be done by any verifiable method, such as in person or by certified letter. When services are to be modified or suspended, staff should establish and communicate the duration of the suspension and inform the client that the resumption of services will depend on the client's willingness and ability to meet certain behavioral expectations. The behavioral expectations should be clearly defined and communicated to the client. The client should also be provided information about alternative methods by which services will be delivered or where such assistance may be obtained. Finally, the service provider should ensure that all actions regarding the modification, suspension, or termination of services are clearly documented in the client's record.

TECHNICAL ASSISTANCE

When desired, the service provider may contact the Administrative Agency to discuss specific situations or to obtain technical assistance. Decisions regarding modifying, suspending, or terminating client services remain with the service provider.

ADMINISTRATIVE AGENCY REVIEW OF DECISIONS TO MODIFY, SUSPEND, OR TERMINATE CLIENT SERVICES

As part of a routine review of the quality of client services or a complaint investigation, AA staff may review the events that led to a modification, suspension, or termination of client services. AA staff will evaluate, at minimum, whether the service provider:

- I.** Followed their internal policies and those of the AA in taking action to resolve the situation;
- II.** respected client rights, and
- III.** Applied the least restrictive limitation on client services necessary to maintain a service delivery setting free of physical and mental abuse or exploitation.

SELF-REFERRALS

Clients can self-refer to core medical and support services and may seek assistance from staff (e.g., a care/case manager) at any time. All agencies are expected to have an intake process and should enroll clients based on service eligibility.

DALLAS ELIGIBLE METROPOLITAN AREA MAP

The Dallas EMA covers eight counties: Collin, Dallas, Denton, Ellis, Henderson, Hunt, Kaufman, and Rockwall.



DALLAS HIV SERVICE DELIVERY AREA MAP

The Dallas HSDA covers eight counties: Collin, Dallas, Denton, Ellis, Hunt, Kaufman, Navarro, and Rockwall.



SHERMAN-DENISON HIV SERVICE DELIVERY AREA MAP

The Sherman-Denison HSDA covers three counties: Cooke, Fannin, and Grayson.



CORE MEDICAL SERVICES

AIDS PHARMACEUTICAL ASSISTANCE

HRSA Description: Local Pharmaceutical Assistance Program (LPAP) is operated by an RWHAP Part A or B recipient or subrecipient as a supplemental means of providing medication assistance when an ADAP has a restricted formulary, waiting list, and/or restricted financial eligibility criteria.²

SERVICES

RWHAP Part A or B recipients using the LPAP service category must establish the following:

- Uniform benefits for all enrolled clients throughout the service area
- Adhere to the DSHS Part B Monitoring Standards
- A recordkeeping system for distributed medications
- Adhere to LPAP advisory board guidance
- Adhere to the drug formulary approved by the LPAP advisory board
- Adhere to the 340B drug distribution system
- Client enrollment and eligibility determination process, including screening for ADAP and LPAP eligibility with rescreening at least every six months.
- Coordination with the state's RWHAP Part B ADAP
 - A statement of need should specify the state ADAP restrictions and the need for LPAP.
- Implementation per requirements of the 340B Drug Pricing Program and the Prime Vendor Program

Activities must include:

Payments to agencies made on behalf of an eligible client for prescribed medications within the locally approved drug formulary to prolong life, improve health, or prevent the deterioration of health. The provider wishing to prescribe medication (including over-the-counter medicines) not on the formulary shall make a request to the LPAP Board for approval.

Activities may not include:

- The LPAP may not duplicate services available through the Texas ADAP program.
- Payment for medications not included in the LPAP formulary.
- Payment for medications dispensed as part of an Emergency Financial Assistance Program (less than 60 days);
- Payment for medications during the application period in the state AIDS Drug Assistance Program;
- Payment for medications that are dispensed or administered during a regular medical visit or are considered part of the services provided during that visit;

² Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. AIDS Pharmaceutical Assistance. [Page 8](#)

- Payment for more than one month of medication at a time and payments for name-brand prescriptions when generic scripts are available.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider:

- 1.1 Shall ensure that medication costs are based on section 340B drug pricing or lower price if available;
- 1.2 Shall develop a memorandum of understanding with one or more pharmacies to ensure continuous availability and best price of medications.
- 1.3 Shall ensure the provision of medication to patients as prescribed by the patient's medical care provider;
- 1.4 Shall maintain appropriate, locked storage of medications and supplies when needed (including refrigeration);
- 1.5 Shall provide and maintain accurate program record keeping, including medication inventory control.

EARLY INTERVENTION SERVICES

HRSA Description: RWHAP Parts A and B Early Intervention Services (EIS) must include the following four components:³

- Targeted HIV testing to help the unaware learn of their HIV status and receive a referral to HIV care and treatment services if found to be living with HIV.
 - Recipients must coordinate these testing services with other HIV prevention and testing programs to avoid duplication of efforts.
 - HIV testing paid for by EIS cannot supplant testing efforts paid for by other sources
- Referral services to improve HIV care and treatment services at key points of entry
- Access and linkage to HIV care and treatment services such as HIV Outpatient/Ambulatory Health Services, Medical Case Management, and Substance Abuse Outpatient Care
- Outreach Services and Health Education/Risk Reduction related to HIV diagnosis

Early Intervention Services are limited to:

- EIS services are limited to counseling and HIV testing, referral to appropriate services based on HIV status, linkage to care, and education and health literacy training for clients to help them navigate the HIV care system. EIS services require coordination with prevention services providers and should be provided at specific entry points.
- Counseling, testing, and referral activities are designed to bring individuals with HIV into Outpatient/Ambulatory Health Services (OAHS). The goal of EIS is to decrease the number of underserved individuals with HIV by increasing access to care. EIS also provides the added benefit of educating and motivating clients on the importance and benefits of getting into care. Individuals found not to have HIV should be referred to appropriate prevention services.

³ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Early Intervention Services. [Page 10](#)

- Telehealth and telemedicine are alternative modalities to provide most Ryan White Part B and State Services-funded services. For the Ryan White Part B/SS-funded providers and Administrative Agencies, telehealth & telemedicine services are to be delivered in real-time via audio and video communication technology and may include videoconferencing software.
- DSHS HIV Care Services requires that for Ryan White Part B or SS-funded services, providers must use features to protect electronic protected health information (ePHI) transmission between clients and providers. RW providers must use a telehealth vendor that provides assurances to safeguard ePHI, including the vendor signing a business associate agreement (BAA). Ryan White Providers using telehealth must also follow DSHS HIV Care Services guidelines for telehealth and telemedicine outlined in DSHS Telemedicine Guidance.

Activities must include:

- Targeted HIV testing to help the unaware learn of their HIV status and receive a referral to HIV care and treatment services if found to be living with HIV;
- Referral services to improve HIV care and treatment services at key points of entry;
- Access and linkage to HIV care and treatment services such as HIV OAHS, Medical Case Management, and Substance Use Care; and
- Outreach Services and Health Education/Risk Reduction related to HIV diagnosis.
- Counseling (pre-test and post-test); and HIV testing to confirm the presence of the disease or diagnose the extent of the deficiency of the immune system;
- Periodic examination and testing to monitor the extent of the deficiency of the immune system until the client can access primary medical care;
- Referrals to primary medical care or biomedical research facilities;
- Providing therapeutic measures for preventing and treating the deterioration of the immune system until the client can access primary medical care;
- Providing continuous follow-up care until there is confirmation the patient has accessed medical services;
- Providing information about other HIV service providers for support services that will increase access to primary care;
- Educating the client on the importance of remaining in primary medical care, including education and counseling in health maintenance and maintenance of the immune system.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure that:

- 1.1** All facilities are appropriately licensed or certified as required by Dallas County for providing early intervention services for HIV, including phlebotomy services.
- 1.2** All staff who provide care and counseling services to clients shall be specifically trained to provide those services for recently diagnosed HIV-positive clients and shall be competently supervised by, at a minimum, a licensed mid-level medical provider.

HEALTH INSURANCE PREMIUM & COST-SHARING ASSISTANCE

HRSA Description: Health Insurance Premium & Cost-Sharing Assistance provides financial assistance for eligible clients living with HIV to maintain continuity of health insurance or to receive medical and pharmacy benefits under a health coverage program. Health care coverage costs that are allowable uses of RWHAP ADAP funds include premiums and medication cost-sharing regardless of the kind of health care coverage (public or private). To use RWHAP funds for health insurance premiums and cost-sharing assistance, a RWHAP Part recipient must implement a methodology that incorporates the following requirements:⁴

- RWHAP Part recipients must ensure that clients buy health coverage that, at a minimum, includes at least one drug in each class of core antiretroviral therapeutics from HHS treatment guidelines, along with appropriate HIV outpatient/ambulatory health services.
- RWHAP Part recipients must assess and compare the aggregate cost of paying for the health coverage option versus the total aggregate cost for medications and other appropriate HIV outpatient/ambulatory health services and allocate funding to Health Insurance Premium and Cost Sharing Assistance only when determined to be cost-effective.

The service provision consists of either or both of the following:

- Paying health insurance premiums to provide comprehensive HIV Outpatient/Ambulatory Health Services and pharmacy benefits that offer a full range of HIV medications for eligible clients.
- Paying cost sharing on behalf of the client.

Activities must include:

- Payment of insurance premiums (premiums will be paid directly to the insurance carrier or its designated agent);
- Payment of related copays and deductibles;
- Copayments for prescriptions included on the formulary approved by the Local Pharmaceutical Assistance Program Board with the exclusions listed in the Local Drug Reimbursement category;
- Payment of three-month prescription copays from mail-order pharmacies where cost-effective or plan-required, with pro-rated monthly costs towards service cap.

Activities may include:

- Copayments, premiums, coinsurance, or deductible costs for individuals enrolled in high-risk pools;
- Supplemental healthcare coverage insurance.

Activities may not include:

- Direct payments to clients;

⁴ Policy Clarification Notice #18-01: Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance. [Page 2](#)

- Use of RWHAP funds to pay for administrative costs outside the premium payment of health plans or high-risk pool (private health insurance coverage).
- Use of RWHAP funds to pay for premiums or cost-sharing assistance for private health plans that are paid for or reasonably expected to be paid for by Medicaid.

ADDITIONAL PROVISIONS FOR RYAN WHITE PART B

Activities must include:

- Financial assistance, according to the Texas Department of State Health Services policies

Activities may include:

- Copayments, coinsurance, or deductible costs for individuals enrolled in the Texas Risk Pool

Activities may not include:

- Copayments, coinsurance, or deductible costs associated with hospitalization and emergency room care;
- Premium assistance for individuals enrolled in the Texas Risk Pool;
- A limit on the assistance an individual may receive under the Texas Department of State Health Services policies for costs associated with copayments, coinsurance, or deductible payments.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure the following:

- 1.1.** That insurance assistance staff who provide direct services to clients have continuing access to the most up-to-date information available about effective medical care of those with HIV/AIDS and about applicable insurance programs and options;
- 1.2.** that it maintains detailed records in legible form, documenting client eligibility, along with premiums, deductibles, and copays that are paid on behalf of the clients; and
- 1.3.** that client eligibility is re-examined at the birth month and half-birth month intervals to align with eligibility requirements as established by HRSA/DSHS national standards of client eligibility.

RWHAP Parts A, B, C, and D may not pay premiums for Medicare Part D alone; however, RWHAP ADAP funds may be used to pay Medicare Part D premiums and cost-sharing assistance alone when it is cost-effective to do so versus paying for the total cost of medications. RWHAP funds must not be used to pay for premiums or cost-sharing assistance for Medicare Part A, as inpatient care is not a RWHAP allowable cost (see Table 1). Ryan White grant subrecipients must vigorously pursue these other sources of premium and cost-sharing assistance to ensure the RWHAP remains the payer of last resort.

Table 1. Medicare Costs Allowable in the Ryan White HIV/AIDS Program⁵	
Medicare Part	RWHAP Funds
Medicare Part A	• Must not be used by any RWHAP recipient to pay premiums or cost sharing.
Medicare Part B	• May be used by all RWHAP recipients to pay premiums or cost-sharing in conjunction with paying for Medicare Part D premiums or cost-sharing.
Medicare Part C	• May be used by all RWHAP recipients to pay premiums or cost-sharing when the Medicare Part C plan includes prescription drug coverage; or • in conjunction with paying for Medicare Part D premiums and cost-sharing for plans that do not include prescription drug coverage.
Medicare Part D	• May be used by RWHAP Part A, B, C, and D recipients to pay premiums or cost-sharing in conjunction with paying Medicare Part B or Medicare Part C premiums or cost-sharing. • May be used by RWHAP ADAP recipients to pay Medicare Part D premiums and cost-sharing when cost-effective versus paying for the total cost of medications.

HOME AND COMMUNITY-BASED HEALTH SERVICES

HRSA Description: Home and Community-based Health Services are provided to a client living with HIV in an integrated setting appropriate to a client's needs, based on a written plan of care established by a medical care team under the direction of a licensed clinical provider. Includes skilled health services furnished to the individual in the individual's home based on a written plan of care established by a medical case management team that includes appropriate health care professionals.

Services include:

- Durable medical equipment;
- home health aide services and personal care services in the home;
- day treatment or other partial hospitalization services;
- home intravenous and aerosolized drug therapy (including prescription drugs administered as part of such therapy);
- routine diagnostic testing administered in the home;

⁵ Policy Clarification Notice #18-01: Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance. [Page 5](#)

- assistance with housing-based testing, treatment, and therapies;
- and appropriate mental health, developmental, and rehabilitation services.

This definition also includes non-medical, non-nursing assistance with cooking and cleaning activities to help clients with disabilities remain in their homes.

Activities may not include:

- Inpatient hospital services;
- Nursing home or other long-term care facility services.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure the following:

- 1.1 They are licensed and certified by the State of Texas to provide home health services.
- 1.2 All provider staff, contractors, and consultants who provide direct-care services and require licensure shall be appropriately licensed by the State of Texas.

HOME HEALTH CARE

HRSA Description: Home Health Care is the provision of services in the home that are appropriate to a client's needs and are performed by licensed professionals. Services must relate to the client's HIV disease and may include the following:⁶

- Administration of prescribed therapeutics (e.g., intravenous and aerosolized treatment and parenteral feeding)
- Preventive and specialty care
- Wound care
- Routine diagnostics testing administered in the home
- Other medical therapies, including physical and rehabilitative treatment

The provision of Home Health Care is limited to clients who are homebound. Home settings do not include nursing facilities or inpatient mental health/ residential substance abuse treatment facilities.

Activities may not include:

- Inpatient hospital services;
- Nursing home or other long-term care facility services.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

⁶ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Home Health Care. [Page 12](#)

- 1.1 Be licensed and certified by the State of Texas to provide home health care services.
- 1.2 Ensure all provider staff, contractors, and consultants who provide direct-care services and require licensure are appropriately licensed by the State of Texas.
- 1.3 Be available to all individuals eligible to receive Ryan White services, regardless of their religious denominational affiliation.

HOSPICE SERVICES

HRSA Description: Hospice services are end-of-life care services provided to clients in the terminal stage of an HIV-related illness.⁷

Allowable services are:

- Mental health counseling
- Nursing care
- Palliative therapeutics
- Physician services
- Room and board
- Social support;
- Spiritual guidance.

Activities must include:

- Medically ordered care.

Activities may not include:

- Service provision in skilled nursing facilities or nursing homes.
- Provision of nutritional services, durable medical equipment, and medical supplies or case management services.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

- 1.1 Be licensed and certified by the State of Texas to provide hospice services.
- 1.2 Ensure all provider staff, contractors, and consultants who provide direct-care services and require licensure are appropriately licensed by the State of Texas.
- 1.3 Ensure that physician certification of life expectancy is specified, as established by terminal illness, and does not exceed six months.
- 1.4 Be available to all individuals eligible to receive Ryan White services, regardless of their religious denominational affiliation.

⁷ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Hospice Services. [Page 13](#)

MEDICAL CASE MANAGEMENT

HRSA Description: Medical Case Management (MCM) is the provision of a range of client-centered activities focused on improving health outcomes in support of the HIV care continuum. Activities may be prescribed by an interdisciplinary team that includes other specialty care providers. Medical Case Management consists of several types of case management encounters (e.g., face-to-face, phone contact, and other communication forms).^{8,9}

Key activities include:

- Initial assessment of service needs
- Development of a comprehensive, individualized care plan
- Timely & coordinated access to medically appropriate levels of health & support services & continuity of care
- Continuous client monitoring to assess the efficacy of the care plan
- Re-evaluation of the care plan at least every six months with adaptations as necessary
- Ongoing assessment of the client's and other key family members' needs and personal support systems
- Treatment adherence counseling to ensure readiness for and adherence to complex HIV treatments
- Client-specific advocacy and review of utilization of services

Activities must include:

- Assessment of client's medical needs and overall acuity;
- Developing and reviewing a care plan (according to the Standards of Care) based on the client's needs and choices, with goals and strategies for completion;
- Medically focused form of case management;
- Linking and coordinating client care to ensure that quality medical care is received, including medical, mental health, vision, and dental care;
- Implementing the care plan through time-lined strategies;
- Coordination with client's medical providers;
- Providing information, referrals, and assistance with linkages to needed medical services;
- Monitoring and following up on the goals of the care plan and revising as necessary;
- Providing education about medical therapies, including the benefits and side effects of medications;
- Providing interventions; treatment adherence counseling to improve adherence to medical therapies; compliance with medical appointments;
- In-patient case management to prevent unnecessary re-hospitalization or to expedite discharge;
- Assessment of the client's need for medical nutrition therapy.

Activities may include:

- Screening for practice that may make an individual susceptible to HIV followed by reduction interventions for persons living with HIV susceptible of transmitting HIV;

⁸ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Medical Case Management. [Page 13](#)

⁹ Texas Department of State Health Services: [Medical Case Management \(including Treatment Adherence Services\) Service Standard](#)

- Implementing interventions or strategies promoting adherence to antiretroviral medications for HIV+ persons with all types of case management, including face-to-face, phone contact, and other forms of communication;
- Benefits Counseling, Enrollment & Outreach Education (e.g., Medicaid, Medicare, Market Place/Exchange, other private insurance, etc.);
- Allow Medical Case Managers to complete intakes, screening for client eligibility, and determine the need for all services;
- Take Charge Texas (TCT) and other types of data entry or documentation directly related to case management performed for/on behalf of a client.
- Virtual Visits
- Telehealth/Telemedicine – addresses virtual visits (per local policy)

Activities may not include:

- Mental health or substance abuse counseling;
- Diagnostic or preventive care;
- Nutrition counseling;
- Complementary or alternative treatments, including chiropractic care, massage therapy, hypnotherapy, herbal therapy other than those prescribed by a physician, and acupuncture;
- Compilation of outcome measures reports;
- Development, distribution, or analysis of client satisfaction surveys;
- Recreational activities

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider must ensure that:

- 1.1. Each staff person who provides medical case management services to patients shall have, at a minimum, a bachelor's degree in social science or behavioral science, nursing, or a related field from an accredited domestic or international college or university. Alternatively, a minimum of one (1) year of employment experience performing medical case management, case management, or client advocacy may substitute for each year of college education.
- 1.2. Each medical case management supervisor shall, at a minimum, be a registered nurse licensed by the State of Texas or a professional with a Master's degree in social science or behavioral science or a related field from an accredited domestic or international college or university.

STANDARD OF CARE 2.0: MEDICAL CASE MANAGEMENT SERVICES CORE COMPONENTS

- 2.1 Coordinating medical care includes scheduling appointments for various treatments and referrals, including lab screenings and medical specialist appointments, as well as mental health, oral health care, and substance abuse treatment.

2.2 Follow-up of medical treatments includes accompanying clients to medical appointments, calling, emailing, texting, or writing letters concerning various treatments to ensure appointments are kept or rescheduled as needed. Additionally, follow-up includes ensuring clients have the appropriate documentation, transportation, and understanding of procedures. MCM staff must also encourage and enable open dialogue with medical healthcare professionals.

2.3 Treatment adherence includes the provision of counseling or special programs to ensure readiness for and adherence to HIV/AIDS treatments.

The HRSA/HAB performance measures for Medical Case Management Services are on the HRSA website at the following link: [Medical Case Management HRSA/HAB Performance Measures](#).

MEDICAL NUTRITION THERAPY

HRSA Description: Medical nutrition therapy must include the following:¹⁰

- Nutrition assessment and screening
- Dietary/nutritional evaluation
- Food and nutritional supplements per a medical provider's recommendation
- Nutrition education and counseling

These services can be provided in individual or group settings, aside from HIV Outpatient/Ambulatory Health Services. All services provided under this category must be according to a medical provider referral and based on a nutritional plan developed by the registered dietitian or other licensed nutrition professional.

Activities may include:

- Referral for BMI (Body Mass Index), Bioelectrical Impedance Analysis (BIA), or other appropriate measures of nutritional status;
- Review of lab results to gauge nutritional/supplement needs;
- Provide counseling in health promotion, disease progression, and disease prevention;
- Food provisions based on the medical care provider's recommendation;
- Provision of nutritional supplements:
 - Nutritional supplements include medical, nutritional formulas, vitamins, and herbs;
 - The provision of food consists of recommending a significant change in daily food intake based on a deficiency, which may directly affect HIV/comorbidities.

Activities may NOT include:

- Provision of food or meals.

¹⁰ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Medical Nutrition Therapy. [Page 14](#)

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

- 1.1 Services must be provided by a licensed, registered dietitian (RD) or other licensed nutrition professional pursuant to a medical provider's written referral.
- 1.2 This level of specialized instruction is above basic nutrition counseling and includes an individualized dietary assessment performed by an RD.

MENTAL HEALTH SERVICES

HRSA Description: Mental health services are the provision of outpatient psychological and psychiatric screening, assessment, diagnosis, treatment, and counseling services offered to clients living with HIV. Services are based on a treatment plan, conducted in an outpatient group or individual session, and provided by a mental health professional licensed or authorized within the state to render such services. Such professionals typically include psychiatrists, psychologists, and licensed clinical social workers.¹¹

Activities must include:

- Outpatient mental health therapy and counseling services provided solely by Mental Health Practitioners licensed in the State of Texas.
- Mental Health Assessment
- Treatment Planning
- Treatment Provision
- Individual psychotherapy
- Conjoint psychotherapy
- Group psychotherapy
- Psychiatric medication assessment, prescription, and monitoring
- Psychotropic medication management
- Drop-In Psychotherapy Groups
- Emergency/Crisis Intervention
- Mental health services can be delivered via telehealth, subject to federal guidelines, Texas State law, and DSHS policy.

Activities may include

- Virtual Visits
- Telehealth/Telemedicine Visit (Address virtual telehealth/telephone visit/consultation)

¹¹ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Mental Health Services. [Page 15](#)

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

Licensure must meet the following criteria:

- 1.1** Level I psychiatric services include individual psychiatric and medication treatment and monitoring of psychiatric disorders provided by a board-certified or board-eligible psychiatrist (D.O. or M.D.) or board-certified mid-level provider licensed and specializing in psychiatry (w/supervision as required by law). Services must be provided in an outpatient clinic setting, OR,
- 1.2** Level II counseling services include intensive mental health therapy and counseling (individual, family, and group) provided solely by a state-licensed mental health professional. Direct service providers must possess postgraduate degrees in psychology, psychiatry, or counseling (Ph.D., Ed.D., DSW, D.O., M.D., M.S., M.A., MSW, M.Ed., or equivalent) and must be licensed by the State of Texas to provide such services; OR,
- 1.3** Level III counseling services include general mental health therapy and counseling (individual, family, and group). Direct service providers must possess a postgraduate degree in the appropriately related field, be in the process of obtaining Level II licensure with the State of Texas, and be properly supervised by a licensed clinical supervisor approved by the state licensing board.

STANDARD OF CARE 2.0

- 2.1** All mental health interventions must be based on proven clinical methods and in accordance with legal and ethical standards.
- 2.2** Confidentiality must be maintained, is critically important, and cannot be overstated unless otherwise indicated based on federal, state, and local laws and guidelines (i.e., abuse, self, or other harm).

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

Service Standard	Performance Measure
Client Orientation Orientation is provided to all new clients to introduce them to program services, ensure their understanding of the need for continuous care, and empower them to access services. Orientation includes written or verbal information provided to the client on the following: • Services available • Clinic hours and procedures for after-hours emergency and non-life-threatening urgent situations • How to reach staff member(s) as appropriate • Scheduling appointments	• Percentage of new clients with documented evidence of orientation to services available in the client's primary record.

• The client's responsibilities for receiving program services and the agency's responsibilities for delivering them • Patient rights, including the grievance process	
Mental Health Assessment All clients referred to the program will receive a Mental Health Assessment by licensed mental health professionals. A mental health assessment should be completed no later than the third counseling session and should include, at a minimum, the following as guided by licensure requirements: • Presenting problems • Completed mental status evaluation (including appearance and behavior, self-attitude, speech, psychomotor activity, mood, insight, judgment, suicidal ideation, homicidal ideation, perceptual disturbances, obsessions/compulsions, phobias, panic attacks) • Cognitive assessment (level of consciousness, orientation, memory, and language) • Current risk of danger to self and others • Living Situation • Social support and family relationships, including client strengths/weaknesses, coping mechanisms, and self-help strategies • Medical history • Current Medications • Substance use history • Psychosocial history to include: ○ Education and employment history, including military service ○ Sexual and relationship history and status ○ Physical, emotional, and sexual abuse history ○ Domestic violence assessment ○ Trauma assessment ○ Legal history ○ Leisure and recreational activities Clients are assessed for care coordination needs, and referrals are made to case management programs as appropriate. If pressing mental health	• Percentage of clients with documented mental health assessment completed by the third (3rd) counseling session, unless otherwise noted, in the client's primary record.

needs emerge during the mental health assessment requiring immediate attention that results in the assessment not being finalized by the third session, this must be documented in the client's primary record.	
Treatment Plan All eligible client files should have documented evidence of a detailed treatment plan and documentation of services provided within the client's primary record. A treatment plan shall be completed within 30 days of the Mental Health Assessment. The treatment plan should include: • Diagnosed mental health issue • Goals and objectives • Treatment type (individual, group) • Start date for mental health services • Recommended number of sessions • Date for reassessment • Projected treatment end date (estimated) • Any recommendations for follow up Treatment, as clinically appropriate, should include counseling regarding: • Risk reduction and health promotion • Substance use disorder • Treatment adherence • Development of social support systems • Community resources • Maximizing social and adaptive functioning • The role of spirituality and religion in a client's life, disability, death and dying, and exploration of future goals The treatment plan must be signed by the mental health professional rendering service and developed in conjunction with the client. Treatment plans are reviewed and modified at a minimum, midway through the number of determined sessions agreed upon for frequency of modality or more frequently as clinically indicated.	• Percentage of clients with documented detailed treatment plan and documentation of services provided within the client's primary record. • Percentage of clients with treatment plans completed and signed by the licensed mental health professional rendering services in the client's primary record. • Percentage of clients with documented evidence of treatment plans reviewed/modified at a minimum midway through the number of determined sessions agreed upon for frequency of modality in the client's primary record.
Psychiatric Referral Clients are evaluated for psychiatric intervention, and appropriate referrals are initiated as documented in the client's primary record.	• Percentage of clients with a documented need for psychiatric intervention are referred to services as evidenced in the client's primary record.
Psychotropic Medication Management	• Percentage of clients accessing medication management services with documented evidence in the client's

Psychotropic medication management services are available for all clients directly or through referrals. PharmDs can provide psychotropic medication management services. The mental health professional will discuss with the client concerns about prescribed medications (side effects, dosage, interactions with HIV medications, etc.). The mental health professional will encourage the client to discuss concerns about prescribed medications with their HIV-prescribing clinician (if the mental health professional is not the prescribing clinician) to manage medications effectively. Prescribing providers will follow all regulations required for prescribing psychoactive medications as outlined by the <u>Texas Administrative Code, Title 25, Part 1, Chapter 415, Subchapter A, Rule 415.10.</u>	primary record of education regarding medications. Percentage of clients with changes to psychotropic/psychoactive medications with documented evidence of this change shared with the HIV-prescribing provider, as permitted by the client's signed consent to share information, in the client's primary record.
Provision of Services Services will be provided according to the individual's treatment plan and documented in the client's primary record. Progress notes are completed according to the service provider's standardized format for each session and will include the following: - Client name - Session date - Focus of session - Interventions - Progress on treatment goals - Newly identified issues/goals - Counselor signature and authentication (credentials). In urgent, non-life-threatening circumstances, an appointment will be made within one (1) business day. If an agency cannot provide the needed services, the agency will offer to refer the client to another organization that can provide the services. The referral must be made within one (1) business day for urgent, non-life-threatening situation(s).	Percentage of clients with documented evidence of progress notes completed and signed in accordance with the individual's treatment plan in the client's primary record.
Coordination of Care Care will be coordinated across the mental health care coordination team members. The client is involved in the decision to initiate or defer treatments. The mental health professional will involve the entire care team in educating the	Percentage of agencies who have documented evidence in the client's primary record or care coordination, as permissible, of shared mental health treatment adherence with the client's prescribing provider.

client, providing support, and monitoring mental health treatment adherence. Problem-solving strategies or referrals are in place for clients who need to improve adherence (e.g., behavioral contracts). There is evidence of consultation with medical care/psychiatric/pharmacist as appropriate regarding medication management, interactions, and treatment adherence.	
Referrals As needed, mental health providers will refer clients to a full range of medical/mental health services, including: • Psychiatric evaluation • Pharmacist for psychotropic medication management • Neuropsychological testing • Day treatment programs • In-patient hospitalization • Family/Couples therapy for relationship issues unrelated to the client's HIV diagnosis	• Percentage of clients with documented referrals, as applicable, for other medical/mental health services in the client's primary record.
Discharge Planning Discharge planning will be done with each client when treatment goals are met or when a client has discontinued therapy, as evidenced by non-attendance of scheduled appointments, as applicable. Documentation for discharge planning will include, as applicable: • Circumstances of discharge • Summary of needs at admission • Summary of services provided • Goals and objectives completed during counseling • Discharge plan • Counselor authentication, in accordance with current licensure requirements	• Percentage of clients with documentation of discharge planning when treatment goals are being met as evidenced in the client's primary record. • Percentage of clients with documentation of case closure per agency non-attendance policy as evidenced in the client's primary record.

ORAL HEALTH CARE

HRSA Definition: Oral health care services provide outpatient diagnostic, preventive, and therapeutic services by dental health care professionals, including general dental practitioners, dental specialists, dental hygienists, and licensed dental assistants.¹²

Activities must include:

- Diagnosis and treatment of existing dental disorders and services aimed at preventing similar disorders in the future.¹³

Activities may include:

- Preventive Services: dental cleanings, examinations, x-rays, adjustments to removable appliances, and one surface restorations;
- Routine Services: initial examinations, emergency appointments, deep cleanings with anesthesia, simple extractions, multiple surface restorations, biopsies, and localized chemotherapy;
- Specialty Service: surgical extractions, extensive restorations, periodontal surgeries, restorations requiring sedation, root canals, occlusal guards, and prosthodontics (partials and dentures).
- Oral health services visits may be delivered via telehealth and are subject to federal guidelines, the Texas Dental Board, DSHS policy, and guidelines established by the Administrative Agency.
- Virtual Visits
- Telehealth/Medicine Visit (Addresses virtual telehealth/telephone visit/consultation)

Activities may not include:

- Cosmetic dentistry for cosmetic purposes only is prohibited.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

- 1.1. All service provider staff, contractors, and consultants who provide direct-care services and require licensure shall be appropriately licensed by the Texas State Board of Dental Examiners.
- 1.2. Dental students and dental hygiene students who provide direct-care services may only do so under the direction and supervision of a licensed dentist.

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

¹² Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Oral Health Care Program. [Page 15](#)

¹³ American Dental Association Parameters. <https://ebd.ada.org/en/evidence/guidelines>

Service Standard	Performance Measure
Dental and Medical History To develop an appropriate treatment plan, the oral health care provider shall obtain complete information about the patient's health and medication status. This information shall include, but not be limited to, the following: • The client's HIV-prescribing primary medical care provider's name and phone number; • Pregnancy status as applicable; • A baseline current CBC laboratory test; • Current CD4 and Viral Load laboratory test results; • Coagulants (PT/INR, aPTT, and if hemophiliac baseline deficient factor level [e.g., Factor VIII activity]) and inhibitor titer (e.g., BIA); • Tuberculosis screening result; • Patient's chief complaint; • Current Medications, including any osteoporotic medications; • Sexually transmitted infections; • HIV-associated illnesses; • Allergies and drug sensitivities; • Alcohol use; • Recreational drug use; • Tobacco use; • Neurological diseases; • Hepatitis A, B, C status; • Usual oral hygiene; • Date of last dental examination; and • Any predisposing conditions that may affect the prognosis, progression, and management of oral health conditions. All lab results documented in the medical and dental history must align with current treatment guidelines.	• Percentage of oral health patients who had a dental and medical health history (initial or updated) at least once in the measurement year (HRSA/HAB Performance Measure).
Limited Physical Examination The oral health provider is responsible for completing an initial limited physical examination in accordance with the Texas Board of Dental Examiners that shall include, but not be limited to: • Blood Pressure; • Pulse/Heart Rate; and	• Percentage of oral health patients with a documented limited physical examination completed in the primary client oral health record.

• Basic vital signs. The dental practitioner shall also record blood pressure and pulse heart rate as indicated for invasive procedures involving sedation and anesthesia. If the dental practitioner is unable to obtain a patient's vital signs, the dental practitioner must document in the patient's oral health care record why the attempt to obtain vital signs was unsuccessful.	
Oral Examination Clinical oral evaluations include evaluation, diagnosis, and treatment planning. A patient must have either an initial comprehensive oral exam or a periodic recall oral evaluation once per year, such as: • Comprehensive oral evaluation, to include bitewing x-rays, new or established patients; • Periodic Oral Evaluation to include bitewing x-rays established patient; • Detailed and Extensive Oral Evaluation, problem-focused by report; • Re-evaluation, limited, problem-focused (established patient; not post-operative visit), or • Comprehensive Periodontal Evaluation, new or established patient.	• Percentage of oral health patients with a documented oral examination completed within the measurement year in the client's primary oral health record.
Periodontal Screening or Examination A periodontal screen shall include the assessment of medical and dental histories, the quantity and quality of attached gingival, bleeding, tooth mobility, and a radiological review of the status of the periodontium and dental implants. A comprehensive periodontal examination includes: • Evaluation of periodontal conditions; • Evaluation and recording of dental caries; • Evaluation and recording of missing or unerupted teeth; • Evaluation and recording of restorations; • Evaluation and recording of occlusal relationships; • Evaluation of oral cancer; • Probing and charting;	• Percentage of oral health patients who had a periodontal screen or examination at least once in the measurement year (HRSA/HAB Performance Measure).

• Evaluation and recording of the patient's dental and medical history; and • General health assessment. Some forms of periodontal disease may be more severe in individuals with immune system disorders. Patients with HIV may have especially severe forms of periodontal disease. The incidence of necrotizing periodontal diseases may increase in patients with acquired immune deficiency syndrome (AIDS).	
Dental Treatment Plan A dental treatment plan that includes preventive care, maintenance, and elimination of oral pathology shall be developed and discussed with the patient. Various treatment options shall be discussed and developed in collaboration with the patient. A treatment plan appropriate for the patient's health status, financial status, and individual preference must include as clinically indicated: • Provision for the relief of pain; • Elimination of infection; • Preventive plan component; • Periodontal treatment plan if necessary; • Elimination of caries; • Replacement or maintenance of tooth space or function; • Consultation or referral for conditions where treatment is beyond the scope of services offered; • Determination of adequate recall interval; • Invasive Procedure Risk Assessment (before oral surgery, extraction, or other invasive procedure); • The dental treatment plan will be signed by the oral care health professional providing the services. (Electronic signatures are acceptable)	• Percentage of oral health patients who had a dental treatment plan developed or updated at least once in the measurement year (HRSA/HAB Performance Measure).
Phase 1 Treatment Plan Phase 1 treatment includes prevention, maintenance, and elimination of oral pathology that results from dental caries or periodontal disease. This includes: • Restorative treatment; • Basic periodontal therapy (nonsurgical);	• Percentage of oral health patients with a Phase 1 treatment plan completed within 12 months (HRSA/HAB Performance Measure).

• Basic oral surgery that includes extractions and biopsy; • Non-surgical endodontic therapy and • Space maintenance and tooth eruption guidance for transitional dentition. A Phase 1 treatment plan will be established and updated annually to include diagnostic, preventive, and therapeutic services that will be provided. The Phase 1 treatment plan, if the care was completed on schedule, is completed within 12 months of initiating treatment.	
Oral Health Education Oral health education must be provided and can be documented by either a licensed dentist, dental hygienist, dental assistant, or dental case manager and shall include: • Oral hygiene instruction • Daily brushing and flossing (or other interproximal cleanings) and prosthetic care to remove plaque; • Daily use of over-the-counter fluorides to prevent or reduce cavities when appropriate and applicable to the patient. If deemed appropriate, the reason is stated in the patient's oral health record; and • Smoking/tobacco cessation counseling as indicated. Additional areas for instruction may include Nutrition. For pediatric patients, oral health education shall be provided to parents and caregivers and be age-appropriate.	• Percentage of oral health patients who received oral health education at least once in the measurement year (HRSA/HAB Performance Measure).
Referrals Referrals for other services must be documented in the patient's oral health care chart. Any referrals provided by the oral health provider must have documented evidence of outcomes of the referral and/or follow-up documentation regarding the referral.	• Percentage of oral health patients with documented referrals provided have outcomes and/or follow-up documentation in the primary oral health care record.

OUTPATIENT/AMBULATORY HEALTH SERVICES

HRSA Definition: Outpatient/Ambulatory Health Services (OAHS) are diagnostic and therapeutic services provided directly to a client by a licensed healthcare provider in an outpatient medical setting. Outpatient medical settings include clinics, medical offices, and mobile vans where clients do not stay overnight. Emergency room or urgent care services are not considered outpatient settings.¹⁴

Allowable activities include:

- Medical history taking
- Physical examination
- Diagnostic testing, including laboratory testing
- Treatment and management of physical and behavioral health conditions, including minor surgeries, care of minor injuries, and continuing care and management of chronic conditions.
- Behavioral risk assessment, subsequent counseling, and referral, including early intervention and risk assessment;
- Preventive care and screening
- Pediatric developmental assessment
- Prescription and management of medication therapy, including antiretroviral medications and prophylaxis and treatment of opportunistic infections;
- Treatment adherence
- Education and counseling on health, prevention, and nutritional issues
- Referral to and provision of specialty care related to HIV diagnosis
- Vision Screening/Eye exam as primary medical care visit
- Telemedicine is an acceptable means of providing OAHS but must conform to the Texas Medical Board (TMB) guidelines for providing telemedicine, [*Texas Administrative Code, Texas Medical Board, Rules, Title 22, Part 9, Chapter 174, RULE §174.1 to §174.12*](#) and the [*February 2020 Texas Medicaid Provider Telecommunication Services Handbook, Volume 2*](#).

Activities must include:

- Provision of care that is consistent with Public Health Service guidelines.

Activities may not include:

- Complementary or alternative treatments, including chiropractic care, massage therapy, hypnotherapy, and acupuncture;
- Inpatient medical services;
- Emergency room, urgent care, hospital, or any inpatient treatment center services;
- Pharmacist consultations.

¹⁴ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Outpatient/Ambulatory Health Services. [Page 15](#)

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

- 1.1. the service provider's facilities shall be appropriately licensed, as required by the State of Texas, for the provision of medical care services.
- 1.2. All service provider staff, contractors, and consultants who provide direct-care services and who require licensure shall be properly licensed by the State of Texas or documented to be pursuing Texas licensure while performing tasks that are legal within the provisions of the Texas Medical Practice Act (or in the case of a nurse, the Nursing Practice Act), including satisfactory arrangements for malpractice insurance.

STANDARD OF CARE 2.0: DIAGNOSTIC LABORATORY TESTING

- 2.1. Diagnostic Laboratory Testing includes all indicated medical diagnostic testing, including all tests considered integral to treating HIV and related complications (e.g., viral load, CD4 (cluster of differentiation 4) counts, and genotype assays). Funded tests must meet the following conditions:
 - a. Tests must be consistent with medical and laboratory standards as established by scientific evidence and supported by professional panels, associations, or organizations;
 - b. Tests must be (1) approved by the FDA when required under the FDA Medical Devices Act; and (2) performed in an approved Clinical Laboratory Improvement Amendments of 1988 (CLIA)-certified laboratory or State-exempt laboratory; and
 - c. Tests must be (1) ordered by a registered, certified, or licensed medical provider and (2) necessary and appropriate based on established clinical practice standards and professional clinical judgment.

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving clinical care throughout the State of Texas within the Ryan White Program. The most current [Guide for HIV/AIDS Clinical Care](#) is cited throughout the standards for additional reference materials for direct care service providers.

Service Standard	Performance Measure
Medical Evaluation/Assessment All HIV patients receiving medical care shall have a completed initial comprehensive medical evaluation/assessment and physical examination that adheres to the current U. S. Department of Health and Human Services (HHS) guidelines within one (1) month of HIV diagnosis¹⁵ or within 15	- Percentage of patients who attended a routine HIV medical care visit within one (1) month of HIV diagnosis (HRSA/HAB Measure – Linkage to Care). - Percentage of existing patients (returning to care and those in current medical care for more than one year) with a documented comprehensive assessment/evaluation completed by a doctor of medicine (MD), nurse

¹⁵ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Page 61](#)

business days of initial contact with a patient who has been in care. Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.	practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA) within 15 business days of initial contact with a patient in accordance with professional and established HIV practice guidelines.
Comprehensive HIV-related History Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. History shall consist of, at a minimum, general medical history, comprehensive HIV-related history, and psychosocial history to include: - Documented past medical and surgical history with regard to chronic diseases such as diabetes, high blood pressure, heart disease, cholesterol, asthma or emphysema, sickle cell disease, etc., per HHS guidelines. - Psychosocial history includes socio-cultural assessment, occupational history, hobbies (as applicable), travel history, mental health, and housing status. - Lifestyle includes tobacco use, alcohol use, illicit substance use, exercise, and travel history. - Sexual Health includes partners, practices, past sexually transmitted infections (STIs), and contraception use (past and present). - HIV-related health history, including most recent CD4 and Viral Load results, current antiretroviral therapy (if applicable), previous adverse ART drug reactions, history of HIV-related illness and infections, HIV treatment history, and staging. The physical examination will include documentation from the complete review of systems, as indicated in the comprehensive medical history.¹⁶ This can be completed during the initial visit or divided over the course of two or three early visits.	- Percentage of new patients with a documented comprehensive HIV-related history that is inclusive of all components listed in the OAHS Standard as referenced in the HHS guidelines. - Percentage of existing patients with a documented comprehensive HIV-related history that is inclusive of all components listed in the OAHS Standard as referenced in the HHS guidelines.
Physical Examination	Percentage of new patients with a documented annual physical examination.

¹⁶ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Pages 61-70](#)

Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.¹⁷ Providers should perform a baseline and annual comprehensive physical examination, with particular attention to areas potentially affected by HIV. Examination of the oral cavity should be included in the initial and interim physical examinations of all HIV patients.	• Percentage of new patients living with HIV who received an oral cavity exam during the physical exam as documented in the patient's primary record. • Percentage of existing patients with a documented annual physical examination. • Percentage of existing persons living with HIV who received an oral cavity exam during the physical exam as documented in the patient's primary record
Initial laboratory tests, as clinically indicated by licensed provider:¹⁸ Tests will include as clinically indicated: • HIV Antibody, if not documented previously; • CD4 Count and/or CD4 Percentage • Quantitative Plasma HIV RNA (HIV Viral Load) • Standard genotypic drug-resistance testing (refer to Table 3 in the <i>"Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV"</i> for guidance on other scenarios where genotype testing is recommended) • Co-receptor Tropism Test (if considering the use of a CCR5 co-receptor antagonist or for patients who exhibit virologic failure on a CCR5 antagonist) • HLA-B*5701 testing (only before initiating abacavir-containing regimen per guidelines) • Complete Blood Count (CBC) with Differential and Platelets • Chemistry Profile: Electrolytes, Creatinine, Blood Urea Nitrogen (BUN) • Liver Transaminases, Bilirubin (Total and Direct) • Urinalysis with Urine Protein and Creatinine • Quantitative HCV RNA viral load testing (for Hepatitis C (HCV)- positive patients who are candidates for treatment)	• Percentage of new patients with documented initial laboratory tests completed according to the OAHS Standard and HHS treatment guidelines. • Percentage of new patients with documented CD4 count (absolute). • Percentage of new patients with documented HIV-RNA viral load (HRSA/HAB Measure). • Percentage of new patients with documented drug resistance testing, as applicable. • Percentage of new patients living with HIV susceptible to STIs who had a test for chlamydia within the measurement year (HRSA/HAB Measure). • Percentage of new patients living with HIV susceptible to STIs who had a test for gonorrhea within the measurement year (HRSA/HAB Performance Measure). • Percentage of new adult patients who had a test for syphilis performed within the measurement year (HRSA/HAB Performance Measure). • Hepatitis B screening was performed at least once since the diagnosis of HIV or for whom there is documented infection or immunity (HRSA/HAB Performance Measure). • Percentage of new patients for whom HCV screening was performed at least once since the diagnosis of HIV (HRSA/HAB Performance Measure).

¹⁷ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Pages 73-77](#)

¹⁸ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Initial Laboratory Tests. [Page C-1](#).

• Hepatitis A (HAV) antibody, Hepatitis B (HBV) surface antigen, core Ab (core antibody), and surface antibody & Hepatitis C antibody screens at initial intake (providers should screen all patients diagnosed for anti-HCV antibodies at baseline) • Lipid Profile (Total Cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), Triglycerides); fasting • Glucose (preferably fasting) or hemoglobin A1C • Pregnancy Test (for clients with cervix of childbearing potential) • RPR or treponemal antibody (Syphilis Screening) • Extra-genital gonorrhea (GC) and Chlamydia (CT) Testing • <i>Toxoplasma gondii</i> immunoglobulin G (IgG) • Trichomoniasis testing Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines.¹⁹	
Other Diagnostic Testing Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. A chest x-ray will be completed if pulmonary symptoms are present; if positive latent tuberculosis infection (LTBI) test (either tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA)); or if prior evidence of LTBI or pulmonary tuberculosis (TB) (perform annually).²⁰	• Percentage of new or existing patients with documented chest x-rays completed if pulmonary symptoms were present, after an initial positive QuantiFERON TB Test (QTF), after initial positive TST, or annually if prior evidence of LTBI or pulmonary TB.
Initial Screenings/Assessments Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. Patients should receive screening for opportunistic infections and assessment of	• Percentage of new patients with documented initial medical screenings and assessments as indicated in the OAHS Standard and in accordance with HHS guidelines. • Percentage of new clients with a cervix living with HIV who were screened for

¹⁹ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Pages 79-89](#)

²⁰ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Page 85](#)

psychosocial needs initially and annually according to the most current HHS guidelines.

Screening should include, at a minimum:

- Mental health assessment that includes screening for clinical depression patient health questionnaire (PHQ-2) at a minimum)
- Psychosocial assessment, including domestic violence and housing status²¹
- Substance use and abuse screening
- Tobacco use screening
- Pediatric patients (14 years and younger) will be screened for child abuse as defined in [Chapter 261 of the Texas Family Code](#) and DSHS policy. Consider screening youth 14-17 for child abuse.
- Oral health exam and assessment
- TB Screening
- Cervical Cancer Screen (following the most current clinical recommendations)²²
- **Women Aged <30 Years with HIV:**
 - If younger than age 21, known to have HIV or newly diagnosed with HIV, and sexually active, a Pap test should be performed within one (1) year of onset of sexual activity regardless of the mode of HIV transmission.
- **Women Aged >30 Years with HIV**
 - Papanicolaou (Pap) Testing Only:
 - Pap test should be done at baseline and every 12 months
 - If the results of three (3) consecutive Pap tests are normal, follow-up Pap tests can be performed every three (3) years

Additional screenings as medically indicated include:

cervical cancer in the last three years
(HRSA/HAB Performance Measure).

- Percentage of new patients aged 12 years and older screened for clinical depression on the date of the encounter using an age-appropriate standardized depression screening tool, AND if positive, a follow-up plan is documented on the date of the positive screen **(HRSA/HAB Performance Measure).**
- Percentage of new patients with documented initial psychosocial assessment to include domestic violence and housing status.
- Percentage of new patients living with HIV who have been screened for substance use (alcohol & drugs) in the measurement year **(HRSA/HAB Performance Measure).**
- Percentage of new patients aged 18 years and older screened for tobacco use one or more times within 24 months AND received cessation-counseling intervention if identified as a tobacco user **(HRSA/HAB Performance Measure).**
- Percentage of new patients, if applicable, with completed child abuse assessment (completed if patient aged 14 years and younger).
- Percentage of new patients aged three months and older living with HIV for whom there was documentation that a TB screening test was performed and results interpreted (for TB skin tests) at least once since the diagnosis of HIV **(HRSA/HAB Performance Measure).**

²¹ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [Page 65](#)

²²Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [Cervical Cancer Screen Guidelines for <30 and over 3 years of age](#)

• Dilated eye exam every 6 to 12 months if the CD4<50 by an ophthalmologist Anal Cancer (Dysplasia) Screening The Anal Cancer (Dysplasia) Screening Guidelines recommend, at a minimum, an annual digital examination to detect masses on palpation that could be anal cancer. However, performing the digital exam alone as a screening procedure for anal dysplasia or cancer will miss many lesions. Anal cancer screening using a Pap test can improve sensitivity for detecting anal dysplasia or cancer.²³ Cytology combined with high-resolution anoscopy (HRA) is considered the best strategy for the screening of precancerous lesions. If anal pap is performed, clinicians should refer patients with abnormal anal cytology for HRA. In communities where HRA is unavailable, clinicians should consider referring patients with abnormal anal cytology to a surgeon for evaluation.	
Immunizations Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. Immunizations/vaccinations will be given according to the most current HHS guidelines and the Centers for Disease Control and Prevention's (CDC) "2019 Recommended Adult Vaccination Schedule." Providers will initiate prophylaxis for specific opportunistic infections. Patients will be offered vaccinations for the following: • Tetanus, Diphtheria, and Pertussis (Tdap) per recommended treatment guidelines for immunizations²⁴ • Measles, Mumps, Rubella (MMR) per recommended treatment guidelines for immunizations.²⁵ Adults and adolescents	• Percentage of patients with Tetanus, Diphtheria, and Pertussis current within ten (10) years, tetanus and diphtheria (TD) booster doses every ten (10) years thereafter, or documentation of refusal. • Percentage of patients aged six months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization (HRSA/HAB Performance Measure). • Percentage of patients living with HIV who completed the vaccination series for Hepatitis B (HRSA/HAB Performance Measure). • Percentage of patients living with HIV who ever received a pneumococcal

²³ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. [pages 83-89](#)

²⁴ Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [TDAP Vaccination Guidelines](#)

²⁵ Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the

with a CD4 cell count <200 cells/μL should not receive MMR. • Influenza (inactivated vaccine)- annually during flu season, October 1st - March 31st • Pneumococcal is recommended for all patients; two separate vaccines are recommended; • Receive a dose of pneumococcal conjugate vaccine (PCV13 (Pneumovax 13)), followed by a dose of pneumococcal polysaccharide vaccine (PPV23 (Pneumovax)) at least eight (8) weeks later.²⁶ • Completion of Hepatitis B (HBV) vaccines series, unless otherwise documented as immune, vaccinated patients should be tested for a hepatitis B surface antibody (HBsAb) response 1–2 months or at the subsequent scheduled clinic visits after the third dose.²⁷ • Completion of Hepatitis A vaccine series, unless otherwise documented as immune. • Varicella-Zoster virus (VZV): Please reference current treatment guidelines for VZV.²⁸ This vaccination is contraindicated in persons with HIV and a CD4 count <200. • The Advisory Committee on Immunization Practices (ACIP) recommends, and HHS states: "because of the potential benefit in preventing HPV-associated disease and cancer in this population, HPV vaccination	vaccine (HRSA/HAB Performance Measure). • Percentage of patients living with HIV who completed the vaccination series for Hepatitis A.
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prevention and treatment of opportunistic infections in adults and adolescents with HIV:

recommendations from the Centers for Disease Control and Prevention, the National Institutes

of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [MMR Vaccination Guidelines](#)

²⁶ Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the

prevention and treatment of opportunistic infections in adults and adolescents with HIV:

recommendations from the Centers for Disease Control and Prevention, the National Institutes

of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [Pneumococcal Vaccination Guidelines](#)

²⁷Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the

prevention and treatment of opportunistic infections in adults and adolescents with HIV:

recommendations from the Centers for Disease Control and Prevention, the National Institutes

of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [Hepatitis B Vaccination Guidelines](#)

²⁸ Panel on Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the

prevention and treatment of opportunistic infections in adults and adolescents with HIV:

recommendations from the Centers for Disease Control and Prevention, the National Institutes

of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. [Varicella Vaccination Guidelines](#)

is recommended for HIV-positive males and females aged 13 through 26”. For providers who need a vaccine to provide their patients at no cost to the provider, please reference the Adult Safety Net Program. For providers who want to refer their patients for vaccines offered at no cost or reduced cost, please review the Eligibility and Benefits for the Adult Safety Net Program.	
Antibiotic Treatment (Recommend Prophylactic Antibiotic Treatment) Antibiotic prophylaxis for opportunistic infections will be initiated if an active infection has been ruled out and the following conditions are met: <i>Mycobacterium avium</i> complex (MAC): if CD4 < 50 - Toxoplasmosis: if CD4 < 100 and toxoplasma IgG is positive - Pneumocystis pneumonia (PCP) prophylaxis will be completed adhering to the current HHS Guidelines. Preventing 1st Episode of PCP (Primary Prophylaxis) Indications for Initiating Primary Prophylaxis: - CD4 count < 200 cells/mm³ or - CD4% < 14% of total lymphocyte count or CD4 count > 200 but < 250 cells/mm³ if ART cannot be initiated and if CD4 cell count monitoring (e.g., every three (3) months) is not possible²⁹	- Percentage of patients, regardless of age, offered MAC Prophylaxis as medically indicated. - Patients aged six weeks or older diagnosed with HIV, with CD4 counts of less than 200 cells/μL or a CD4 percentage below 15%, will be prescribed PCP prophylaxis (HRSA/HAB Performance Measure).
Antiretroviral Therapy Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. ART will be prescribed in accordance with the HHS-established guidelines.	Percentage of patients, regardless of age, living with HIV, are prescribed ART for the treatment of HIV during the measurement year (HRSA/HAB Performance Measure).

²⁹ Panel on Opportunistic Infections in Adults and Adolescents with HIV. [Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV](#): recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America.

Patients who meet current guidelines for ART are offered and/or prescribed ART.³⁰	
Drug Resistance Testing Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. "HIV drug-resistance testing is recommended for persons diagnosed with HIV at entry into care. Genotypic testing is recommended as the preferred resistance testing to guide therapy in ARV-naïve patients."^{31,32} Drug resistance testing must follow the most recent, established guidelines on resistance testing, including genotypic testing on all ARV-naïve patients. The patient's medical practitioner, a registered nurse, or other appropriately licensed healthcare providers (if designated by the practitioner) must provide counseling and education about drug resistance testing.³³ Drug Resistance Assay Not Usually Recommended After therapy is discontinued: Drug-resistance testing is not usually recommended more than four (4) weeks after ARV drugs are discontinued. In patients with low HIV RNA levels, Drug-resistance testing is not usually recommended in patients with a plasma viral load of <500 copies/mL.	Percentage of patients, regardless of age, living with HIV who had an HIV drug resistance test performed before initiation of HIV ART if therapy started during the measurement year (HRSA/HAB Performance Measure).
Health Education/Risk Reduction Health education will adhere to the most current HHS guidelines.	- Percentage of patients living with HIV who received HIV counseling in the measurement year (HRSA/HAB Performance Measure). - Percentage of patients aged 18 years and older screened for tobacco use one or

³⁰ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Antiretroviral Therapy. [Pages 207-220](#)

³¹ Panel on Opportunistic Infections in Adults and Adolescents with HIV. [Guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV](#): recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America.

³² Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. [Page C-12](#)

³³ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Drug Resistance Testing. [Page 81](#)

Providers will provide routine HIV-reduction counseling and behavioral health counseling for HIV-infected patients. Since patients' behaviors change over time as the course of disease changes and their social situations vary, health education providers will tailor routine risk-reduction counseling and behavioral health counseling not only to the individual patient but also to the particular point in time in the patient's life. The following will be conducted initially and as needed: • Providers should discuss safer sexual practices to decrease the probability of transmitting HIV. • Providers should counsel persons living with HIV about the possibility of acquiring syphilis and other STIs from unprotected sexual contact, including all sites of possible transmission, such as the anus, cervix, vagina, urethra, and oropharynx.³⁴ • Providers should discuss family planning with patients • Contraception counseling/hormonal contraception • Drug interaction counseling Providers should counsel patients on tobacco cessation annually for those patients that were screened and positive for smoking (or documented decline of tobacco use)³⁵ • When current alcohol or other substance use is identified, providers should discuss the possible effects of such use on the patient's general health and HIV medications, as well as options for treatment if indicated. • Providers should routinely discuss with patients the importance of disclosure to partners. Patients should be educated about the options for voluntary partner notification. • When HIV patients are diagnosed with early syphilis (primary, secondary, or early	more times within 24 months AND received cessation-counseling intervention if identified as a tobacco user (HRSA/HAB Performance Measure). • Percentage of patients with documented counseling about family planning method appropriate to patient's status, as applicable. • Percentage of patients with documented instruction regarding new medications, as appropriate. • Percentage of patients with documented counseling regarding the importance of disclosure to partners.
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³⁴ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Patient Education. [Pages 57-59](#)

³⁵ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Smoking Cessation. [Pages 189 -196](#)

latent), providers should intensify reduction counseling, including discussing the importance of condom use. • Nutritional Counseling regarding:³⁶ ○ Quality and quantity of daily food and liquid intake ○ Exercise (as medically indicated)	
Treatment Adherence Assessment of treatment adherence and counseling will be provided that adheres to current HHS guidelines.³⁷ Patients are assessed for treatment adherence and counseling at a minimum of twice a year. Those prescribed ongoing ART regimen must receive adherence assessment and counseling on every HIV-related clinical encounter. If an adherence issue is identified by another member of the healthcare team (Medical Case Manager (MCM), medical assistant (MA), licensed vocational nurse (LVN), or registered nurse (RN)), there should be documented evidence of adherence counseling and follow-up action. This adherence counseling documentation must be evident in the patient's medical record and indicate that the prescribing provider was aware of the adherence issue.	• Percentage of patients with documented assessment for treatment adherence two or more times within the measurement year if the patient is on ART. • Percentage of patients with documented adherence issues who received counseling for treatment adherence two or more times within the measurement year.
Referrals Providers will refer to specialty care or other systems as appropriate in accordance with current HHS guidelines. At a minimum, patients should receive referrals to specialized health care/providers/services as needed or medically indicated to augment medical care:³⁸ • If the CD4 count is below 50, the patient should be referred for examination by an ophthalmologist. • AIDS Drug Assistance Program (ADAP) • Medication Assistance Programs	Percentage of patients, as medically indicated, who had documentation of referrals for: • Mental Health and/or Substance Use • Oral Health • Ophthalmological services • Child abuse (if abuse is suspected) • Disease intervention specialist • Other specialty services. • Percentage of patients with a documented referral in the measurement year has a progress note in the patient's chart regarding attendance and outcomes of the referral.

³⁶ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Nutrition. [Pages 197-202](#)

³⁷ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Adherence. [Page 273](#)

³⁸ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Initial Physical Examination. [Page 73](#)

• Medical care coordination • Medical Specialties • Mental health and substance use services • Treatment education services • Partner counseling and referral • Annual oral hygiene and intraoral examinations, including dental caries and soft-tissue examinations. • Medical Nutrition Therapy (MNT) • Health maintenance, as medically indicated, such as: ○ Cervical Cancer Screening ○ Family Planning ○ Colorectal cancer screening ○ Breast cancer screening • Specialty medical care for any preexisting chronic diseases • Case Management Services or a Disease Intervention Specialist (DIS) for follow-up if a client misses appointments. Service providers/staff are expected to follow up on each referral to assess attendance and outcomes. Refer to the United States Preventive Services Task Force (USPSTF) for details on specific screening modalities and timeframes.	
Follow-up Visits Outpatient Medical Care will adhere to the current HHS guidelines for ongoing health care. Reassessment/reevaluation of health history, comprehensive physical examination, and annual laboratory testing should be documented in the patient's medical record. All HIV patients should have the following lab tests documented annually: urinalysis, with urine protein and creatinine; fasting lipid profile; syphilis screening; and gonorrhea and chlamydia testing (screen all sites of possible exposure). These tests may need to be performed more frequently if clinically indicated. Every 3-6 months:³⁹	• Percentage of existing patients with documented initial medical screenings and assessments as indicated in the OAHS Standard and in accordance with HHS guidelines. • Percentage of patients, regardless of age, living with HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits (HRSA/HAB Performance Measure). • Percentage of patients, regardless of age, living with HIV who did not have a medical visit in the last six (6) months of the measurement year (HRSA/HAB Performance Measure). • Percentage of patients, regardless of age, living with HIV with an HIV viral load less

³⁹ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. [Table 3](#)

• HIV-RNA viral load; CBC with differential; chemistry profile (to include electrolytes, BUN, creatinine, bicarbonate (HCO₃), estimated glomerular filtration rate (eGFR)); • liver function tests (to include transaminases, total and direct bilirubin); • and glucose⁴⁰ (preferably fasting) or hemoglobin A1c. These tests may need to be performed more frequently if clinically indicated. Providers will continually evaluate patients for adverse outcomes and document the actions taken, outcomes, and follow-up.⁴¹	than 200 copies/mL at the last HIV viral load test during the measurement year (HRSA/HAB Performance Measure). • Percentage of existing clients with cervix living with HIV who were screened for cervical cancer in the last three years (HRSA/HAB Performance Measure). • Percentage of existing patients living with HIV susceptible to STIs who had a test for chlamydia within the measurement year (HRSA/HAB Performance Measure). • Percentage of existing patients living with HIV susceptible to STIs who had a test for gonorrhea within the measurement year (HRSA/HAB Performance Measure). • Percentage of existing adult patients living with HIV who had a test for syphilis performed within the measurement year (HRSA/HAB Performance Measure). • Percentage of existing patients aged 12 years and older screened for clinical depression (annually) on the date of the encounter using an age-appropriate standardized depression screening tool, AND if positive, a follow-up plan is documented on the date of the positive screen (HRSA/HAB Performance Measure). • Percentage of existing patients with documented annual psychosocial assessment to include domestic violence and housing status. • Percentage of existing patients living with HIV who have been screened for substance use (alcohol & drugs) in the measurement year (HRSA/HAB Performance Measure). • Percentage of existing patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user (HRSA/HAB Performance Measure).
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⁴⁰ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. [Table 3](#)

⁴¹ U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Adverse Reactions to HIV Medications. [Page 527](#)

	• Percentage of existing patients, if applicable, with completed child abuse assessment (completed if patient aged 14 years and younger). • Percentage of existing patients aged three (3) months and older living with HIV for whom there was documentation that a TB screening test was performed and results interpreted (for TB skin tests) at least once since the diagnosis of HIV (HRSA/HAB Performance Measure). • Percentage of existing patients, regardless of age, for whom Hepatitis B screening was performed at least once since the diagnosis of HIV or for whom there is documented infection or immunity (HRSA/HAB Performance Measure). • Percentage of existing patients for whom HCV screening was performed at least once since the diagnosis of HIV (HRSA/HAB Performance Measure). • Percentage of patients, regardless of age, living with HIV who were prescribed HIV ART and who had a fasting lipid panel during the measurement year (HRSA/HAB Performance Measure).
Documentation in Patient's Medical Chart Primary medical care for the treatment of HIV includes the provision of care that is consistent with the most current HHS treatment guidelines. Clinicians will develop/update the plan of care at each visit. If a patient refuses a treatment, such as vaccinations, documentation of denial will be written in the patient's medical chart. The provider developing the plan will sign each entry.	• Percentage of patient medical records with signed clinician entries. • Percentage of flow sheets present and updated in the patient medical records. • Percentage of problem lists present and updated in the patient medical records. • Percentage of medication lists present and updated in the patient medical records.
Documentation of Missed Patient Appointments and Efforts to Bring the Patient into Care.	• Percentage of patient medical records with documentation of specific barriers and efforts to address missed appointments.

The service provider or staff will conduct the following:⁴²

- Contact patients who have missed three (3) consecutive appointments, using at least three (3) different forms of contact (email, phone, mail, emergency contact, phone call, referral to a DIS for home visit) prior to determining they are lost to follow-up;
- Address any specific barriers to accessing services;

Document the number of missed patient appointments and efforts to bring the patient into care

SUBSTANCE ABUSE OUTPATIENT CARE

HRSA Description: Substance abuse outpatient care is the provision of outpatient services for treating drug or alcohol use disorders.⁴³

Services include:

- Screening
- Assessment
- Diagnosis and
- Treatment of substance use disorder, including:
 - Pretreatment/recovery readiness programs
 - Harm reduction
 - Behavioral health counseling associated with substance use disorder
 - Outpatient drug-free treatment and counseling
 - Medication-assisted therapy
 - Neuropsychiatric pharmaceuticals
 - Relapse prevention

Services are limited to the services below, as stated in the HRSA National Monitoring Standards. RWHAP funds shall not be used to establish or operate any programs for distributing sterile needles or syringes for the hypodermic injection of any illegal drugs. Please reference the [*Texas Health and Safety Code, Title 6, Subtitle C, Chapter 481, Subchapter A. General Provisions.*](#)

⁴² U.S. Department of Health and Human Services, Health Resources and Services Administration, Guide for HIV/AIDS Clinical Care – 2014 Edition. Supporting Patients in Care. [Page 1](#)

⁴³ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Substance Abuse Outpatient Care. [Page 16](#)

Activities may include:

- Individual and group therapy;
- Skills training;
- Discharge planning;
- Aftercare and follow-up;
- Harm reduction counseling.
- Virtual Visits
- Telehealth/Medicine Visit
- (Address virtual telehealth/telephone visit/consultation

Activities may not include:

- Residential health services.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

- 1.1** Be appropriately licensed by DSHS Substance Abuse Outpatient Services.
- 1.2** Satisfy all requirements, as outlined in DSHS Substance Abuse Services Licensure Rules and Counselor Licensure Rules. All service provider staff and contractors who deliver direct client care shall be properly licensed/credentialed.
- 1.3** Provide access to its system of substance abuse treatment for those with HIV/AIDS twenty-four (24) hours/day, and must provide mechanisms for urgent and emergency care; and
- 1.4** provide a means for clients who have discontinued service due to discharge, discontinuation, relapse, etc., to return to services with the service provider or be referred to a more appropriate service provider.
- 1.5** Work with the client to develop and implement goals, objectives, and strategies within an individualized, written treatment plan, which the client shall sign. The plan shall identify services and support needed to address problems and needs identified during a comprehensive psychosocial assessment consistent with DSHS Substance Abuse Services rules and regulations. The agency shall review the plan at least every six months, revise it as necessary,
- 1.6** identify discharge criteria, and include an initial discharge plan. The discharge plan shall address the continuity of services and ongoing needs of the client. The service provider shall document follow-up no sooner than 60 days and no later than 90 days after discharge.

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

Service Standard	Performance Measure
Initial Appointment/Screening	• Percentage of client charts with documentation of an appointment

Face-to-face client orientation is provided to all new clients to introduce them to program services, ensure their understanding of the need for continuous care, and empower them to access services. In accordance with the Texas Administrative Code (TAC), clients will be informed of opportunities for the family to be involved in the client's treatment. An appointment will be scheduled within a reasonable amount of time, not more than ten (10) business days, from a client's request for substance use services. The agency may provide written orientation materials to the client that support the above information, are culturally sensitive, promote equity, and are linguistically appropriate. In urgent, non-life-threatening emergency circumstances, an appointment will be made as soon as possible but no later than within one (1) business day, subject to licensure requirements. If an agency cannot provide the needed services, the agency will offer to refer the client to another organization that can provide the services. The referral must be made within one (1) business day for urgent, non-life-threatening situation(s). Each client must complete a documented screening based on best practice standards of care using the Texas Department of Insurance criteria per TAC standards. The screening process shall collect the necessary information to determine the services required to meet the client's needs.⁴⁴	scheduled after request (referral) for substance use outpatient services. Percentage of client charts with documentation of completed screening as indicated.
Comprehensive Psychosocial Assessment All clients referred to the program will receive a Comprehensive Psychosocial Assessment (in accordance with TAC Standards) by a licensed substance use counselor. Initial comprehensive psychosocial assessment protocols shall provide for screening individuals to determine the level of need and appropriate treatment plan development. A comprehensive psychosocial assessment will be completed before the third counseling session* and will include the following: Presenting problems resulting in need;	

⁴⁴ [Texas Administrative Code, Title 25, Part 1, Chapter 448, Subchapter H, Rule §448.801, Screening](#)

• Alcohol and other drug use; • Psychiatric and chemical dependency treatment; • Medical history and current health status, to include an assessment of Tuberculosis (TB), HIV, and other sexually transmitted infections (STI) as permitted by law; • Relationships with family, including domestic/intimate partner violence; • History of trauma/related events; • Stigma; • Housing Stability, expelled from home; • Treatment adherence (e.g., HIV meds); • Social and leisure activities; • Education and vocation training; • Employment history; • Legal issues; • Mental/emotional functioning; and • Strengths and weaknesses.⁴⁵ The assessment shall result in a diagnosed substance use issue, as allowed by the counselor's license and scope of practice. *Note: Clients are assessed for care coordination needs, and referrals are made to other case management programs as appropriate. If pressing needs emerge during the assessment requiring immediate attention that results in the assessment not being finalized by the third session, this must be documented in the client's primary record. Specific assessment tools such as the Substance Abuse and Mental Illness Symptoms Screener (SAMISS) and Addiction Severity Index (ASI) may be used for substance use and sexual history, and the Mini-Mental State Examination (MMSE) may be used for cognitive assessment.	
Treatment Modalities Providers must discuss treatment options with substance-using clients and ask which treatment options they prefer. Providers should inquire about the use of multiple substances and consider the full spectrum of the client's drug use when discussing treatment options.	• Percentage of client charts with documentation of discussion of treatment modalities with the client. • Percentage of client charts for clients on medication-assisted therapies, with documentation of contact with the client's medical provider within 72 hours of treatment initiation or the client's refusal to authorize the communication.

⁴⁵ [Texas Administrative Code, Title 25, Part 1, Chapter 448, Subchapter H, Rule §448.801, Screening](#)

Providers must discuss alternative treatment modalities with the client(s) targeted toward the substance(s) that the client is still using. Providers must rely on the ASAM Criteria (formerly known as the ASAM Patient Placement Criteria) of the American Society of Addiction Medicine (ASAM) for guidance on selecting the best treatment alternatives for specific clients. Medical treatment for substance use must adhere to current HIV Clinical Guidelines.	Percentage of clients with acupuncture services rendered with documented evidence of a physician's order.
Treatment Plan A treatment plan shall be completed within 30 calendar days of completing a comprehensive psychosocial assessment specific to individual client needs. The treatment plan shall be prepared and documented for each client. Treatment planning will be a collaborative process through which the provider and client develop desired treatment outcomes and identify the strategies for achieving them. Individual and family case records will include documentation of the following: - Identification of the substance use disorder - Goals and objectives - Treatment modality (group or individual) - Start date for substance use counseling - Recommended number of sessions - Date for reassessment - Projected treatment end date - Any recommendations for follow up Treatment, as appropriate, will include counseling about (at minimum): - Prevention and transmission, including root causes and underlying issues related to increased HIV transmission. - Treatment adherence - Development of social support systems - Community resources - Maximizing social and adaptive functioning - The role of spirituality and religion in a client's life, disability, death and dying, and exploration of future goals The substance use counselor rendering service will sign the treatment plan. In accordance with TAC	- Percentage of client charts that have documentation of treatment plans completed within 30 calendar days of the completed comprehensive assessment. - Percentage of client charts with documented evidence of treatment plans reviewed/modified at a minimum midway through the number of determined sessions agreed upon for frequency of modality in the client's primary record.

on Substance Abuse, the treatment plan shall be reviewed at a minimum midway through the number of determined sessions agreed upon for frequency of modality and must reflect an ongoing reassessment of the client's problems, needs, and response to therapy.	
Progress Notes Services will be provided according to the individual's treatment plan and documented in the client's record. Progress notes are completed for every professional counseling session and include the following: • Client name • Session date • Clinical observations • Focus of session • Interventions • Assessment • Duration of session • Newly identified issues/goals • Client's responses to interventions and referrals • HIV medication adherence • Substance use treatment adherence • Counselor authentication per current TAC Standards of Care for Substance Abuse Services.	• Percentage of client charts with documented progress notes for each counseling session as indicated.
Referrals The service provider will make appropriate referrals when necessary.	• Percentage of client charts, as applicable, with documented referrals made based on need demonstrated in the assessment and progress notes.
Discharge Planning Discharge planning will be done with each client when treatment goals are met and include: • Circumstances of discharge • Summary of needs at admission • Summary of services provided • Goals and objectives completed during counseling • Referral after completing substance use treatment to the case manager and primary care provider, as appropriate • Discharge plan	• Percentage of client charts with documentation, as applicable, of discharge planning with the client prior to case closure.

Counselor authentication, in accordance with TAC Standards and the counselor licensure requirements. In all cases, providers/case managers shall ensure that, to the greatest extent possible, clients who leave care are linked with appropriate services to meet their needs.	
Discharge Services may be discontinued when the client has: - Reached goals and objectives in their treatment plan - Missed three (3) consecutive appointments in six (6) months. - Continued non-adherence to a treatment plan - Chooses to terminate services - Unacceptable client behavior - Deceased Completed discharge summary in accordance with <i>TAC Standards (§448.805)4</i>, as applicable.	- Percentage of client charts with documentation of case closure (discharge), the reason for discharge, or discharge summary if applicable. Proposed System Level Outcome Measure: Percentage of clients who demonstrate improved viral suppression after completing Substance Use Outpatient Treatment Plan objectives.

SUPPORT SERVICES

CHILD CARE SERVICES

HRSA Description: The RWHAP supports intermittent childcare services for the children living in the household of HIV clients to enable clients to attend medical visits, related appointments, and RWHAP-related meetings, groups, or training sessions.⁴⁶

Allowable uses of funds include:

- A licensed or registered childcare provider to deliver intermittent care
- Informal childcare provided by a neighbor, family member, or another person (with the understanding that existing federal restrictions prohibit giving cash to clients or primary caregivers to pay for these services)

Activities must include:

- Continuing or intermittent provision of basic childcare, including child development activities that promote cognitive learning and social skills development;

Activities may not include:

⁴⁶ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Child Care Services. [Page 17](#)

- Off-site recreational or social activities or to pay for a gym membership.
- Daycare while the HIV+ parent, guardian, or caretaker is at work or school.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

- 1.1 Ensure that its child care facility is licensed by either the Texas Department of State Health Services as a Special Care Facility, the Texas Department of Family and Protective Services as a Day Care Facility, or the Texas Department of Aging and Disability Services as a Pediatric Extended Care Facility and that its license(s) are current and available;
- 1.2 ensure that staff and volunteers who require licensure or certification are appropriately licensed/certified and consistent with their professional categories;
- 1.3 ensure that its child/adolescent care facility meets health, fire, and safety standards, including adequate ventilation, clean water, and heating and cooling units, as evidenced by passing the most recent inspections by appropriate regulatory bodies;
- 1.4 obtain an initial test for tuberculosis for prospective staff and volunteers, and a repeat test at least annually to protect clients; and
- 1.5 ensure the availability of age-appropriate services.
- 1.6 Except where grant funds may be specifically restricted (e.g., Minority AIDS Initiative funds), provide its services to eligible children and adolescents (birth through age 18) living with or affected by HIV/AIDS, regardless of gender, race, color, religion (or lack thereof), national origin, disability, or inability to pay, to the extent resources allow.

EMERGENCY FINANCIAL ASSISTANCE

HRSA Description: Emergency financial assistance (EFA) provides limited one-time or short-term payments to assist the RWHAP client with an emergent need for paying for essential utilities, housing, food (including groceries and food vouchers), transportation, and medication. **NOTE:** Part A and Part B programs require Emergency funds to be allocated, tracked, and reported by type of assistance.⁴⁷ Emergency financial assistance can be directly paid to an agency or through a voucher program.⁴⁸

Activities may include:

- Payment of short-term payments for antiretroviral medication.
- Dispensing fee for ADAP medications during the ADAP eligibility determination period.
- Provision of short-term payments/vouchers for housing, transportation (bus/gas voucher), food, and medication assistance.

⁴⁷ HIV/AIDS Bureau, Division of Metropolitan HIV/AIDS Programs [National Monitoring Standards for Ryan White Part A Grantees: Program – Part A](#)

⁴⁸ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Emergency Financial Assistance. [Page 17](#)

- Provision of short-term payments for essential utilities, including water, gas, and electric bills, paid directly to the utility provider.

Activities may not include:

- Provision of short-term payments made directly to clients.

EFA is an allowable support service with an \$800/year/client cap.

- The agency must set priorities and delineate and monitor what part of the overall allocation for emergency assistance is obligated for each subcategory. Careful monitoring of expenditures within a subcategory of "emergency assistance" is necessary to ensure that planned amounts for specific services are implemented and determine when reallocations may be required. Policies and procedures should be implemented to avoid duplication of services.
- Limitations on providing emergency assistance to eligible individuals/households should be delineated and consistently applied to all clients. It is expected that all other sources of funding in the community for emergency assistance will be effectively used and that any allocation of EFA funding for these purposes will be the payer-of-last-resort and for limited amounts, limited use, and limited periods.⁴⁹

Initial medications purchased and reimbursed dispensing fees associated with purchased medication are not subject to the \$800/client/fiscal year cap. EFA to individual clients is provided with limited frequency and for a limited period, with specified frequency and duration of assistance. Emergent needs must be documented each time funds are used.

Assistance is provided only for the following essential services/subcategories:

- Utilities such as household utilities, including gas, electricity, propane, water, and all required fees
- Housing such as rent or temporary shelter. EFA can only be used if HOPWA assistance is not available
- Food such as groceries and food vouchers
- Prescription medication assistance such as short-term, one-time assistance for any medication and associated dispensing fee as a result of component of a primary medical visit (not to exceed a 30-day supply)

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

Service Standard	Performance Measure
Assisting Clients during the ADAP Eligibility Determination Period	• Percentage of clients that have documented evidence in the client primary record of short-term HIV

⁴⁹ Texas Department of State Health Services HIV/STD Program Policies: [DSHS Funds as Payment of Last Resort \(Policy 590.001\)](#).

HIV+ clients with documented evidence of the emergency need for HIV medications can receive short-term medication assistance (30-day supply) with limited use of EFA for no more than 60 days (2 months or less). Assisting Clients with Short-Term Medications HIV+ clients with documented evidence of pending health insurance medication plan approval can receive short-term HIV medication assistance no more than 60 days through EFA.	medication assistance provided during the ADAP application period. Percentage of clients that have documented evidence in the client primary record of short-term HIV medication copay assistance provided during the health insurance application period.
Client Determination for Emergency Financial Assistance Applicants must demonstrate an emergent need resulting in their inability to pay their utility bills or prescriptions without assistance and risk disconnection of service due to one or more of the following: - A significant increase in bills - A recent decrease in income - High unexpected expenses on essential items - They are unable to provide for basic needs and shelter - A failure to provide EFA will result in danger to the physical health of the client or dependent children - Other emergency needs as deemed appropriate by the agency Agency staff will conduct an assessment of the presenting problems/needs of the client with emergency financial issues. A service plan will be developed documenting the client's emergent need resulting in their inability to pay bills/prescriptions without assistance, and other resources pursued noted before using EFA funding for assistance. The client will be assessed for the ongoing status and outcome of the emergency assistance. Referrals for services, as applicable, will be documented in the client file. The resolution of the emergency status will be documented in the client record.	- Percentage of clients with documented evidence of determination of EFA needs noted in the client's primary record. - Percentage of clients with documented service plan for EFA in the client's primary record that indicates an emergent need, other resources pursued, and outcome of EFA provided. - Percentage of clients with documented evidence of resolution of the emergency status and referrals made (as applicable) with outcome results in the client's primary record.

Emergency Financial Assistance Provided Short-term assistance will only be provided for the following: • Prescription medication assistance All completed requests for assistance shall be approved or denied within three (3) business days. Assistance shall be issued in response to an essential need (as identified by the staff person providing EFA) within three (3) business days of approval of the request. Payment for assistance made to service providers will protect client confidentiality. Use checks and envelopes that de-identify the agency as an HIV/AIDS provider to protect client confidentiality.	• Percentage of clients with documented evidence of payments made by the agency for resolution of emergency status (copies of checks/vouchers available).
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FOOD BANK/HOME-DELIVERED MEALS

HRSA Description: Food Bank/Home Delivered Meals refers to the provision of actual food items, hot meals, or a voucher program to purchase food. This also includes the provision of essential non-food items that are limited to the following:⁵⁰

- Personal hygiene products
- Household cleaning supplies
- Water filtration/purification systems in communities where issues of water safety exist

This category includes providing actual food, prepared meals, or food vouchers to purchase prepared meals. Food bank services are the provision of actual food and personal care items in a food bank setting.

Activities may include:

- Providing food including fresh fruit, vegetables, meats, dairy products, staples, etc.;
- Providing personal hygiene products, including toothpaste, feminine hygiene, bathing soap, shampoo, and deodorant;
- Providing cleaning and paper goods such as toilet paper;
- Delivery of food, personal hygiene items, and cleaning goods to a client's home (rural areas only);
- Provision of nutritional supplements for meal replacement;
- Provision of education for safe food preparation practices;

⁵⁰ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Food Bank/ Home Delivered Meals.
[Page 17](#)

- Provision of nutritionally balanced meals, on-site in a congregate housing setting or home-delivered meals to non-ambulatory individuals with a documented medical need for meal assistance.

On-site/Home Delivered Meals are the provision of prepared meals or food vouchers for prepared meals in either a congregate dining setting or delivered to clients who are homebound and cannot shop for or prepare their own food. This service includes the provision of both frozen and hot meals.

Activities may not include:

- The provision of prepared meals if receiving funding for food pantry services*;
- The provision of food pantry services if receiving funding for home-delivered meals*;
- The provision of pet food or products, household appliances;
- Nutrition counseling;
- Cash to purchase food.

* Approval from the AA is required

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The food bank shall:

- 1.1** ensure that its food pantry program meets all requirements of the local health department for food handling and storage;
- 1.2** maintain and show evidence that all required inspections are current and resulted in acceptable findings;
- 1.3** provide adequate space and equipment to store food in a sanitary manner;
- 1.4** if bulk foods are repackaged, all handlers should be licensed food handlers and
- 1.5** have a Food Product Establishment Permit, if required by the local municipality.
- 1.6** Ensure that if they operate within the City of Dallas, at least one person on staff with direct responsibility for the provision of food is certified by the City of Dallas as a Food Service Manager or is certified by the Texas Department of State Health Services Retail Foods Division as having satisfactorily completed a state-accredited food protection management program.

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

Service Standard	Performance Measure
Provision of Food Distribution Services Clients referred to or otherwise accessing food banks without a referral must be screened for other eligible resources, such as the Supplemental	• Percentage of clients with documentation in the client's primary record of other food resources accessed prior to clients accessing the food bank.

Nutrition Assistance Program (SNAP), as evidenced in their primary record. Clients accessing food banks have documentation in the client's primary record of the reason/need assessed. Assessment of the client's immediate or ongoing need for food bank services is documented in the client's primary record.	Percentage of clients with documentation in the client's primary record of the assessment of the need for food resources.
Dietary Guidance A registered dietician must be consulted to develop a dietary/nutritional policy that lists specific food items offered in the food bank/pantry or prepared for home-delivered meals. There is a plan to address the needs of clients' special diets. As applicable, clients are referred to an RD for specific dietary issues. Clients are offered counseling, if requested, to help with meal planning and food appropriateness. The program must ensure that available foods are selected, considering special nutritional needs (incorporating generally accepted nutritional standards), religious requirements, and ethnic food preferences, as appropriate. Attempts must be made on a regular basis to provide choices on food items that meet the individual dietary needs of clients, including the foods that fall into the recognized food categories for a healthy diet identified in the dietary guidelines issued by the U.S. Department of Agriculture and U.S. Department of Health and Human Services.	- Percentage of clients accessing food banks are referred, as applicable, to an RD for specific dietary issues as documentation in the client's primary record. - Percentage of clients accessing food banks offered counseling for meal planning and food appropriateness.
Home-Cooked/Hot Meals Clients assessed for food security and offered home-cooked meals/hot meal programs have evidence of the need documented in the client's primary record. Clients provided vouchers for hot meal programs have an increase in food security.	- Percentage of clients accessing hot meal programs have documented evidence of assessment of need in the client's primary record. PILOT: Percentage of clients accessing hot meal programs have increased food security as documented in the client's primary record.
Discharge/Termination The service provider will develop discharge/termination for cause criteria and procedures.	Percentage of clients discharged from food bank/home delivered meals have documentation of reason of discharge in the client's primary record.

HEALTH EDUCATION/RISK REDUCTION

HRSA Description: Health Education/Risk Reduction is the provision of education to clients living with HIV about HIV transmission and how to reduce the risk of HIV transmission. It includes sharing information about medical and psychosocial support services and counseling clients to improve their health status. This service may not be funded using Ryan White Part B funds. DSHS must approve the provision of services not found in other service categories. Topics covered may include:⁵¹

- Education on risk reduction strategies to reduce transmission, such as pre-exposure prophylaxis (PrEP) for clients' partners and undetectable equals untransmittable (U=U)
- Education on health care coverage options (e.g., qualified health plans through the Marketplace, Medicaid coverage, Medicare coverage)
- Health literacy
- Treatment adherence education

Activities must include:

- Preparation and dissemination of the informational handbook, including the following information;
- Chart to track labs and medications;
- Efficient and useful comprehensive service agency listings;
- HIV-reduction messages;
- Reasons to enter and remain in primary medical care;
- Information on Ryan White services;
- Information on eligibility for Ryan White services;
- A method to track referrals;
- General information for newly diagnosed;
- Space to write in provider information (physician, case manager, pharmacy, etc.);
- General health information, including space to document and track body weight, blood pressure, nutrition questions, and questions about medications;
- Explanation of HOPWA;
- Phone numbers of other EMAs;
- Comprehensive Care Coordination section;
- Maintaining a distribution list that includes, at a minimum, key points of entry, Part A, MAI, Part B, State Services, and State HOPWA-funded providers.

Activities may not include:

- Provision of professional and volunteer training and education;
- Provision of verbal information and education about reduction and available HIV-related services.
- Services delivered anonymously.

⁵¹ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Health Education/ Risk Reduction.
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HOUSING

HRSA Description: Housing provides transitional, short-term, or emergency housing assistance to enable a client or family to gain or maintain outpatient/ambulatory health services and treatment, including temporary assistance necessary to prevent homelessness and to gain or maintain access to medical care. Housing may provide some core medical or support service and be essential for a client or family to gain or maintain access to and compliance with HIV-related outpatient/ambulatory health services and treatment.⁵²

HRSA/RWHAP recipients and subrecipients that use funds to provide Housing must have mechanisms to assess and document new clients' housing status and housing service needs, at least annually for existing clients. HRSA/RWHAP recipients, subrecipients, and local decision-making planning bodies are strongly encouraged to institute duration limits to housing activities.

HRSA/HAB recommends recipients and subrecipients align duration limits with those definitions used by other housing programs, such as those administered by the Department of Housing and Urban Development, which currently uses 24 months for transitional housing. Housing provides transitional, short-term, or emergency housing assistance to enable a client or family to gain or maintain outpatient/ambulatory health services and treatment, including temporary assistance necessary to prevent homelessness and to gain or maintain access to medical care. Housing services include housing referral services and transitional, short-term, or emergency housing assistance.

Activities must include:

- The development of an individualized housing plan, updated quarterly, to guide the client's linkage to permanent housing.
- Documentation of the necessity of housing services for the purposes of medical care.

Activities may include:

- Housing referral services, assessment, search, placement, and housing advocacy services are provided on behalf of the eligible client and fees associated with these activities.
- Housing referral services provided by a housing case manager or other professionals to include assessment, search, placement, and advocacy services, which possess a comprehensive knowledge of local, state, and federal housing programs and how these programs can be accessed.

Activities may not include:

- Direct payments to eligible clients cannot be used for mortgage payments.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

⁵² Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Housing. [Page 18](#)

- 1.1** ensure that each of its housing facilities is licensed by DSHS as an assisted living facility or as a special care facility, as appropriate;
- 1.2** keep its license current and available;
- 1.3** Ensure that housing facilities meet health, fire, and safety standards, including adequate ventilation, clean water, and heating and cooling units, as evidenced by passing the most recent inspections by appropriate regulatory bodies, and comply with applicable local government zoning and occupancy codes in its housing facilities.

Service Standard	Performance Measure
Emergency Housing Assistance Agency staff will initiate an intake within three (3) business days' onset of the emergency housing need. Assessment of client housing status and housing service needs must be documented. Reason(s) for emergency assistance may include but are not limited to: • The client is unable to pay rent due to a recent job loss, unpaid medical leave of absence, exhausted all leave balances • The client is unable to work due to recent hospitalization • The client had to recently purchase unexpected costly HIV medications or pay for unexpected HIV-related medical expenses out of pocket. Assessment that the household need is: • Actual costs to avoid eviction • Other resources are not reasonably available to address the unmet housing need. • The client will maintain or have stable housing as a result of housing assistance. Staff will contact the client at the end of the month to determine if the housing emergency has been resolved. If not resolved and the client needs additional assistance, the client may be assessed for short-term housing assistance.	Percentage of client charts with documented evidence of emergency housing needs assessed. Percentage of client charts that have a documented assessment of other resources reviewed and determined not available to assist the client in a housing emergency. Percentage of client charts with documented evidence of follow-up to housing need with a resolution of housing emergency. Percentage of patients with an HIV diagnosis who were homeless or unstably housed in the 12-month measurement period (HRSA/HAB Performance Measure). Percentage of client charts accessing housing assistance, with stabilized housing documented as a result of the assistance provided.
Housing Plan for Transitional (temporary) and Short-Term Housing All clients receiving assistance for transitional or short-term housing must have a Housing	Percentage of client charts with a documented housing plan developed.

Plan documented within the client files that includes: • Housing status; • Reason for housing assistance need; • Other resources screened for housing assistance. Plans must detail the ongoing housing stability goal, focusing on access to medical treatment and supportive services. The plan must include: • Sustainable short-term and long-term goals for alleviating susceptibility to homelessness, establishing affordable permanent housing stability, and improving access to health care and supportive services. • Identification of barriers to sustainable housing; • Steps to address housing needs; • Referral(s) to available housing support services; and • Budget and money management skills building, if indicated. Documentation in the client's primary record/progress notes that the housing plan is reviewed monthly.	Percentage of client charts with documented evidence of monthly updated housing plans with progress toward goals identified.
Housing Referral Services Housing-related referrals provided by housing assistance/referral providers include housing assessment, search, placement, and advocacy services to seek housing (application to funding sources, visits to court systems). Staff will document all activities in the client's primary record to assist the client in securing housing and the outcome of the assistance.	Percentage of client charts with documented evidence of housing referral services provided, as applicable, including all elements as indicated. Percentage of clients who received housing referral services that obtained secure, stable housing as a result of the assistance

LINGUISTIC SERVICES

HRSA Description: Linguistic services provide interpretation and translation services, both oral and written, to eligible clients. Qualified linguistic services providers must provide these services as a component of HIV service

delivery between the healthcare provider and the client. These services are to be provided when necessary to facilitate communication between the provider and client or support the delivery of RWHAP-eligible services.⁵³

Activities may include:

- Verbal interpretation between a client or caregiver and other service providers to facilitate the delivery of services;
- Written translation of documents into another language, or Braille, for other Dallas County pass-through grant-funded agencies to facilitate the delivery of services to a client or clients;
- Sign language interpretation between a client or caregiver and other service providers to facilitate the delivery of services.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure the following:

- 1.1 That services be provided by a qualified linguist service, both oral and written, including a language line.
- 1.2 The services must comply with the [National Standards for Culturally and Linguistically Appropriate Services](#).
- 1.3 That its interpretation/translation/sign language program staff who provide direct services to clients shall have had at least one year of college and a minimum of six (6) months of experience providing services in this or a related field. One year of stable and relevant employment in the areas of outreach work, community service, supportive work with families and individuals, supportive work with youth, corrections, public relations, or customer service can substitute for the education requirement;
- 1.4 that, if its contract with Dallas County Health and Human Services allows for services for the visually impaired, it makes written materials available in large print;
- 1.5 that staff and volunteers who provide sign language services hold at least Level I American Sign Language (ASL) certification from the [Texas Office for Deaf and Hard of Hearing Services](#) (DHHS);
- 1.6 that it does not utilize Ryan White Part A or Part B funds to provide interpretation/translation services for ineligible individuals or agencies; and
- 1.7 that it maintains detailed records in legible form, documenting all clients, the number of interpretation/translation/sign language units, phone contacts with clients, contacts with service providers on behalf of clients, and contacts with service providers requesting interpretation/translation/sign language services.

MEDICAL TRANSPORTATION

HRSA Description: Medical transportation provides non-emergency transportation services that enable an eligible client to access or be retained in core medical and support services.⁵⁴

⁵³ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Linguistic Services. [Page 19](#)

⁵⁴ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Medical Transportation. [Page 19](#)

Activities must include:

- Transporting an eligible client to an HIV-related medical or support service appointment, HRSA RWHAP-related local planning council/committee meetings, or training sessions.
- Delivering HIV-related medications to an eligible client or in bulk quantity to community-based agencies;
- Distributing bus passes, taxi/ride-sharing vouchers, or gas vouchers to provide access to HIV-related appointments.

Activities may not include:

- Direct maintenance expenses (tires, repairs, etc.) of a privately-owned vehicle
- Any other costs associated with a privately owned vehicle, such as lease, loan payments, insurance, license, or registration fees.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure the following:⁵⁵

- 1.1** through a contractual arrangement, lease agreement, or ownership, that its vehicle service fleet is operated, maintained, and insured exclusively by the service provider;
- 1.2** that it maintains vehicle liability insurance coverage on each vehicle, or as a fleet, with a minimum acceptable limit of \$300,000 combined single limit coverage per vehicle, and that each vehicle used by the provider maintains a current Texas State Inspection, registration, and license plates;
- 1.3** that each driver maintains a current, valid Texas Driver's License, and it shall keep a copy on file;
- 1.4** that it maintains detailed records in legible form of mileage driven, name of individuals provided with transportation, and origin and destination for all trips;
- 1.5** that it has in place a means to communicate with the transport vehicle (a radio, cell phone, or other devices, preferably hands-free);
- 1.6** that it does not utilize Ryan White Part A or Part B funds to transport clients to off-premise social or recreational activities and
- 1.7** It has a written policy defining an "acceptable driving record" and that each driver meets the policy's requirements.

NON-MEDICAL CASE MANAGEMENT SERVICES

HRSA Description: Non-Medical Case Management Services (NMCM) provide guidance and assistance in accessing medical, social, community, legal, financial, and other needed services. Non-medical case management services may also include assisting eligible clients in obtaining access to other public and private programs for which they may be eligible, such as Medicaid, Medicare Part D, State Pharmacy Assistance Programs, Pharmaceutical

⁵⁵ [State of Texas Transportation Code Title 7, Subtitle C, Chapter 545. Operation and movement of Vehicles.](#)

Manufacturer's Patient Assistance Programs, other state or local health care and supportive services, or health insurance Marketplace plans.⁵⁶

This service category includes several methods of communication, including face-to-face, phone contact, and any other forms deemed appropriate by the RWHAP recipient.

Key activities include:

- Initial assessment of service needs
- Development of a comprehensive, individualized care plan
- Continuous client monitoring to assess the efficacy of the care plan
- Re-evaluation of the care plan at least every six (6) months with adaptations as necessary
- Ongoing assessment of the client's and other key family members' needs and personal support systems

Activities must include:

- Completing intakes, screening for client eligibility, and determining the need for all services;
- Assessing and reassessing (according to current Standards of Care) a client's bio-psychosocial history, including the needs of the client and support system;
- Developing and reviewing a care plan based on the client's needs and choices with goals and strategies for completion every six (6) months;
- Implementing the care plan through time-lined strategies;
- Providing information, referrals, and assistance with linkages to needed services;
- Monitoring and following up on the goals of the care plan;
- Advocating on behalf of a client to remove barriers to service;
- Collaborating with other service providers to coordinate client care;
- Providing appropriate crisis intervention as needed.

Activities may include:

- Case management to prevent unnecessary hospitalization or to expedite discharge;
- Screening followed by reduction interventions for HIV-positive persons susceptible of transmitting HIV;
- Benefits Counseling, Enrollment & Outreach Education (e.g., Medicaid, Medicare, Market Place/Exchange, other private insurance, etc.).
- Take-Charge-Texas (TCT) and other types of data entry or documentation directly related to case management performed for/on behalf of a client.

Activities may not include:

- Coordination and follow-up of medical treatments;
- Compilation of outcome measures reports;
- Development, distribution, or analysis of client satisfaction surveys;

⁵⁶ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Non-Medical Case Management Services. [Page 20](#)

- Recreational activities.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure that:

- 1.1 Each staff person who provides case management services to clients shall have, at a minimum, a bachelor's degree in social science or behavioral science, nursing, or a related field from an accredited domestic or international college or university. As an alternative, a minimum of one (1) year of employment experience performing medical case management, case management, or client advocacy may substitute for each year of college education;
- 1.2 each case management supervisor shall have, at a minimum, a bachelor's degree in social science or behavioral science, nursing, or a related field from an accredited domestic or international college or university. As an alternative, a minimum of one (1) year of employment experience performing medical case management, case management, or client advocacy may substitute for each year of college education.
- 1.3 Its case management staff, who provide direct services to clients, have continuing access to the most up-to-date information available about effective medical care for those with HIV/AIDS and
- 1.4 case management supervisors and case managers shall each hold a valid driver's license in accordance with Texas law if needed to carry out work responsibilities.
- 1.5 Case managers complete the [HIV Case Management training series](#) for case management annually.

NON-MEDICAL CASE MANAGEMENT SERVICES - HOUSING-BASED CASE MANAGEMENT

Housing-based case management is non-medical case management in a congregate housing setting. This category is a local exception for the Dallas EMA/HSDA but must comply with the requirements outlined in Non-Medical Case Management.

OTHER PROFESSIONAL SERVICES (LEGAL SERVICES)

HRSA Description: Other Professional Services allow for the provision of professional and consultant services rendered by members of particular professions licensed or qualified to offer such services by local governing authorities.⁵⁷

Such services may include:

⁵⁷ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Other Professional Services. [Page 21](#)

- Legal services provided to or on behalf of the individual living with HIV and involving legal matters related to or arising from their HIV disease, including:
- Assistance with public benefits such as Social Security Disability Insurance (SSDI)
- Interventions necessary to ensure access to eligible benefits, including discrimination or breach of confidentiality litigation as it relates to services eligible for funding under the RWHAP

Preparation of:

- A healthcare power of attorney
- Durable powers of attorney
- Living wills
- Permanency planning to help clients/families make decisions about the placement and care of minor children after their parents/caregivers are deceased or are no longer able to care for them, including:
 - Social service counseling or legal counsel regarding the drafting of wills or delegating powers of attorney
 - Preparation for custody options for legal dependents, including standby guardianship, joint custody, or adoption

Activities may include:

- The preparation of powers of attorney, do not resuscitate orders;
- Interventions necessary to ensure access to eligible services, including discrimination or breach of confidentiality litigation related to services eligible for funding under the Ryan White HIV/AIDS Treatment Modernization Act.

Activities may not include:

- Legal services related to criminal defense, class action suits, or any legal matters unrelated to CARE Act service access;
- Legal services that arrange for guardianship or adoption of children after the death of their normal caregiver;
- Wills, trusts, and bankruptcy proceedings.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure that:

- 1.1 All attorneys, both staff and volunteer, meet the requirements for licensure and are in good standing with the State Bar of Texas; law students, law school graduates, and other legal professionals will be supervised by a qualified licensed attorney.
- 1.2 all staff and volunteer paraprofessionals and notaries possess and maintain proper licenses and certifications as required in the State of Texas;
- 1.3 legal services provided are related to clients' HIV status.
- 1.4 Staff will attend and have continued access to training activities:
 - Agency-paid legal staff and contractors must complete two (2) hours of HIV-specific training annually.

- The new agency-paid legal staff and contractors must complete two (2) hours of HIV-specific training within 90 days of the start date.
- Volunteer legal staff are encouraged to complete HIV-specific legal training.
- Documentation of training on current applicable laws related to HIV is located in the personnel file.
- The agency maintains a system for disseminating HIV/AIDS information relevant to the legal assistance needs of PLWH to staff and volunteers.
- The agency will document the provision of in-service education to staff regarding current treatment methodologies and promising practices.

OUTREACH SERVICES

HRSA Description: Outreach services include the provision of the following three activities:⁵⁸

- Identification of people who do not know their HIV status and linkage to Outpatient/Ambulatory Health Services
- Provision of additional information and education on healthcare coverage options
- Reengagement of people who know their status in Outpatient/Ambulatory Health Services

Activities must include:

- Identifying HIV-positive individuals who know their HIV status and are not receiving care;
- Providing targeted verbal and written information with explicit and clear links to health care services; Directing individuals to early intervention services (EIS) or primary care (HIV counseling and testing, diagnostic, and clinical ongoing prevention counseling services with appropriate providers of health and support services);
- Educating the client on the importance of remaining in primary medical care;
- Completing follow-up by tracking linkages to primary medical care and services that will retain them in primary medical care and treatment;
- Outreach services conducted in conjunction with a primary medical care program.

Activities may include:

- Providing referrals to case management;
- Condom distribution;
- Individual prevention education, which includes screening of practices that may make an individual susceptible to acquiring HIV, followed by reduction interventions for persons living with HIV who may be susceptible to transmission.

Activities may not include:

⁵⁸ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Outreach Services. [Page 22](#)

- HIV counseling/testing;
- Needle distribution;
- Broad scope awareness activities that address the general public;
- Marketing efforts for specific agencies that do not include information about services available in the continuum;
- Outreach conducted in group settings.

OUTREACH (STREET)

HRSA Description: Outreach services are programs that have as their principal purpose the identification of people with unknown HIV disease or those who know their status so that they may become aware of and may be enrolled in care and treatment services (i.e., case finding), not HIV counseling and testing or HIV prevention education. These services may target high-risk communities or individuals. Outreach programs must be planned and delivered in coordination with local HIV prevention outreach programs to avoid duplication of effort; be targeted to populations known through local epidemiologic data to be at disproportionate risk for HIV; be conducted at times and in places where there is a high probability that individuals with HIV will be reached, and be designed with quantified program reporting that will accommodate local effectiveness evaluation.⁵⁹

Activities must include:

- Providing referrals to case management;
- Providing targeted verbal and written information;
- Directing individuals to early intervention services (EIS) or primary care (HIV counseling and testing, diagnostic, and clinical ongoing prevention counseling services with appropriate providers of health and support services;
- Educating the client on the importance of remaining in primary medical care;
- Completing follow-up by tracking linkages to early intervention services, primary medical care, and services that will retain them in primary medical care and treatment;
- Targeting populations identified in local needs assessment, epidemiological data, and service utilization data as being susceptible to HIV disease.

Activities may include:

- Condom distribution;
- Prevention education, which includes screening of practice followed by reduction interventions to reduce acquisition/transmission of HIV; HIV counseling/testing.

Activities may not include:

- HIV counseling/testing;
- Needle distribution;
- Marketing efforts for specific agencies that do not include information about services available in the continuum;

⁵⁹ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Outreach Services. [Page 22](#)

- Outreach conducted in group settings of more than ten (10) individuals.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall ensure the following:

- 1.1** That its outreach workers know about and have experience working with underserved populations;
- 1.2** That its supervisor(s) of outreach workers has, at a minimum, at least two years of experience conducting HIV-related outreach activities with potential clients. In the absence of a supervisor, such as may be the case in a small agency, the agency shall have in place a collaborative agreement with another agency to provide access/outreach training and supervision;
- 1.3** that each outreach supervisor and worker holds a valid driver's license in accordance with Texas law if needed to carry out work responsibilities and
- 1.4** that it has ongoing access to names and last-known locating information for individuals known to be HIV+ and to have become lost to follow-up.

STANDARD OF CARE 2.0: CLIENT RIGHTS AND CONFIDENTIALITY

The service provider shall:

- 2.1** Provide information to potential clients regarding how to access services that may be available to them and their rights and obligations should they become agency clients.

STANDARD OF CARE 3.0: ACCESS, CARE, AND PROVIDER CONTINUITY

The service provider shall:

- 3.1** Provide access for staff, outreach contacts, and clients to current resource information relevant to the population of the EMA/HSDA;
- 3.2** address an outreach contact's specific barriers to accessing services to be able to make appropriate referrals and
- 3.3** establish and maintain an association with prisons, homeless shelters, substance abuse treatment centers, and other entities that have ongoing contact with persons known to be disproportionately impacted by HIV and subject to access barriers.

REFERRAL FOR HEALTHCARE AND SUPPORT SERVICES

HRSA Description: Referral for Health Care and Support Services directs a client to needed core medical or support services in person or through telephone, written, or other types of communication. Activities provided under this

service category may include referrals to assist HRSA/RWHAP-eligible clients in obtaining access to other public and private programs for which they may be eligible (e.g., Medicaid, Medicare Part D, State Pharmacy Assistance Programs, Pharmaceutical Manufacturer's Patient Assistance Programs, and other state or local health care and supportive services, or health insurance Marketplace plans).⁶⁰

ADAP Eligibility Worker

The ADAP eligibility worker assists with an ADAP application, including documentation and follow-up needed to ensure the ADAP eligibility process is accomplished per DSHS Standards of Care.

Program Guidance

Referrals for Health Care and Support Services provided by outpatient/ambulatory healthcare providers should be reported under the Outpatient/Ambulatory Health Services category.

Referrals for health care and support services provided by case managers (medical and non-medical) should be reported in the appropriate case management service category (i.e., Medical Case Management or Non-Medical Case Management).

Activities must include:

- Referral Worker: A documented encounter wherein the Referral Worker directs a client to a service in person or through telephone, written, or other types of communication, including management of such services where they are not provided as part of Outpatient Ambulatory Health or Case Management Services.
- ADAP Eligibility Worker: A completed ADAP application **accepted by** the Texas HIV Medication Program (THMP).

Activities may include:

- Efforts related to ensuring clients can access other public and private programs for which they are eligible.

Activities may not include:

Case Management services.

SERVICE STANDARDS AND PERFORMANCE MEASURES ⁶¹

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part B and State Services Program.

Service Standard	Performance Measures
Benefits Counseling	• Percentage of clients with documented evidence of education provided on other public and

⁶⁰ Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Referral Services. [Page 24](#)

⁶¹ Referral for Health Care and Support Services: [Service Standard](#)

Activities should be client-centered, facilitating access to and maintaining health and disability benefits and services. It is the primary responsibility of staff to ensure clients are receiving all needed public and private benefits and resources for which they are eligible. Staff will educate clients about available benefit programs, assess eligibility, assist with applications, provide advocacy with appeals and denials, assist with re-certifications, and advocate for other areas relevant to maintaining benefits/resources. Staff will explore the following as possible options for clients, as appropriate: • AIDS Drug Assistance Program (ADAP) • Health Insurance Plans/Payment Options (CARE/HIPP (Health Insurance Premium Payment), Consolidated Omnibus Budget Reconciliation Act (COBRA), Omnibus Budget Reconciliation Act (OBRA), Health Insurance Assistance (HIA), Medicaid, Medicare, Private, Affordable Care Act (ACA)/Marketplace) • SNAP • Pharmaceutical Patient Assistance Programs (PAPS) • Social Security Programs (Supplemental Security Income (SSI), SSDI, State Disability Insurance (SDI)) • Temporary Aid to Needy Families (TANF) • Veteran's Administration Benefits (VA) • Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) • Other public/private benefits programs • Other professional services Staff will assist eligible clients with completing benefits application(s) as appropriate within 14 business days of the eligibility determination date. Conduct a follow-up within 90 days of the completed application to determine if additional and ongoing needs are present.	private benefits programs in the primary client record. • Percentage of clients with documented evidence of other public and private benefit applications completed as appropriate within 14 business days of the eligibility determination date in the primary client record. • Percentage of eligible clients with documented evidence of the follow-up and result(s) to a completed benefit application in the primary client record.
Health Care Services Clients should be assisted in accessing health insurance, or Marketplace plans to assist with	• Percentage of clients with documented evidence of assistance to access health insurance or Marketplace plans in the primary client record.

engagement in the health care system and HIV Continuum of Care, including medication payment plans or programs. Eligible clients are referred to Health Insurance Premium and Cost-Sharing Assistance to assist clients in accessing health insurance, or Marketplace plans within one (1) week of the referral for health care and support services intake. Eligible clients are referred to other core services (outside of a medical, MCM, or NMCM appointment) as applicable to the client's needs, with education provided to the client on how to access these services. Eligible clients are referred to additional support services (outside of a medical, MCM, or NMCM appointment) as applicable to the client's needs, with education provided to the client on how to access these services. Staff will follow up within ten (10) business days of a referral to HIA to determine if the client accessed HIA services. Staff will follow up within ten (10) business days of a referral to any core services to ensure the client accessed the service. Staff will follow up within ten (10) business days of a referral to support services to ensure the client accessed the service.	• Percentage of clients who received a referral for other core services who have documented evidence of the education provided to the client on accessing these services in the primary client record. • Percentage of clients who received a referral for other support services who have documented evidence of the education provided to the client on accessing these services in the primary client record. • Percentage of clients with documented evidence of referrals provided for HIA assistance that had follow-up documentation within ten business days of the referral in the primary client record. • Percentage of clients with documented evidence of referrals provided to any core services that had follow-up documentation within ten (10) business days of the referral in the primary client record. • Percentage of clients with documented evidence of referrals provided to support services that had follow-up documentation within ten (10) business days of the referral in the primary client record.
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RESPITE CARE FOR ADULTS

HRSA Description: Respite care is the provision of community or home-based, non-medical assistance designed to relieve the primary caregiver responsible for providing day-to-day care of a client with HIV/AIDS.⁶²

Activities must include:

- Structured home or center-based activities that promote skills-building and social interaction that contribute to the maintenance and improvement of the client's support system;
- Periodic and time-limited respite for the caregiver(s) of the infected individual.

Activities may not include:

- Care of a child/youth.

STANDARD OF CARE 1.0: LICENSURE OR ASSURANCES

The service provider shall:

- 1.1** Ensure that center-based facilities meet health, fire, and safety standards and,
- 1.2** Make available daily, structured program activities in each client's care, for clients, and promote the importance of client socialization; and
- 1.3** provide required, non-medical support services to all clients as needed.
- 1.4** Obtain an initial test for tuberculosis for prospective staff and volunteers and a repeat test at least annually to protect clients; and
- 1.5** ensure the availability of age-appropriate services.

SERVICE STANDARDS AND PERFORMANCE MEASURES

The following standards and performance measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part A, Part B, and State Services Program.

Service Standard	Performance Measure
Initial Brief Assessment Service provider staff will initiate an intake within five (5) business days of the referral to include: • Client's support system • Needs of the client	• Percentage of clients with documented evidence of a brief initial assessment completed within five (5) business days of the referral in the client's primary record.

⁶² Policy Clarification Notice #16-02: Eligible Individuals and Allowable Uses of Funds. Respite Care. [Page 24](#)

Supporting documentation of the need for respite care will be included in the assessment. If informal respite care is to be used, the assessment must include the qualifications of the client's personal support network provider.	
Plan of Care In collaboration with the client and the client's family, a plan of care will be developed within ten (10) business days of the brief initial assessment. The plan of care should be signed and dated by both the client and the client's family or legal guardian and located in the client's primary record. A copy of the plan will be offered and documented in the client's record. The plan of care should include: • the objective of respite care • estimate of the number of respite care visits anticipated and services to be provided • type of setting in which respite services will be provided for the client Documentation that the plan of care is being followed may include, at a minimum: • Sign-in sheet documenting attendance in a facility or documentation of informal personal support network provider attendance in the home. • The objective should be listed at the top of the sign-in sheet or documentation for reimbursement by the informal personal support network provider. The plan of care should be reviewed at least every six (6) months to see if progress is being made towards meeting the objective of the respite care with documentation present in the client's primary record.	• Percentage of clients with a documented plan of care developed within ten (10) business days of the initial assessment in the client's primary record. • Percentage of clients with updated and reviewed plans of care every six (6) months documented in the client's primary record.
Referrals If the client's needs are beyond the scope of the services provided by the service provider or the	• Percentage of clients with documented referrals for services beyond the scope of respite care provider in the client's primary client record.

client's informal support network, an appropriate referral to another level of care is made. Documentation of referral and outcome of the referral is present in the client's primary record.	Percentage of clients referred to another level of care have documentation of referral outcome in the client's primary record.
Discharge Once objectives have been met, the agency and client will collaborate on a discharge plan. Reasons for discharge may include: - Services are no longer needed. - Services needed are outside the scope of respite care - Client is deceased - The client has moved out of the area - Unacceptable client behaviors - The client has not attended or received respite care per agency policy and procedure.	Percentage of clients with documented evidence of the reason for discharge in the client's primary record.

RESPITE CARE FOR CHILDREN/YOUTH/ADOLESCENTS

HRSA Description: Respite care is the provision of community or home-based, non-medical assistance designed to relieve the primary caregiver responsible for providing day-to-day care of a client with HIV/AIDS.

Activities may include:

- Provision of basic childcare, including child development activities that promote cognitive learning and social skills development for a child/youth with HIV;
- Periodic and time-limited respite for the caregiver of a child/youth with HIV.

Activities may not include:

- Off-site recreational or social activities
- Care of an adult.

APPENDICES

APPENDIX A: HOW BEST TO MEET THE PRIORITY

Fiscal Year 2023 Ranking	Service Category	Special Instructions
2	AIDS Pharmaceutical Assistance	• Provide information on drug reimbursement programs to formerly incarcerated individuals who are recently released. • Provide information to populations in the Stemmons Corridor area (see the zip code table attached). • Provide information to consumers on copayment assistance available through Ryan White and alternative insurance funding.
7	Health Insurance Premium & Cost Sharing Assistance	• Educate consumers about the various types of insurance, program requirements, and necessary documentation in medical clinics.
3	Medical Case Management	• Educate consumers about the differences between medical and social case management and the appropriate usage of each. • Provide information about the importance of remaining in primary care and maintaining dental hygiene.

		• Collaborate with and refer clients to prevention case managers or reduction specialists to encourage the reduction of practices that may make an individual susceptible to HIV. • Inform newly diagnosed individuals about the importance of entering and remaining in primary medical care. • Provide information in English and Spanish about the availability of local drug reimbursement programs. • Increase the number of bilingual medical case managers as funding allows. • Provide information and referrals to gender-segregated programs (if any) appropriate to the client's self-affirmed gender identity and sense of safety. • Educate and collaborate with alternatively funded substance abuse programs on the treatment of PLWH.
5	Mental Health Services	• Provide information about the importance of remaining in primary care while retaining mental health counseling and information on available primary medical care services. • Collaborate with Early Intervention Services to support newly diagnosed clients and consumers reentering HIV medical care.

		Educate and collaborate with alternatively funded substance abuse programs on the treatment of PLWH.
6	Oral Health Care	- Inform medical and non-medical case managers about dental care options and providers to make appropriate referrals. - Stagger appointments, so the waiting room is not full (no more than two (2) people in the waiting room). - Longer wait times could be due to the provider relocating to a new site - Sites providing services adhere to safety recommendations from the CDC.
1	Outpatient Ambulatory/Health Services	- When and where applicable, provide for the rapid start of medication for newly diagnosed within 48-72 hours; 2 weeks for those returning to care; 6 months for viral suppression once the medication is accessed. - Provide information about Ryan White programs to reduce financial concerns about seeking care. - Ensure providers are knowledgeable regarding managing patients co-infected with HIV and HCV. - Provide information about the importance of remaining in primary care and maintaining dental hygiene. - Provide information in English and Spanish about the availability of local drug reimbursement programs. - Incorporate prevention messages into the medical care of PLWH.

		• Educate and collaborate with alternatively funded substance abuse programs on treatment for PLWH. • Educate and collaborate with alternatively funded mental health programs on treatment for PLWH. • Telehealth and telemedicine should be allowed wherever and whenever possible, i.e., case management, eligibility, • Provider feedback - good responses to telehealth • Receiving services by telephone/ virtual • Meal programs are to-go, and bus passes are distributed using minimal contact. • Business agreements with virtual platforms • Flexibility needs to be maintained when accessing this service • In-person eligibility screening is not required federally • Patient-centered care should be considered • Personal protective equipment (PPE) should be available to clients
9	Substance Abuse Services	• Educate and collaborate with alternatively funded substance abuse programs on treatment for PLWH. • Educate and collaborate with alternatively funded mental health programs on treatment for PLWH. • Placement in/or assignment to gender-segregated programs (if any)

		shall be based on the client's self-affirmed gender identity. A client's sense of where they will be safest and receive the most benefit should be considered. • Personal protective equipment (PPE) should be made available for clients • Virtual group activity to educate and support clients with substance misuse. • COVID-19 education should be provided.
Fiscal Year 2023 Ranking	Service Category	Special Instructions
3	Non-Medical Case Management	• Collaborate with non-Ryan White key points of entry anywhere a client may present for HIV care to provide information on Ryan White Case Management services. • Provide educational materials and activities to promote self-empowerment and reduce fear and denial to facilitate entry into primary medical care. • Provide information about the benefits and security of the Take Charge Texas (TCT) system to promote client sharing. • Collaborate with and refer clients to prevention case managers or reduction specialists to encourage a reduction in practices that may make an individual susceptible to HIV. • Educate clients on the importance of remaining in primary medical care.

		• Provide information in English and Spanish about the availability of local drug reimbursement programs. • Target outreach to African American, Hispanic, and other vulnerable populations to increase utilization of insurance assistance programs. • Increase the number of bilingual non-medical case managers as funding allows. • Educate consumers on their role in the case management process to encourage self-efficacy. • Provide information and referrals to gender-segregated programs (if any) appropriate to the client's self-affirmed gender identity and sense of safety. • Ensure that intake data for transgender clients is sufficient to fully use the transgender-related categories available in Take Charge Texas (TCT). • Incorporate prevention messages into the medical care of PLWH. • PPE should be available for all clients visiting the facility • Ensure there is a workforce that is sensitive to transgender clients • Education about COVID-19 • Offer telehealth and telemedicine whenever possible.
11	Child Care Services	• Evaluate options for providing childcare at medical clinics or other appointments, not including work, to

		encourage clients (especially women) to attend medical appointments. • Offer telehealth and telemedicine whenever possible. • COVID-19 education should be provided. • Personal protective equipment (PPE) should be made available for clients.
2	Housing (Congregate)	• Provide information about the importance of remaining in primary care while addressing housing needs and provide information on available primary medical care services. • Placement in/or assignment to gender-segregated programs (if any) shall be based on the client's self-affirmed gender identity and consider a client's sense of where they will be safest and benefit most. • Care plans and advocacy to remove barriers to service should consider a client's self-affirmed gender identity and sense of safety where appropriate. • COVID-19 education should be provided. • Personal protective equipment (PPE) should be made available for clients • Offer telehealth and telemedicine whenever possible. • Adhere to CDC social distancing guidelines. • Protocol for screening, testing, and quarantining individuals who test positive for COVID-19 and any other

		airborne pathogens as identified by CDC. • Create a wellness station near entrances and lobbies with masks and hand sanitizer.
1	Food Bank	• Provide quality and comprehensive food pantry services in both rural and urban areas. • Provide information about available primary care services. • Provide special non-perishable food items to be taken with medication specifically for the chronically homeless population. • If possible, provide food delivery services. • Create a plan or system to ensure clients at home receive food. • Meet with food banks and service providers and establish an MOU. • Maintain CDC guidelines for social distancing.
3	Case Management (Housing-based)	• Collaborate with non-Ryan White key points of entry anywhere a client may present for HIV care to provide information on Ryan White Case Management services. • Provide referrals to non-Ryan White community resources when appropriate. • Provide educational materials and activities to promote self-empowerment and reduce fear and denial to facilitate entry into primary medical care.

		• Provide information about the benefits and security of the Take Charge Texas (TCT) system to promote client sharing. • Collaborate with and refer clients to prevention case managers or reduction specialists to encourage a reduction in practices that may make an individual susceptible to HIV. • Collaborate with homeless shelters to link out-of-care PLWH to housing services. • Placement in/or assignment to gender-segregated programs (if any) shall be based on the client's self-affirmed gender identity and consider a client's sense of where they will be safest and benefit most. • Care plans and advocacy to remove barriers to service should consider a client's self-affirmed gender identity and sense of safety where appropriate. • COVID-19 education should be provided. • Personal protective equipment (PPE) should be made available for clients • Maintain CDC guidelines for social distancing • Protocol for screening, testing, and quarantining individuals who test positive for COVID-19 and any other airborne pathogens as identified by CDC.
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		• Create a wellness station near entrances and lobbies with masks and hand sanitizer.
4	Medical Transportation	• Identify additional options for those living in suburban and rural areas with limited public transportation. • Identify and exhaust all other transportation options, including paratransit. • Personal protective equipment (PPE) should be made available for clients • Maintain CDC guidelines for social distancing
6	Outreach Services	• Track the barriers to care that caused clients to cease accessing medical care and provide an annual report to the Ryan White Planning Council. Each client contacted must be asked why they dropped out of care and whether they reconnected to care. Each answer should be recorded.

No special instructions exist for the following service categories:

- **Core Medical Services**
 - Early Intervention Services
 - Home and Community-based Health Services
 - Home Health Care
 - Hospice Services
 - Medical Nutrition Therapy
 - State AIDS Drug Assistance Program
- **Support Services**
 - Health Education/Risk Reduction

- Home Delivered Meals
- Linguistic Service
- Other Professional Services (Legal Services)
- Outreach – Street
- Referral for Health Care and Support Services
- Respite Care for Adults
- Respite Care for Children/Youth/Adolescents

ZIP CODES WITH HIGH RATES OF INCIDENCE

Zone 1: East Dallas, Mesquite/Garland, Vickery	
Geographic Location	Zip Code
East Dallas	75204
East Dallas	75206
East Dallas	75214
East Dallas	75218
East Dallas	75223
East Dallas	75226
East Dallas	75228
East Dallas	75246
Mesquite/Garland	75040
Mesquite/Garland	75041
Mesquite/Garland	75042
Mesquite/Garland	75043
Mesquite/Garland	75044
Mesquite/Garland	75048
Mesquite/Garland	75088
Mesquite/Garland	75150
Mesquite/Garland	75182
Vickery	75231
Vickery	75238
Vickery	75243

Zone 2: Grand Prairie, Irving, West Dallas, Northern Corridor	
Geographic Location	Zip Code
Grand Prairie	75050
Grand Prairie	75051
Grand Prairie	75052
Grand Prairie	75053
Grand Prairie	75102
Irving	75001
Irving	75006
Irving	75015
Irving	75019
Irving	75038
Irving	75039
Irving	75060
Irving	75061
Irving	75062
Irving	75063
Irving	75234
Irving	75261
West Dallas	75212
Northern Corridor	75080
Northern Corridor	75081
Northern Corridor	75205
Northern Corridor	75225
Northern Corridor	75230
Northern Corridor	75240
Northern Corridor	75244
Northern Corridor	75248
Northern Corridor	75251

Zone 4: South East Dallas, South Dallas	
Geographic Location	Zip Code
Southeast Dallas	75141
Southeast Dallas	75149
Southeast Dallas	75159
Southeast Dallas	75172
Southeast Dallas	75180
Southeast Dallas	75181
Southeast Dallas	75217
Southeast Dallas	75227
Southeast Dallas	75253
South Dallas	75210
South Dallas	75215

Zone 5: Stemmons Corridor	
Geographic Location	Zip Code
Stemmons Corridor	75201
Stemmons Corridor	75202
Stemmons Corridor	75207
Stemmons Corridor	75209
Stemmons Corridor	75219
Stemmons Corridor	75220
Stemmons Corridor	75229
Stemmons Corridor	75235
Stemmons Corridor	75247

APPENDIX B: UNITS OF SERVICE AND BILLING LIMITATIONS

Service Category	Units of Service	Billing Limitation
AIDS Pharmaceutical Assistance	One (1) prescription	- Generic medications should be used when available; - Prescriptions issued for cosmetic purposes, non-medically necessary purposes, and over-the-counter medications are not reimbursable; - Only one month of medications may be filled at a time; - Erectile dysfunction and human growth hormone prescriptions are not reimbursable, and - Medications must be on the approved Local Pharmaceutical Assistance Program (LPAP) formulary to be eligible for reimbursement.
Case Management (Non-Medical)	- One (1) fifteen (15) minute face-to-face/other encounter - One (1) virtual visit - One (1) telehealth/telemedicine visit/consultation	- Units billed must be based on documented time spent delivering the service; - Generic newsletters, invitations, etc., sent to clients may not be billed, and - Messages left for clients or on behalf of a client may not be billed.
Case Management (Non-Medical – Housing)	- One (1) fifteen (15) minute face-to-face/other encounter - One (1) virtual visit - One (1) telehealth/telemedicine visit/consultation	- Units billed must be based on documented time spent delivering the service; - Administrative activities may not be billed as units of service;

		- Generic newsletters, invitations, etc., sent to clients may not be billed, and - Messages left for clients or on behalf of a client may not be billed.
Child Care Services	One (1) hour of childcare	None
Early Intervention Services	- One (1) medical visit - One (1) fifteen (15) minute counseling and referral contact	None
Emergency Financial Assistance	One (1) payment or voucher	\$800/year/client cap
Food Bank	One (1) visit for up to a seven (7) day supply of food	None
Health Education/ Risk Reduction	- One (1) fifteen (15) minute individual intervention - One (1) fifteen (15) minute group- level intervention	None
Health Insurance Premium and Cost Sharing Assistance	One (1) monthly payment	Payment(s) for monthly premiums, related copays, and deductibles shall not exceed nine hundred dollars (\$900.00) as established by the Ryan White Planning Council and AA.
Home and Community-based Health Services	- One (1) visit by non-licensed healthcare workers - Durable medical equipment	- Any service provided to an individual eligible for home health coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available under the plan and, - No units of service will be reimbursed without a physician's order.
Home Health Care	One (1) visit by licensed healthcare workers	Any service provided to an individual eligible for home health coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available

		under the plan and, No units of service will be reimbursed without a physician's order.
Home Delivered Meals	One (1) on-site meal or nutritional supplement	None
Hospice Services	One (1) day of hospice care	None
Housing	One (1) day of housing, not to exceed the monthly lease rate	- Effective March 27, 2008, there is a 24-month cumulative period of eligibility per household for housing services (<i>HRSA HAB Policy 99-02</i>). - Transitional housing assistance is based on need and available resources and is limited to no more than (6) continuous months of funding within a contract year. Emergency housing assistance is limited to one (1) month of rental/utility assistance within a contract year.
Other Professional Services (Legal Services)	One (1) fifteen (15) minute period of consultation or legal advocacy by an attorney or a paraprofessional	None
Linguistic Services	- One (1) fifteen (15) minute increment of interpretation or sign language - One (1) document	- Units billed must be based on documented time spent delivering the service and, - Interpretation or translation provided for another agency or a group will be reimbursed for the time spent interpreting or translating, not the number of clients receiving the interpretation.
Medical Case Management	- One (1) fifteen (15) minute face-to-face/other encounter - One (1) virtual visit - One (1) telehealth/telemedicine visit/consultation	Units billed must be based on documented time spent delivering the service;

		• Generic newsletters, invitations, etc., sent to clients may not be billed, and • Messages left for clients or on behalf of a client may not be billed.
Medical Nutrition Therapy	• One (1) visit	• No more than one (1) visit per client per day may be reimbursed; • Any service provided to an individual eligible for medical care coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available under the plan.
Medical Transportation Services	• One (1) van trip per one-way • One (1) bus pass/token • One (1) taxi/ride-share voucher • One (1) gas voucher • One (1) delivery of medications (regardless of the number of medications to be delivered in a single delivery) per one-way	• Pick-up and return van trips during which clients or medications are not being transported may not be billed as units of service, and • Only one (1) unit of medication delivery may be billed regardless of the number of medications to be delivered in a single one-way delivery per client.
Mental Health Services	• One (1) individual Level I psychiatric evaluation visit • One (1) individual Level I medication management visit • One (1) Level II individual forty-five (45) minute session • One (1) Level III individual fort-five (45) minute session • One (1) patient participating in a sixty (60) minute Level II group session • One (1) patient participating in a sixty-(60) minute Level III group session • One (1) virtual visit	• Mental health therapy groups may have no more than twelve (12) participants per group; • Individual sessions should be at least 45 minutes in length and will be reimbursed by the session; • Group sessions should be at least 60 minutes in length and will be reimbursed by the session; • No more than four (4) psychiatric evaluation visits per year per client may be reimbursed; • Fractions of a unit may not be billed;

	One (1) telehealth/telemedicine visit/consultation	- Any service provided to an individual eligible for mental health services covered under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available under the plan and, - Inpatient psychiatric or psychological services may not be reimbursed.
Oral Health Care	- One (1) dental prophylaxis - One (1) dental routine visit - One (1) dental specialty visit - One (1) prosthetic device - One (1) virtual visit - One (1) telehealth/telemedicine visit/consultation	\$3,000 per year cap unless a waiver is approved - A maximum of two (2) visits per day per client may be reimbursed. A single visit may include multiple services or procedures, and - Any service provided to an individual eligible for dental health services coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available under the plan.
Outpatient Ambulatory/Health Services	- One (1) visit - One (1) virtual visit - One (1) telehealth/telemedicine visit - One (1) laboratory service - One (1) diagnostic service	- No more than two (2) visits per client per day may be reimbursed; - Outpatient medical services provided over the phone are reimbursable as units of service - Any service provided to an individual eligible for medical care coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has exhausted the benefits available under the plan.

Outreach Services	One (1) documented encounter	None
Outreach - Street	One (1) documented encounter	None
Referral for Health Care and Supportive Services	- One (1) Referral - One (1) fifteen (15) minute, face-to-face/other encounters with a referral worker to assist a client with access to other services the client may be eligible for - One (1) virtual visit - One (1) telehealth/telemedicine visit/ (Address virtual telehealth/telephone visit/consultation)	None
Respite Care for Adults	One (1) hour of respite care to an HIV+ adult (aged 25+ years)	Units billed must be based on documented time spent delivering the service.
State AIDS Drug Assistance Program	Not Applicable—Not for bid	
Substance Abuse Services	- One (1) individual forty-five (45) minute counseling session - One (1) patient participating in a sixty (60) minute group session (not to exceed ten (10) grant-funded patients per group) - One (1) virtual visit - One (1) telehealth/telemedicine visit (address virtual telehealth/telephone visit/consultation)	- Any service billed to DCHHS must be provided at the facility location licensed by the Department of State Health Services to provide that level of treatment; - Individual sessions should be at least 45 minutes in length and will be reimbursed by the session; - Group sessions should be at least 60 minutes in length and will be reimbursed by the session; - Fractions of a unit may not be billed, and - Any service provided to an individual eligible for substance abuse services coverage under another third-party reimbursement plan may not be billed to DCHHS unless the client has

		exhausted the benefits available under the plan.
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Unit(s) of Service vs. Time Billing Table				
Unit(s) of Service	1	2	3	4
Time	1-29 minutes	30-44 minutes	45-59 minutes	60 minutes

APPENDIX C: CLIENT ELIGIBILITY REQUIREMENTS

Services must be available to all eligible clients seeking care in the Dallas EMA/HSDA. All clients will be served regardless of age, sex, race, color, religion, national origin, or sexual orientation, in accordance with the American Disabilities Act (ADA). No eligible client will be refused services.

All clients, both new and already enrolled in care, shall be screened in accordance with [*TDSHS Client Eligibility Policy 220.001*](#). Clients may self-refer to all services supported by funds awarded through the request for proposal (RFP) for Part A, Part B, State Services, and State Rebate of the RWHAP. To the extent feasible, subrecipients will implement consistent, standardized intake and documentation processes that will utilize common forms, minimize the burden on clients, and reduce duplication of data-gathering and reporting on service providers. At a minimum, all subrecipients must comply with the eligibility criteria listed below.

Initial Eligibility and Annual 12-Month Recertification of HIV Status, Texas Residency, and Income

Upon initiation of services, as well as every 12 months, providers must determine whether a respondent meets the following RWHAP Part B/State Services eligibility criteria:

- have a diagnosis of HIV;
- provide documentation of Texas residency and
- provide complete and accurate income documentation.

Recertification of HIV status after initial eligibility determination is not required.

Clients must be screened for program eligibility every six months (no later than the last day of the clients' birth month for the annual 12-month recertification and no later than the last day of the clients' half-birth month for the 6-month self-attestation).

Initial Eligibility Determination Period

A 30-day determination period for all funded services can be accessed by clients who are:

- Newly diagnosed within the previous six months;
- New to the State of Texas/Local EMA/HSDA and in need of medical services;
- Engaging in care for the first time after being diagnosed for longer than six months;
- Returning to medical care after an absence of six months or longer and/or;
- In need of early intervention services.

As applicants are being linked to services, providers should work to complete the eligibility process and collect the required documents. An eligibility determination must be completed within 30 days of program application initiation.

Providers must have an established alternative source of funding should a client be found to be ineligible for Ryan White Part B or state-funded services. This must be documented in agency policy and tracked in

the client file if applicable. The policy must delineate the process for any necessary administrative adjustments if a cost is determined to be unallowable.

Documentation of HIV Status

To be eligible for services paid for by RWHAP and State Services, an individual must have an HIV-positive diagnosis. Affected individuals (people not living with HIV) may be eligible for RWHAP services in limited situations; services for affected individuals must always benefit PLWH. For further clarification on providing services to affected individuals, please refer to [*HRSA Policy Clarification Notice \(PCN\) #16-02, Eligible Individuals and Allowable Uses of Funds*](#). **For EHE services, the only client eligibility requirement is an HIV diagnosis. Services presently funded through EHE include the following:**

- Health Education/ Risk Reduction
- Non-Medical Case Management
- Oral Health
- Outpatient/Ambulatory Health Services
- Outreach Services
- Referral for Healthcare and Support Services

There are many different ways to document HIV infection. Some examples of acceptable forms of documentation are provided below; however, this should not be viewed as a complete list.

Laboratory Documentation

Proof of HIV diagnosis may be found in laboratory test results that bear the client's name. Some examples include:

- A positive result from HIV screening test (HIV 1/2 Combo Ab/Ag enzyme immunoassay [EIA]);
- A positive result from an HIV 1 RNA qualitative virologic test such as an HIV 1 Nucleic Acid Amplification Test (NAAT) or
- Detectable quantity from an HIV 1 RNA quantitative virologic test (e.g., viral load test)

NOTE: HIV testing technology changes rapidly, and standards of HIV confirmation continue to evolve. Providers must stay informed of advances in testing technology as newer tests may also provide proof of HIV diagnosis.

Other Forms of Documentation

Some examples include:

- A signed statement from an entity with prescriptive authority attesting to the HIV-positive status of the person or,
- A complete THMP Medical Certification Form signed by a physician (required by THMP) or,
- A hospital discharge summary documenting the individual is HIV-positive.

NOTE: Exposed infants born to people living with HIV can be served with documentation of the mother's HIV-positive status up to 12 months of age. Children older than 12 months must meet the same criteria for proof of HIV as listed above to continue services.

Facilitating Linkage with an HIV Preliminary Positive Result

A preliminary positive is a positive result from an HIV screening test. Although a preliminary positive is not considered proof of HIV status (because it is not a supplemental test in the current HIV testing algorithm), individuals with such a result are very likely to have HIV infection and would benefit from quick linkage to ongoing medical care. Having only a preliminary positive result from one HIV test should not be a barrier in linkage to medical care.

The ability to rely upon a preliminary positive test result to facilitate linkage to care does not negate the responsibility of the HIV testing site to conduct supplemental testing. The receiving medical provider must be informed of the individual's unconfirmed preliminary positive HIV test result. Once the supplemental results are received from the lab, HIV testing staff must provide these results to the individual and, if a Release of Information is signed, to the HIV care provider. Clinics receiving such individuals may choose to arrange an abbreviated first appointment, during which the individual could receive counseling on HIV infection, orientation to medical care, conduct eligibility screening, and/or begin laboratory work.

NOTE: HIV medical providers may elect to conduct the HIV supplemental test if a memorandum of understanding (MOU) is signed with the HIV testing agency.

Documentation of Texas Residency

To be eligible for services paid for by RWHAP Part B/State Services/THMP, an applicant must reside within the geographic boundaries of Texas and express intent to remain within the state and not claim residency in any other state or country. Texas residency is not a requirement for services exclusively funded by RWHAP Part A. Consult with the DCHHS Ryan White Grants Management Division for more information.

Individuals do not lose their Texas residency status because of a temporary absence from the state. For example, a migrant or seasonal worker may leave the state during certain periods of the year but maintain a home in Texas and return to that home after this temporary absence. This individual will not lose their Texas residency status.

Students

Students from another state living in Texas who are going to attend school may claim Texas residency based on their student status while residing in Texas.

Acceptable proof of residency documents must include the applicant's full legal name and residential address and be unexpired or from the last 30 days.

Documentation of proof of Texas residency can be determined using one of the following:

- valid (unexpired) Texas Driver's License;
- Texas State identification card (including identification from criminal justice systems);

- recent Social Security, Medicaid/Medicare, or Food Stamp/TANF benefit award letters;
- IRS Tax Return Transcript, Verification of Non-Filing, W2, or 1099;
- current employment records (pay stub);
- post office records;
- official state mail;
- current voter registration;
- rent or utility receipts for one month before the month of application in the client's name;
- a mortgage or official rental lease agreement in the client's name;
- valid (unexpired) motor vehicle registration;
- proof of current college enrollment or financial aid;
- property tax receipt;
- a letter of identification and verification of residency from a verifiable homeless shelter or community center serving homeless individuals or,
- a statement/attestation (does not require notarization) with the client's signature declaring that the client has no resources for housing or shelter. For THMP, a letter from an agency worker attesting that the individual has no resources for housing or shelter will be accepted.

If none of the items listed above are available, Texas residency may be verified through:

- Credit card, phone, or cable bill with the client's address clearly indicated on the document; or
- Bank brokerage statement with address clearly indicated on the document; or
- statement from landlord/neighbor/another reliable source; or
- submission of the DSHS-THMP Supporter Statement. This is only accepted when no other proof of residency is available and must be accompanied by a signed statement on agency letterhead from the agency enrollment worker detailing steps that were taken to obtain proof of residency and why they were not successful; or
- observance of personal effects and living arrangement (e.g., visit to the residence). For THMP, a signed statement on agency letterhead detailing this observance and why other forms of proof of residency were not available will be accepted.

There are no further proof of residency requirements (e.g., the requirement for a photo ID or documentation of immigration status) other than those listed above. Subrecipients and providers may not impose more stringent proof of residency requirements regarding eligibility for RWHAP and State HIV-funded services than those listed. Subrecipients must document that all eligibility staff have been made aware of this policy no less frequently than annually. Subrecipients should contact the DCHHS Ryan White Grants Management Division for questions about acceptable documentation of Texas residency.

Documentation of Income

To be eligible for services paid for by RWHAP Part A, MAI, Part B, and State Services, including State Rebate, an applicant must submit proof of income and FPL. Subrecipients must use the DSHS-provided [Income Calculation Worksheet](#) to calculate an applicant's income. Consult the DSHS policy for detailed instructions.

Local Criteria for Eligibility Determination

Dallas RWPC determines the financial eligibility for each prioritized service category. This limit may not exceed 500% of the FPL. Periodically, the Dallas RWPC may alter financial eligibility limits. The financial eligibility for FY 2025-2026 services is listed in Appendix E. Subrecipients should contact the DCHHS Ryan White Grants Management Division for questions regarding financial eligibility limits.

APPENDIX D: DOCUMENTATION REQUIREMENTS

For agencies receiving funding awards, documentation requirements for all service categories must be completed before submission for a reimbursement request. Documentation should occur after each contact, resulting in a reimbursable unit of service. Documentation should include the following elements for all service categories unless noted below:

- I. WHO RECEIVED:** Who received the service? The client's name or identifying number should be on all backup documentation. Not required for Outreach-Street.
- II. WHO PROVIDED:** Who provided the service? For every unit of service for which reimbursement is requested, someone at the agency level had to interface with the client – the backup documentation for every encounter should include their name, signature, and credentials, if appropriate. Not required for Insurance Assistance and Drug Reimbursement.
- III. WHAT:** What service was provided? All documentation should indicate the service provided: medical case management, transportation, food pantry, etc.
- IV. WHEN:** Date and time of service provided; the duration of time on that date or start and stop times.
- V. HOW MUCH:** How many units of the service were provided? Each unit of service billed to DCHHS should match the number of units documented. This documentation of units should follow the guidelines in the Dallas Planning Area Standards of Care and Service Delivery Guidelines for each service category.
- VI. WHERE:** Where was the service provided? Specify the location: clinic, street corner, client's home, van, health fair, etc. This is not required for Health Insurance and Premium Cost Sharing Assistance and Drug Reimbursement.
- VII. WHY:** What was the purpose or intent of the service encounter? Documentation should always reflect the client's needs and address the goals or objectives identified in the care plan. This is not required for Outreach-Street.
- VIII. STATUS:** Progress or lack of progress in achieving goals outlined in the care plan. This is not required for Health Insurance and Premium Cost Sharing Assistance, Drug Reimbursement, Outreach-Street, and Interpretation/ Translation.

To be an allowable cost under the HRSA RWHAP and DSHS, all services must:

- Relate to HIV diagnosis, care, and support,
- Adhere to established HIV clinical practice standards consistent with the U.S. Department of Health and Human Services Clinical Guidelines for the Treatment of HIV and other related or pertinent clinical guidelines, and
- Comply with state and local regulations provided by licensed or authorized providers, as applicable.

Agencies may develop documentation formats to meet their needs while incorporating these required elements. Sample documentation forms for each service category may be obtained from a DCHHS program monitor.

APPENDIX E: FINANCIAL ELIGIBILITY FOR THE DALLAS PLANNING AREA BASED ON FEDERAL POVERTY GUIDELINES

Background: Planning Councils can identify categorically specific activities that address “how best to meet the need.” Specific components or interventions can be modified for and within categories, populations, and geographic focus areas to enhance HIV programming and service delivery within the Dallas EMA.

Rationale: Increase financial eligibility percentages for the FY 2020 Dallas EMA/HSDA for the Outpatient Ambulatory/Health Services, Medical Case Management, AIDS Pharmaceutical Assistance, Health Insurance Premium and Cost Sharing Assistance, and Non-Medical Case Management service categories for Ryan White Part A, B, and State Services based on federal poverty guidelines.

Justification: Due to the increased cost of insurance plans, HIV medications, and outpatient medical care visits, the Planning and Priorities Committee proposes an increase in financial eligibility percentages in core medical & support service categories based on federal poverty guidelines to assess the impact on service utilization, linkage to care, treatment retention, and viral suppression. Additional provisions include an analysis to track/document the number of individuals who qualified or were denied services at 300-400% & 400-500% intervals.

Recommendation: The Planning and Priorities Committee recommends increasing the financial eligibility percentages for FY 2020 Dallas EMA/HSDA for the Outpatient Ambulatory/Health Services, Medical Case Management, AIDS Pharmaceutical Assistance, Health Insurance Premium and Cost Sharing Assistance, and Non-Medical Case Management service categories based on the federal poverty guidelines (subject to HRSA guidance).

Statement of Conflict: All RWPC members employed by RWHAP-funded service providers are conflicted.

Financial Eligibility for the Dallas Planning Area Based on Federal Poverty Guidelines						
Service Category	Funding Source	Percentages for FY 2018	Percentages Proposed for FY 2019	Percentages Approved for FY 2019	Percentages Proposed for FY 2020	Percentages Approved for FY 2023
CORE MEDICAL SERVICES						
Outpatient Ambulatory/Health Services	Part A, B, State Services	300%	400%	400%	500%	500%
Oral Health Care	Part A, B	300%		300%	300%	400%
Mental Health Services	Part A, State Services	300%		300%	400%	500%
Medical Case Management	Part A, B, State Services	300%	400%	400%	500%	500%
AIDS Pharmaceutical Assistance	Part A, B, State Services	300%	500%	500%	500%	500%
Substance Abuse Services	Part A	300%		300%	300%	500%
Health Insurance Premium and Cost-sharing Assistance	Part A, B	300% ACA Plans: must have a subsidy	400%	400%	400%	400%
Early Intervention Services	Part A	300%	Not Funded	Not Funded		Not Funded
Home and Community-based Health Services		Not Funded		Not Funded		Not Funded
Home Health Care		Not Funded		Not Funded		Not Funded
Medical Nutrition Therapy		Not Funded		Not Funded		400%
Hospice Services		Not Funded		Not Funded		Not Funded

Financial Eligibility for the Dallas Planning Area Based on Federal Poverty Guidelines						
Service Category	Funding Source	Percentages for FY 2018	Percentages Proposed for FY 2019	Percentages Approved for FY 2019	Percentages Proposed for FY 2020	Percentages Approved for FY 2023
SUPPORT SERVICES						
Food Bank	Part A, B, State Services	300%		300%	300%	400%
Case Management (Non-Medical)	Part A, B, State Services	300%		300%	500%	500%
Medical Transportation	Part A, B, State Services	300%		300%	300%	400%
Case Management (Non-Medical - Housing-Based)	Part A, B, State Services	300%		300%	300%	400%
Emergency Financial Assistance	Part A, B, State Services	300%		300%	400%	400%
Outreach Services	Part A, B	300%		300%	300%	400%
Housing	State Services	10% of Gross Income; 30% of Adjusted Income				400%
Other Professional Services (Legal Services)	Part A, B, State Services	300%		300%	300%	400%
Home Delivered Meals	Part A, B, State Services	300%		300%	300%	400%
Health Education/ Risk Reduction	State Services	300%		300%	300%	400%
Respite Care for Adults/ Youth/ Children/Adolescents	Part A, B, State Services	300%		300%	300%	400%
Child Care Services	Part A, State Services	300%		300%	300%	Not funded
Linguistic Services	Part A	300%		300%	300%	400%
Referral for Health Care and Support Services	Part B, State Services				500%	500%

The Ryan White Legislation prohibits imposing the first-party charge on individuals whose income is at or below 100% of the Federal Poverty Level (FPL). Costs to clients with incomes higher than 100% of the FPL are based on a discounted fee schedule and sliding fee scale. **For services rendered using Ending the HIV Epidemic (EHE) funding, the FPL is non-applicable.**

Individual Income	Maximum Charge
At or below 100% of FPL	\$0
101% to 200% of FPL	No more than 5% of gross annual income
201% to 300% of FPL	No more than 7% of gross annual income
Over 300% of FPL	No more than 10% of gross annual income

Ryan White Services should not be denied due to a client's inability to pay.

APPENDIX F: HIV/STD PROGRAM POLICY 530.002: SECTION EXPECTATIONS AND PROVIDER RIGHTS REGARDING THE DELIVERY OF CLIENT SERVICE

1.0 Purpose

This policy clarifies the rights of a Contractor/Subcontractor (Provider) in responding to unacceptable client behavior while providing HIV/STD prevention, treatment, and social services under a contract with the Texas Department of State Health Services (DSHS), TB/HIV/STD Section (Section). Providers reviewing this policy should be able to identify unacceptable client behavior and respond accordingly with reasonable confidence that the actions taken on behalf of the provider agency regarding a client were appropriate. The policy will also outline what the Section expects from the Provider in delivering client services.

2.0 Background

One part of the Section's mission is to provide a wide array of services to persons with HIV. That mission is achieved through contracts with various Providers who deliver those services. The Section is responsible for ensuring that Providers understand their rights when addressing client behaviors that may be questionable or disruptive. The Provider will, therefore, be able to ensure that services are offered in a manner free from disruption. In addition, the Section also has certain expectations of how those services are to be delivered to clients and how client rights are to be respected.

3.0 Authority

Civil Rights Code, Title 42, Chapter 21; Rehabilitation Act of 1973, Sect. 794; Age Discrimination Act of 1974; Public Law 88-352; Title VI, and Part 80 of 45 CFR; 25 TAC §§98.41-98.44.

4.0 Definitions as Applied to this Policy

Contractor - a legal entity under contract with DSHS to provide goods or services to people infected or affected by HIV, AIDS, or STDs or to implement goals supporting the Section's mission.

Provider - a person, agency, or facility approved by the DSHS that has entered into a contract with DSHS or with a DSHS contractor to deliver state or federal HIV/STD programs to clients.

Services - program activities offered by a Provider on behalf of the Section for prevention, health, medical, and social services.

5.0 Section Expectations Regarding the Provider/Client Relationship

The Section expects the Provider to maintain client relations of the highest possible quality.

5.1 General Section Expectations

1. Treat each client with respect, consideration, and recognition of the client's dignity and individuality.
2. Communicate the need for treatment, care, or services in a culturally sensitive and equitable manner.
3. Allow the client to select comprehensive outpatient health and psychosocial support services or to refuse any service without fear of reprisal.
4. Inform the client about treatment or service options, emphasize that it is the client's right to choose, and advise them of alternatives when multiple providers are available for the same service.
5. Assure that service planning, medical treatment, and counseling plans are determined in cooperation with the client.
6. Maintain a climate in the office or other service delivery setting free of physical or mental abuse or exploitation.
7. Enforce local, state, or federal laws or regulations (such as no smoking or maintaining a drug-free environment) required to conduct business.
8. Review any decision to modify, suspend, or terminate services.
9. Re-evaluate any modification, suspension, or termination to determine if the client's situation has changed.
10. Give clients an avenue to formally complain about treatment or services and the Provider's decision to deny an application, modify, suspend, or terminate client benefits, a mechanism to receive an appropriate and fair review of the complaint, and ensure that there is no reprisal of any type against the client for filing the complaint or grievance.

5.2 Confidentiality

The Provider is required to maintain the confidentiality of all information according to state and federal laws. The right to confidentiality begins when the client applies for services, when the Provider first conducts an evaluation, or when counseling begins.

5.3 Equal Access to Programs and Services

The Provider is required to consider client eligibility regardless of age, gender, sexual orientation, gender expression/identity, marital status, ethnic origin, physical challenge, or religious practice. Conversely, the client has a right to refuse any recommended services.

5.4 Impartial Treatment

Providers must allow the client to apply for any service or program. The client must be given fair, impartial treatment in receiving and processing the application and receiving services.

5.5 Filing a Complaint or Grievance

Contractors are required to have a written client complaint procedure in place to meet the minimum requirements for client complaints.

All clients have a right to file a complaint or grievance regarding inappropriate Provider behavior, actions, or perceptions of discrimination. The complaint may be filed in accordance with the grievance procedures of the Provider or with the local organization responsible for monitoring the Provider. When all other sources have been exhausted, the client may file the complaint or grievance with the Section by calling 1-512-533-3000.

In the case of a complaint related to the delivery of clinical services, the client may file a complaint directly to the Section without filing a complaint locally if the client chooses. The Section will investigate all complaints in accordance with HIV/STD Policy 020.050, "Public Complaints and Allegations Related to the Delivery of HIV or STD Programs."

6.0 General Provider Rights When Dealing with a Client

Each Provider should develop written procedures to deal with clients who may be disruptive or uncooperative. The Provider's responsibility is to ensure that staff is well informed about the procedures and use them consistently in every situation. Providers are expected to use good judgment and attempt to resolve these situations fairly without undue limitation or denial of client services.

7.0 Modifying, Suspending, or Terminating Client Services

The Provider is responsible for providing a work environment free from undue disruption, turmoil, or interference. Whenever possible, the Provider should take steps to serve clients and support a healthy work environment.

During the course of serving clients, clients may behave in a disruptive, abusive, or threatening manner toward staff or other clients. When this type of behavior occurs, the Provider may take the following progressive action:

1. Modify all or part of the services provided to the client
2. Suspend all or part of the services provided to the client
3. Terminate all or a portion of the services provided to the client

Depending on the severity of the client's behavior, such as threatening the life of staff or other clients, the Provider may skip one or more of the above steps and take appropriate action. Refer to [HIV/STD Policy No. 530.003](#) for information on dealing with clients who threaten to harm themselves or others.

7.1 Modifying Client Services

The Provider may modify all or part of the services provided to the client when the client is disruptive or uncooperative. Modification may include, but is not limited to:

1. rescheduling the client's appointment for a time later that day or in the near future,

2. arranging client services by telephone and
3. mailing food vouchers, bus passes, etc.

7.2 Suspending Client Services

Suspension is the temporary withdrawal of a service or services provided to a client by a Provider. It may be necessary for the Provider to suspend all or part of the services provided to the client for a specific period when alternative service delivery methods have not produced appropriate client behavior (i.e., the client is repeatedly disruptive or abusive towards staff or other clients).

7.3 Terminating Client Services

The Provider may choose to terminate all or part of the services provided to the client when alternative services delivery methods are not appropriate to the situation (i.e., the client threatens injury or homicide to a staff member or another client, etc.) or when modification or suspension of services has not produced appropriate client behavior.

Clinical service providers (e.g., physicians, advanced practitioners, and registered nurses) who terminate services should follow professional practice standards concerning how client services are terminated. Professional organizations and licensing bodies can guide clinical service providers in managing these situations.

7.4 Denying, Suspending, or Terminating a Client's Service on the Basis of Substance Abuse

The Provider may not deny, suspend, or terminate any service funded through DSHS because the client is **suspected** of substance abuse or refuses to accept treatment for substance abuse.

Exceptions to this may occur in the course of delivering medical care when a client's active substance abuse contraindicates the prescription of certain medications or treatments.

The treating clinician must evaluate these professional decisions on a case-by-case basis.

7.5 Notification of the Decision to Modify, Suspend, or Terminate Client Services

The decision to modify, suspend, or terminate services must be communicated to the client promptly and appropriately. This may be done by any verifiable method, such as in person or certified letter. When services are to be modified or suspended, staff should establish and communicate a specific period for the suspension and inform the client that the resumption of services will depend on the client's willingness and ability to meet certain behavior expectations. The behavior expectations should be clearly outlined and communicated to the client. The client should be given information about alternative methods by which services will be delivered or where such assistance may be obtained.

7.6 Documentation

The Provider should ensure that all modification, suspension, and termination actions are clearly documented in the client's record.

7.7 Technical Assistance

When desired, the Provider may contact the Section to discuss specific situations or to obtain technical assistance. **Decisions regarding modifying, suspending, or terminating client services remain with the Provider.**

7.8 Section Review of Decisions to Modify, Suspend, or Terminate Client Services

As part of a routine review of the quality of client services or a complaint investigation, Section staff may review the events that led to a modification, suspension, or termination of client services. Section staff will evaluate, at minimum, whether the Provider:

1. followed their internal policies and those of the Section in taking action to resolve the situation;
2. respected client rights, and
3. applied the least restrictive limitation on client services necessary to maintain a service delivery setting free of physical and mental abuse or exploitation.

APPENDIX G: HIV/STD PROGRAM POLICY 530.003: HOW TO DEAL WITH CLIENTS WHO THREATEN TO HARM THEMSELVES OR OTHERS

1.0 Purpose

To provide guidance to Contractors/Subcontractors (Providers) in responding to a client's violent or threatening behavior or when a client threatens suicide or exhibits suicidal behavior while providing HIV/STD prevention, clinical treatment, and social services under a contract with the Texas Department of State Health Services (DSHS), TB/HIV/STD Section (Section).

2.0 Authority

Vernon's Texas Code Annotated (VTCA) Health and Safety Code 611.002, Confidentiality of Information and Prohibition Against Disclosure; Health and Safety Code 611.004, Authorized Disclosure of Confidential Information Other than in Judicial or Administrative Proceeding; Health and Safety Code 81.046, Confidentiality; Health and Safety Code 81.103, Confidentiality, Criminal Penalty; Texas Administrative Code, Title 25, 98.44, Denial of Application; Modification, Suspension, or Termination of Client Benefits; Criteria; HIV/STD Policy No. 530.002, Section Expectations and Provider Rights Regarding the Delivery of Client Services.

3.0 Definition as Used in this Policy

Professional - a person licensed or certified by the state or an employee of a facility licensed, certified, or operated by the state.

Provider - a person, agency, or facility approved by the DSHS that has entered into a contract with DSHS or with a DSHS contractor to deliver state or federal HIV/STD programs to clients.

4.0 Provider Rights When Dealing With a Client

Providers should develop written procedures to deal with clients who are violent or exhibit threatening behavior. Providers are expected to use good judgment and attempt to resolve these situations fairly without denying services whenever possible as long as the work environment can remain free from violence or threats (See [HIV/STD Policy No. 530.002](#), Section Expectations and Provider Rights Regarding the Delivery of Client Service).

4.1 Responding to Clients Who Display Violent or Threatening Behavior

When responding to clients who display violent or threatening behavior, staff should take the following actions as appropriate to the situation:

1. Remain calm and speak in a calming voice.

2. If possible, summon a qualified mental health professional for assistance or make a referral.
3. Reschedule the client's appointment for a time later that day or in the near future.
4. When warranted, use alternative service delivery methods, such as telephone for case management, mailing food vouchers, or bus passes.
5. Notify the director of the contracting agency regarding serious client behavior problems for additional appropriate action.
6. Take whatever action is legally available to ensure the work environment is free from violence or threats.
7. Call the proper authorities when a client threatens staff or other clients with a weapon or creates a situation in which other clients and staff fear their safety.
8. Follow-up on any referrals or other actions taken to manage the client.
9. Document any action(s) taken in the client's case file.

4.2 Responding To Clients Who Make Homicidal Threats or Exhibit Homicidal Behavior

A client who makes homicidal threats or exhibits homicidal behavior should be taken seriously. Staff should attempt to take the following actions as appropriate to the situation:

1. Remain calm and leave the area, if possible.
2. Alert another staff member, preferably a supervisor, to the situation (this person should call the police immediately).
3. Try to calm the threatening individual (do not argue or talk back).
4. If possible, summon a qualified mental health professional for assistance or make a referral.
5. Notify the director of the contracting agency regarding serious client behavior problems for additional appropriate action.
6. Call the proper authorities when a client threatens staff or other clients with a weapon or creates a situation in which other clients and staff fear their safety.
7. Follow-up on any referrals or other actions taken to manage the client.
8. Document any action(s) taken in the client's file.

4.3 Responding to Clients Who Threaten Suicide or Exhibit Suicidal Behavior

A client who threatens suicide or exhibits suicidal behavior shall be taken seriously. Staff should carefully question clients to determine the seriousness of the threat before taking any action. Unqualified staff should

not attempt to diagnose clients' mental health status beyond identifying a potential suicidal situation. The following questions may be used to obtain more information from the client:

1. Ask the client what is meant by the threat.
2. Ask the client if they have ever attempted suicide before.
3. Ask the client if there is a history of suicide in the client's family or if someone close to the client has ever committed suicide.
4. Try to find out if the client has a plan and a means to commit suicide.

Any staff member confronted with a suicidal threat should take the following actions as appropriate to the situation:

1. Attempt to detain the client until the extent of the client's need for further help can be determined and the appropriate referral made or action taken.
2. Attempt to persuade the client to talk with a mental health professional or, if they already have one, assist the client in contacting their mental health professional.
3. Contact a family member or friend of the client, if the client is willing, and discuss a protection/safety plan.
4. Complete a "No Harm Agreement" (see attached example) that will cover the period from the current occurrence until the client's next contact with a case manager or mental health provider (the client should keep a copy, and a copy should be placed in the client's chart)
5. If none of the above, the staff member should contact the appropriate mental health center and refer the client (the most likely contact will be the Mental Health and Mental Retardation provider in the local county).
6. Give the client written instructions on contacting their local crisis hotline and hospital emergency room.
7. If unsuccessful with the above, call 911 and request a mental health officer.
8. Notify the director of the contracting agency regarding serious client behavior problems for additional appropriate action.
9. Follow-up on any referrals or other actions taken to manage the client.
10. Document any action taken on behalf of the client in the client's case file.

5.0 Obligation to Report

Communications between a patient and a professional and records of a patient's identity, diagnosis, evaluation, or treatment created or maintained by a professional are confidential (Health and Safety Code §611.002). However, a professional **may** disclose confidential information to medical or law enforcement

personnel if the professional determines that imminent physical injury is probable by the patient, to the patient, or others, or immediate mental or emotional harm is possible to the patient (Health and Safety Code §611.004).

6.0 Where to Go for Help

When desired, the Provider may contact the TB/HIV/STD Section to discuss specific situations or to obtain technical assistance. Decisions regarding whether to continue, modify, suspend, or terminate client services remain with the Provider. (See "[*HIV/STD Policy No. 530.002, Section Expectations and Provider Rights Regarding the Delivery of Client Service*](#)" for more information.)

For an online directory of suicide hotlines, go to www.suicide.org/hotlines/texas-suicide-hotlines.html or call the National Hope Line Network at **1-800-SUICIDE (1-800-784-2433)**.

INNOVATIVE STRATEGIES

EXHIBIT J

GUIDE FOR **HIV/AIDS** Clinical Care

U.S. Department of Health and Human Services

Health Resources and Services Administration

HIV/AIDS Bureau

April 2014



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Editor: Susa Coffey, MD

Contributing Authors

- **Bruce D. Agins, MD, MPH;**
AIDS Institute/New York State Department of Health
- **Oliver Bacon, MD;** *University of California San Francisco*
- **Kirsten Balano, PharmD;** *San Francisco AETC; University of California San Francisco*
- **Julie Barroso, PhD, ANP, APRN, BC, FAAN;** *Duke University*
- **Robin Bidwell, RNC, BSN, CCRC;** *Christiana Care Health Services*
- **Carolyn K. Burr, EdD, RN;** *AETC National Resource Center; Rutgers University*
- **Diane L. Casdorff, RPh, PharmD, BCPS, AAHIVE**
- **Susa Coffey, MD;** *AETC National Resource Center; University of California San Francisco*
- **Jonathan Allen Cohn, MD, MS, FACP;** *Midwest AETC, Michigan Local Performance Site*
- **Francine Cournos, MD;** *New York/New Jersey AETC*
- **Ross D. Cranston, MD;** *University of Pittsburgh Medical Center*
- **Dena Dillon, PharmD;** *Midwest AETC*
- **Minda Dwyer, ANP-C;** *New York/New Jersey AETC, Upstate Local Performance Site and Regional Resource for Corrections; Albany Medical College*

- **Douglas G. Fish, MD;** *New York/New Jersey AETC, Upstate Local Performance Site and Regional Resource for Corrections; Albany Medical College*
- **Rena K. Fox, MD;** *University of California San Francisco*
- **Rebecca Fry, MSN, APN;** *formerly AETC National Resource Center*
- **Abigail V. Gallucci, BS;** *New York/New Jersey AETC, Upstate Local Performance Site and Regional Resource for Corrections; Albany Medical College*
- **Marshall Glesby, MD, PhD;** *New York/New Jersey AETC, Cornell Clinical Trials Unit*
- **Katherine Grieco, MD;** *University of California San Francisco*
- **Elaine Gross, MS, RN, APNC;** *formerly AETC National Resource Center*
- **Geeta Gupta, MD;** *Pacific AETC*
- **Lois Hall, ARNP, MSN;** *Florida/Caribbean AETC*
- **Bethsheba Johnson, MSN;** *Midwest AETC*
- **Marta Kochanska, MD;** *University of California San Francisco*
- **Jeffery Kwong, MS, MPH, ANP, ACRN;** *formerly Mountain Plains AETC*
- **Annie Luetkemeyer, MD;** *University of California San Francisco*

- **Mary Monastesse, NP;** *Texas/Oklahoma AETC*
- **John Nelson, PhD, CPNP;** *AETC National Resource Center; Rutgers University*
- **Tonia Poteet, PA;** *Southeast AETC*
- **David Reznik, DDS;** *Southeast AETC*
- **Susan Richardson, MN, MPH, FNP-BC;** *Southeast AETC*
- **Barbara Scott, MPH, RD;** *Pacific AETC*
- **Suzan Stringari-Murray, RN, MS, ANP;** *University of California San Francisco*
- **Alfredo Tiu, DO, FACP, FASN;** *University of California San Diego*
- **Milton Wainberg, MD;** *New York/New Jersey AETC*
- **Sarah J. Walker, MS;** *New York/New Jersey AETC, Upstate Local Performance Site and Regional Resource for Corrections; Albany Medical College*
- **Dianne Weyer, RN, MS, CFNP;** *formerly Southeast AETC*
- **Sophie Wong, MD;** *University of California San Francisco; Asian Health Services*

Introduction

HIV/AIDS clinical care has improved dramatically over the decades, given the availability of new medications and a better understanding of how best to use antiretrovirals and deliver primary care to persons living with HIV/AIDS. Positive change on such a massive scale, however, brings with it new demands on clinicians.

Along with innovations in HIV drug therapies, HIV/AIDS care has become more complex than ever before due to increasing comorbidities that are attributable to HIV treatment and the aging of the HIV-infected population in the United States. Patient needs also have expanded across a broad spectrum of medical, psychological, behavioral, and social issues. Notably, significant numbers of infected individuals are identified and enter care late in the course of their HIV disease, confronting clinicians with complex and immediate care challenges.

Since the early days of the epidemic, clinicians have received training in HIV/AIDS clinical care through the AIDS Education and Training Centers (AETCs) Program – the clinical training arm of the Ryan White HIV/AIDS Program that is administered by the Health Resources and Services Administration (HRSA) and its HIV/AIDS Bureau (HAB). The AETC network conducts more than 14,000 training events each year with approximately 143,000 health care providers in attendance.

The *Guide for HIV/AIDS Clinical Care* is a pillar of the Ryan White HIV/AIDS Program's mission to continuously improve HIV/AIDS clinical care. The *Guide* was first published in 1993 as a collaborative effort of several regional AETCs. It was subsequently updated and expanded in 2006 and 2011. The version before you incorporates many new insights, but the time-tested format has been retained – easy access to crucial facts for a busy clinician.

The developers of the *Guide* strive to be responsive to how HIV/AIDS clinical care is provided today.

- With more routine HIV testing in medical settings, a large number of individuals are entering care via primary care sites that have relatively limited experience managing HIV/AIDS disease.
- A notable proportion of HIV/AIDS primary care in the United States is provided by advanced practice nurses and physician assistants.
- Shortages in the health care work force are worsening. Experienced staff members are aging and retiring, a limited number of new clinicians are entering primary care and specializing in HIV/AIDS care, and fewer clinicians are available in geographic areas with limited resources.

As a result, front line primary care providers may be less familiar with management of HIV/AIDS disease, as outlined in U.S. Department of Health and Human Services treatment guidelines (available at aidsinfo.nih.gov) and clinical practices presented in this *Guide*.

By presenting best practices in the clinical management of HIV/AIDS disease, the *Guide* can help us continue the remarkable advances in HIV/AIDS care that have made the Ryan White HIV/AIDS Program a model for health care delivery for our Nation and for the world.

— Laura W. Cheever, MD, ScM
Associate Administrator
HIV/AIDS Bureau
U.S. Department of Health
and Human Services
Health Resources and Services
Administration (HRSA)

Abbreviations for Dosing Terminology

BID = twice daily

BIW = twice weekly

IM = intramuscular (injection), intramuscularly

IV = intravenous (injection), intravenously

PO = oral, orally

Q2H, Q4H, etc. = every 2 hours, every 4 hours, etc.

QAM = every morning

QH = every hour

QHS = every night at bedtime

QID = four times daily

QOD = every other day

QPM = every evening

TID = three times daily

TIW = three times weekly

Important Notice

The U.S. Department of Health and Human Services (HHS) HIV/AIDS Bureau is committed to providing accurate information on the care of HIV-infected persons. It is important to be aware that management options and protocols change over time. Forthcoming HHS guidance on certain topics may differ from recommendations contained in this *Guide*. Readers are encouraged to check for updates to treatment guidelines at AIDS Info (aidsinfo.nih.gov) and for updates to drug information at Drugs@FDA (www.accessdata.fda.gov/scripts/cder/drugsatfda).

Supporting Patients in Care

Robin Bidwell, RNC*

* Based on Sheffield and Casale, see "References."

Background

Patients infected with HIV face a complex array of medical, psychological, and social challenges. A strong provider-patient relationship, the assistance of a multidisciplinary care team, and frequent office visits are key aspects of care. Through both the specific services they provide and their overall approach to patients, clinics can have a substantial impact on the quality of care for HIV-infected persons. For example, a patient-centered clinic environment in which education and supportive interventions are emphasized will greatly enhance patients' knowledge about HIV infection. Improving patients' skills in self-management will increase their participation in making health care decisions and provide a stimulus for more active involvement in their own care.

Special Challenges of Caring for HIV-Infected Patients

Providers need to be mindful of several special issues, including the following:

- Many medical, psychological, and social challenges confront persons living with HIV. The delivery of effective care usually requires a strong provider-patient relationship, a multidisciplinary approach, and frequent office visits.
- The stigma associated with HIV places a major psychosocial burden on patients. Stigma and discrimination must be addressed through strong confidentiality protections, emotional support, and cultural sensitivity. It is important to inform all patients of their rights and responsibilities in a language or manner that is respectful and understandable.
- Underserved racial and ethnic groups are overrepresented among people with HIV. Efforts to understand and acknowledge the beliefs of patients from a variety of cultural backgrounds are necessary to establish trust between providers and patients. Cultural competency is imperative in the field of HIV care.
- Providers play a key role in the public health system's HIV prevention strategy. Disease reporting, partner notification, and risk assessment are important aspects of care. Patients may see this as threatening and may need education and emotional support in order to participate in this process. Patients need to be informed of their rights under the Health Insurance Portability and Accountability Act (HIPAA) and understand the public health implications of HIV.
- Many patients have inaccurate information about HIV infection that can heighten their anxiety, sabotage treatment adherence, and interfere with prevention behaviors. Patients need assurance that HIV is a treatable disease and that, with successful treatment, they can experience a normal life expectancy. They also need to hear explicitly that HIV may be transmitted through sexual contact, injection drug use and other blood contact, and perinatal exposure, and that they can take specific measures to prevent transmission to others.
- Many patients need the support that only a peer can provide. Peer educators should be available to help patients navigate difficult health care systems, medication regimens, and lifestyle changes.

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- HIV-infected patients need to have an active voice in their health care. Patient advisory groups can provide valuable program evaluation, which can be used to promote the patient-centered focus of the health care system.

These issues are discussed further in the sections that follow.

Components of HIV Care and Ways to Enhance Care

Important Components of HIV Care

A first step in ensuring that patients are “engaged in care” is the establishment of systems that include mechanisms for coordination and communication of care.

- Clinics must offer a nonjudgmental and supportive environment, because of the sensitive nature of issues that must be discussed.
- A multidisciplinary approach, utilizing the special skills of nurses, pharmacists, nutritionists, social workers, case managers, patient navigators, and others is highly desirable to help address patient needs regarding housing, medical insurance, emotional support, financial benefits, mental health and substance abuse counseling, and legal issues.
- Providers and other clinic staff members should be prepared to conduct appropriate interventions and make timely referrals to community resources and institutions.
- The primary provider should coordinate the various aspects of health care, with close communication among providers across disciplines.
- Individual office visits should be long enough to allow time for thorough evaluation.
- Providers must be able to see patients as frequently as their medical and psychosocial needs require, and clinic scheduling should be flexible so that patients with acute

problems can be seen quickly and new patients can receive and access care in a timely manner.

- A range of medical resources, including providers with subspecialty and laboratory expertise, needs to be established. Co-locating services within testing and counseling sites or within HIV clinics is an excellent way to enhance patient compliance (see chapter *Clinic Management*).
- Patient education is a vital aspect of care that begins during the initial evaluation and continues throughout the course of care (see chapter *Patient Education*).

Taking Steps to Enhance Care

Providing comprehensive care for HIV-infected patients requires a patient-centered focus, a multidisciplinary team, and a willingness to spend time on building relationships with patients. Providers should do the following:

- With the help of case management agencies, counseling and testing centers, and patient-care navigators, provide quick and easy access to care to those newly diagnosed and entering into treatment.
- Front-end staff members need to be knowledgeable, compassionate and efficient with the initial patient contact in order to establish a warm and welcoming environment of care for the new patient.
- Make available self-management education to help patients identify problems, teach decision making techniques, and support patients to take appropriate actions to make necessary changes in their lives.
- Offer care in a patient-centered environment that allows the patient to actively participate in care decisions and provides patient-specific education.
- Encourage patients to learn all they can about their condition.
- Give accurate information regarding prognosis and antiretroviral therapy.

- Foster an atmosphere of nonjudgment, trust, and openness.
 - Anticipate that significant time will be required for patient education.
 - Outline the range of clinic operations and state the expectations for provider-patient communication. Outline how appointments are scheduled and how prescription refill requests are managed.
 - Arrange to see patients with acute problems quickly. Establish a triage system to provide efficient service delivery.
 - Ensure that there are open lines of communication with all patients to receive and answer questions, assess treatment effectiveness, and manage side effects.
 - Provide safe and secure access for patients to communicate with staff. Patient portals can provide quick and direct access to nonemergent information and can provide accurate answers to questions that arise between visits.
- disclose their diagnosis to friends, family, or employers as well as support in dealing with HIV infection. Patients often feel hesitant about seeking emotional and practical support.
- Deliver important information in easily understood terms and in small amounts. Reassess patient understanding of crucial information at subsequent visits, and repeat important information as necessary. Realize that many visits may be required before patients are comfortable with their care and the navigation of the health care system.
 - Screen for anxiety, depression (including suicidal ideation), and substance use.
 - Refer patients to community resources for crisis counseling, support groups, and, if appropriate, psychiatric treatment to help them achieve emotional stability.
 - Assist patients in finding a case manager or patient navigator who can help them learn to navigate the health care system and reduce anxiety about keeping their lives in order.
 - Assist patients in linking to social work services to assist with enrollment into medical insurance and to meet other social service needs, such as housing, food, child care, and substance abuse treatment.

Helping Patients Cope with Emotional Issues

Patients coming to terms with HIV infection often experience a range of emotions, including anger, fear, shock, disbelief, sadness, and depression. Loss is a major issue for patients with HIV because health, employment, income, relationships with friends, lovers, and family, and hope all may be threatened. Many patients feel overwhelmed, and even patients who seem to be adjusting reasonably well can find it difficult to keep all of the many appointments that may be scheduled as they initiate care. Providers need to recognize that patients' emotional states affect their ability to solve problems and attend to important medical or social issues. Providers can do the following:

- Assess each patient's emotional state and the availability of friends and family for emotional support. Some patients will need counseling to help them decide whether to

Helping Patients Develop Self-Management Skills

Self-management support is defined by the Institute of Medicine as the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and setbacks, goal setting, and problem solving.

It can be viewed as a portfolio of techniques and tools to help patients choose healthy behaviors, and as a fundamental shift of the provider-patient relationship toward a collaborative partnership.

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After patients have come to terms with their HIV infection, they are ready to embark upon the lifelong process of caring for themselves. Patient self-management involves adopting new health behaviors and requires changes that will occur as a progression of motivational skills. Motivation is defined as the “probability” that a person will enter into, continue, and adhere to a specific change strategy. Patients will feel empowered as they gain the skills and confidence to be active participants in their care.

The following practices should be adopted to foster patient self-management:

- Train staff at all levels on patient self-management concepts and how to incorporate them into care.
- Create an atmosphere conducive to learning these self-management skills, including but not limited to the following areas:
 - Problem solving
 - Medication issues
 - Working with the health care team
 - Planning for the future
 - Goal setting
 - Dealing with difficult emotions
 - Healthy eating
 - Advance directives
 - Sex, intimacy, and disclosure
- Adopt a team approach to health care with the patient as the central team player (patient-centered care).
- Incorporate problem-solving skills into all education efforts.
- Allow the patient time to set small obtainable goals as “first steps” in self-management.
- Realize that many appointments with multiple members of the health care team may be necessary before a patient has all the necessary skills.

Helping Patients Make Positive Changes in Health Care Behaviors

Regardless of whether a patient is new to care or has been in care for many years, the burden of a chronic disease is wearing. Positive change in behavior needs to be an ongoing focus of patient-centered care. After patients have self-management skills, they still need help setting action plans for their health care. The provider needs to help patients adopt realistic action plans by:

- Realizing that new health behaviors require motivation and occur as a progression of learned skills
- Bolstering patients’ self-confidence by adopting action plans that:
 - Are realistic
 - Are something that patients find of value (i.e., something they want to do)
 - Are reasonable (it is better to underestimate and exceed the goal than to overestimate and fail)
 - Are action-specific, with small, obtainable goals

Peer Educators and Patient Advisory Groups

Patients need to be active participants in making decisions regarding their health care. Peer educators and patient advisory groups can help patients become more involved in their care.

In order to best support patients, it is helpful to have peer educators available for them during initial and subsequent visits. This helps to decrease patient anxiety and promotes a patient-centered atmosphere. Providers need to realize that peer educators are HIV-infected individuals who:

- Provide a unique approach to client-centered care
- May attend clinical sessions with patients and provide them with referrals for one-on-one counseling and support

- Are “seasoned clients” who have a desire to help patients in their care
- Work under the same confidentiality guidelines as all other staff members

Another valuable tool for patient-centered care is the use of a patient advisory group (PAG). The PAG is the voice of the people that the clinic serves. The HIV program will listen to this group’s suggestions and use them to improve patient satisfaction and clinic functionality. The PAG’s role could involve identifying clinic problems, recommending changes in the care delivery system, and discussing new treatment approaches. A successful PAG does the following:

- Provides comprehensive, individualized client-based education to all active patients
- Encourages clients to actively participate in treatment decisions and to involve family members and others who comprise their support system
- Designates members who facilitate meetings, promote upcoming meetings, coordinate speakers, and provide feedback to clinic staff and management
- Allows members to serve as cofacilitators, choose topics of discussion, set meeting guidelines, and invite new members
- Fulfills requirements of grants and other funding streams to have enhanced patient involvement

Stigma and Discrimination

Stigma is founded on fear and misinformation. Theodore de Bruyn observed that stigma is associated with HIV because, “It is a life-threatening disease; people are afraid of contracting HIV; it is associated with behaviors that are considered deviant; a belief that HIV has been contracted due to unacceptable lifestyle choices; and, some believe it is the result of a moral fault which deserves punishment.”

Stigma can adversely affect how patients are perceived by others and how they view themselves. The stigma associated with HIV/AIDS is such that individuals known to be or suspected of being infected with HIV may be excluded from community activities and suffer isolation or abandonment. Some patients may feel ambivalent about seeking medical care if, by doing so, they risk disclosing their condition. Others may have learned from experience to expect rejection and therefore may not trust care providers. It is essential for providers to be supportive of patients who are dealing with the burden of stigma.

Stigma of Fear of Contagion

Unfortunately, patients and their families are often unaware that routine household contact with a person with HIV poses no risk of contagion. They should be educated about that, and also taught what to do in situations that do pose risk, such as when bleeding occurs. Clinic staff members must model behavior in this area. For example, gloves should be worn only as appropriate during physical examinations and as consistent with universal precautions. There should not be separate facilities or special procedures for HIV-infected patients.

Stigma Associated with Being Gay, Lesbian, Bisexual, or Transgender

Demonstrating respect and providing excellent care to patients with various cultural backgrounds, beliefs, and sexual orientations are central to medical professionalism. Providers should approach patients in an open and nonjudgmental fashion and be familiar with medical management issues unique to these populations, such as appropriate screening for sexually transmitted diseases for men who have sex with men (MSM) and hormonal treatment for transgender patients. Clinic staff members also must be respectful and supportive; having a staff that is familiar with lesbian, gay, bisexual, and transgender (LGBT) cultures is a natural way to create a welcoming environment. Providers and social workers should be aware of community

agencies with resources available to people who are lesbian, gay, or transgender. In addition, providers and clinic staff members should be aware of special legal issues that affect these populations. For example, designating a durable power of attorney for medical decision making can be particularly important in states that do not recognize same-sex partners or spouses as legal next of kin.

Other Special Cultural Issues

African-Americans, Hispanics, and some immigrant groups are disproportionately affected by HIV, and many people of color with HIV infection have major socioeconomic problems such as poverty, homelessness, lack of medical insurance, lack of acculturation, and undocumented immigration status. Many young people with HIV face similar issues. All these obstacles can make accessing health care difficult and attending to health problems less of a priority for the individual. A patient's cultural background influences health-related beliefs and behaviors, and personal or historical adverse experiences may make some patients distrustful of medical care. In addition, some patients' distrust of medical research can impede their willingness to access new drug therapies. Culturally competent communication between provider and patient may substantially affect adherence with therapies. For all these reasons, providers should do the following:

- Carefully explore what each patient believes about his or her health, what would be appropriate treatment, and who should be involved in medical decision making.
- Use professional interpreters to help overcome language barriers.
- Use case managers and peer educators to help bridge social barriers. The team of peer educators should be culturally diverse in order to be effective with all minority groups.

Confidentiality and Disclosure

Confidentiality of medical information is always mandatory, but the stakes are particularly high for patients infected with HIV, who risk losing medical insurance, employment, and the support of friends or family if their diagnosis is disclosed inappropriately. Although people with HIV infection are protected against discrimination under provisions of the Americans with Disabilities Act, discrimination can be difficult to prove, and there are strict time limits after which charges of discrimination can no longer be made.

Protecting Patient Confidentiality

Adherence to the HIPAA regulations is an important aspect of protecting patient confidentiality. Personnel policies should reinforce measures such as requirements that papers and computer screens containing patient-identifying information not be left unattended and should include provisions for documenting whether phone messages can be left for the patient, and if so, with whom.

Helping Patients Disclose Their HIV Status

Patients who have a support network function better than those who are isolated. However, patients' fears of disclosure are often well founded, and providers must find a balance between accepting patients' unwillingness to disclose their HIV status and the need to develop support networks. Patients may find support groups or individual psychotherapy sessions beneficial in deciding when to disclose, and to whom.

The sex and needle-sharing partners of people with HIV need to be informed about their possible exposure to HIV. Local health departments can either assist patients in making these disclosures or provide anonymous partner notification for them.

A patient-centered clinic staff can help patients with disclosure. For example, staff members

could encourage patients to bring their partners to one of their clinic or counselor appointments in order to disclose their HIV serostatus in the context of the clinic visit. This could allow the health care professional to answer the partners' questions and would provide a neutral environment for the disclosure discussion. Risk of intimate-partner violence should be assessed.

Public Health Role of Providers in the HIV Epidemic

Primary care providers must consider their public health role in curbing the spread of HIV. The incidence of HIV remains unacceptably high, and may be increasing in some populations, especially in communities with relaxed adherence to safer sex recommendations.

All AIDS diagnoses and, in some states, all positive HIV test results must be reported to the state health department. State laws vary in reporting requirements and subsequent notification of potentially exposed individuals (see the National HIV/AIDS Clinicians' Consultation Center *Compendium of State HIV Testing Laws* at www.nccc.ucsf.edu), but the name of the source contact is never divulged to the person being notified. Providers should become familiar with the laws of their jurisdiction by contacting their health department. (The Association of State and Territorial Health Officers provides links to all state health departments at www.astho.org.) Providers are required to do the following:

- Inform patients that their AIDS diagnosis or positive HIV status (depending on individual state requirements) must be reported to the state health department, tell them whether partner notification is required, and explain what they should expect regarding efforts that must be made by the patient, provider, or health department to notify sex partners or individuals who may have been exposed to HIV through

their needle sharing. Assure them that their names are always kept confidential and are never given to potentially exposed individuals by the health department.

- Carefully assess patients' risk-taking behaviors, educate them regarding HIV transmission, and perform screening for sexually transmitted diseases. (See chapters *Preventing HIV Transmission/Prevention with Positives*, *Initial History*, *Initial Physical Examination*, and *Initial and Interim Laboratory and Other Tests*.)
- Provide counseling to encourage safer sexual practices and make referrals to drug rehabilitation or needle exchange centers as indicated. (See chapter *Preventing HIV Transmission/Prevention with Positives*.)
- Provide information about the role of antiretroviral therapy in reducing the risk of HIV transmission.

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Clinic Management

Jonathan A. Cohn, MD

Background

HIV outpatient care is unique in that it combines two very different approaches to patient care: long-term health care for individuals with a chronic condition, and the vital public health service of reducing transmission of an infectious disease. Thus, chronic treatment and retention in care are important both for individual patients and for public health.

HIV services often are provided to persons who have challenges in regard to participation in their own health because of discrimination, poverty, active substance use, or mental health disorders. The context of HIV care still is one of persistent stigma regarding HIV infection itself and discrimination against racial, ethnic, and sexual minorities who constitute the groups with the highest HIV prevalence and incidence. At the same time, funding streams from federal, state, and local governments have created opportunities for treatment of uninsured and underinsured individuals and provide resources for creating innovative, effective programs. The Affordable Care Act creates new opportunities to provide care for previously uninsured persons through two insurance mechanisms and other benefits described below. Treatment guidelines, operations research data, and technical support are available to assist in designing, operating, and improving service programs.

Patient Recruitment into Clinic

The persons who were easy to recruit and retain in care are already enrolled; the more challenging patients await recruitment. The U.S. Centers for Disease Control and Prevention (CDC) estimates that up to 25% of HIV-infected persons in the United States are not aware of their HIV infection (Branson, 2006), so there is still much work to be done to diagnose those individuals and link them to care. For newly diagnosed patients, studies show that there often is a substantial delay in attendance at an initial HIV care visit, with only 20–40% of them accessing care within 6 months of diagnosis (Mugavero, 2008). However, for the clinics, the number of newly diagnosed patients who present for care is substantial. A recent survey of 15 HIV programs across the country (median of 1,300 active patients each year) showed that a median of 250 (range 60–730) new patients were enrolled in each clinic each year (Yehia, 2008).

To facilitate linkage to care, every HIV clinic should 1) be linked to agencies that provide HIV testing and services for persons with HIV, and 2) make clinic access easy and comfortable for the clients of those outside services. Many HIV clinics establish referral linkages with community HIV counseling and testing services (CTS), AIDS service organizations (ASOs), sexually transmitted disease (STD) treatment facilities, family planning agencies, drug treatment facilities, local health departments, regional HIV hotlines, and local hospitals and emergency rooms. Many clinics also offer free confidential or anonymous CTS using state or federal funding.

Clinic personnel should build personal relationships with agencies that may provide referrals, invite staff of community agencies to visit the clinic, or hold open houses. Providers from ASOs, such as case managers, can be invited to accompany patients on clinic visits. Referring agencies must know what services the clinic provides and which patients it serves, as well as those it cannot serve.

Various approaches may help facilitate the patient's entry into care. A randomized study showed that using case managers to increase linkage of newly diagnosed persons to care can be effective: 78% of patients who had "strength-based" case management that promoted patient empowerment and self-efficacy kept an appointment within 6 months, whereas only 60% of patients without case management kept an appointment in the time frame (Mugavero, 2008).

Frequently, there is a delay of several weeks for a new appointment with an HIV clinician. Model programs have been established nationwide to improve linkage to HIV care. For example, the HIV clinic at the University of Alabama at Birmingham offers new patients an orientation visit in the HIV program within 5 days of their request for a new patient appointment. In this clinic, an HIV program staff member initiates a welcoming interaction during the patient's first phone call requesting an appointment and invites the patient to an orientation visit. During that visit, a psychosocial assessment is performed, specimens are taken for baseline laboratory tests, any immediate health issues are addressed, and referrals for mental health or substance use disorder care are initiated, if indicated. The orientation visit is used to give patients information on how to use the clinic effectively, provide other on-site nonmedical services, and start processes to access health insurance or AIDS Drug Assistance Program (ADAP) services as needed. The full initial medical visit is scheduled for a later date. In a nonrandomized comparison, the no-show rate at that clinic dropped from 31% to 19% with that approach (Mugavero, 2008).

Success in linking newly diagnosed persons to care may be enhanced through the participation of HIV-infected consumers as peer advocates and peer navigators (see chapter *Supporting Patients in Care*). Either volunteer or paid peer advocates can meet newly

diagnosed patients who have been referred to the clinic, help familiarize them with the clinic services and staff, and help them adjust to both the fact of their HIV infection and their role as a chronic care patient. Groups for newly diagnosed persons co-led by a peer advocate and a professional as well as one-on-one interactions with patients within or outside the clinic (e.g., through a buddy system) can help newly diagnosed persons succeed in the clinic. In clinics that use peers, particular attention must be paid to confidentiality issues. The peers must be trained and supervised (see below), and the patients must agree to participate with peers, either individually or in groups.

Clinics differ in terms of the characteristics of people living in their catchment area and in regard to the levels of expertise of clinic staff members. Some successful clinics target a narrow but underserved population and concentrate on meeting the needs of that population. The environment and services offered by the clinic may be tailored to the patient population. For example, a youth-friendly clinic may differ in these respects from one targeting the working poor.

Retaining Patients in Care

Retaining patients in care is an ongoing challenge (see chapter *Supporting Patients in Care*). Among the 15 surveyed HIV clinics mentioned above, the median no-show rate for appointments was 28% (range 8-40%). For new patients, the range was 5-54% and for returning patients it was 2-40%. Across all the clinics there was a median annual loss-to-follow-up rate of 15% (range 5-25%) (Yehia, 2008). A number of approaches may help patients maintain continuous care in the clinic. An AIDS Education and Training Centers (AETC) working group is creating a toolkit for clinics to assist them in applying evidence-based methods to retention in care; this is available from the National Resource Center (NRC) of the AETC (see resources below).

Respect and cultural competence:

Respecting patients and providing them with effective care builds trust and keeps them coming back. New clinic attendees may have strong feelings related to HIV infection (e.g., fear of death) or how they acquired it (e.g., issues of shame or of secrecy). They may lack trust in medical care (from prior personal experiences or from historic events such as the Tuskegee syphilis experiments) or in current treatments (e.g., “Everyone I knew who took AZT died ...”). Some patients believe that HIV was created in government laboratories to target African-Americans and may or may not believe that the clinic staff is part of the conspiracy. It is important that all staff members be trained to anticipate, recognize, and work with issues such as these.

Patients may experience obstacles to care when there are cultural differences or language barriers between themselves and the staff members. Diversity among health care staff can further improve the experience of racial, ethnic, and sexual minority patients.

Welcoming staff attitude:

Providers must know the target population and build a system that will make patients feel welcome. Patients always should be made to feel that they came to the right place (even in cases in which they must be referred on to another provider or clinic). Patients should receive understanding and support, even if they arrive at the clinic without the required managed care referral form (at least for the first few visits).

Welcoming environment:

Physically comfortable waiting and examination areas, with linguistically and culturally appropriate decoration and reading material, are important for patient retention. A clinic that serves parents or children should make available toys or children’s books.

Orientation to clinic systems and rules:

New patients need a brief description of clinic staff and services, routine and emergency procedures, prescription refill procedures, and after-hours follow-up. They must understand requirements for referrals from managed care providers, and new patients may need help with fulfilling such requirements. Patients also must be oriented to what is expected of them (e.g., arriving on time, calling to cancel or reschedule appointments) and the consequences of not fulfilling their responsibilities (e.g., clinic rules regarding late arrivals). A handout or pamphlet with this information can be very helpful. Patients need to know how to determine the insurance coverage and other benefits for which they may qualify, and how to find out their options if their insurance coverage changes.

Peer support:

Many programs have HIV-infected staff members who provide specific peer-support services. Patients who have had unpleasant experiences seeking medical care in the past, or those who are not used to engaging in medical care, may get better support from another consumer than from a nonpeer staff member. Youth especially may trust information from peers more so than from adult professional staff members.

Peer advocates or peer navigators may work in this role part time or full time, as either volunteers or paid staff. Often they work specifically to make new or recently returned patients comfortable in the clinic. Some programs designate consumers as peer navigators, emphasizing their role in helping new patients, or patients returning after being lost to care, in finding their way through the health care system and support systems. Peer advocates also can help patients ask questions or make their needs known to the clinic staff. Advocates or peer-support persons can be instrumental in helping patients build self-

esteem and acquire new habits that will enable them to use health care services in a proactive manner. Peers are especially helpful when they model good health behaviors, including adherence with appointments and medications and with avoiding unsafe sex or other HIV transmission activities. In some cases, peers have been the basis of a successful program, but in other cases peers model poor health behaviors and themselves become ill. Peers need to adhere to confidentiality rules and good work habits and need to provide accurate information to other clinic staff. Effective selection, training, and supervision of peers are extremely important.

Systems to support attendance:

Clinics should provide feedback and encouragement to patients about the importance of attending scheduled visits. This can be done through written materials such as posters and pamphlets, as well as through comments made by providers during clinic visits. These very inexpensive interventions have been shown to improve clinic attendance (Gardner, 2012).

Patients should receive appointment reminders about 48 hours before each appointment. Reminders typically are given by phone or mail, although text messaging or other forms of electronic communication may be more useful in some settings. It also may be effective to have a staff member contact patients who have missed appointments to find out what prevented them from attending, offer to reschedule, and try to eliminate barriers to clinic attendance.

Factors such as child care needs, work schedules, and transportation problems can be substantial barriers to attending clinic appointments. Addressing these and other challenges may require coordinated efforts by the clinic staff, case manager, and others. In some instances, AIDS service organizations and other community organizations may have funding available to assist with these efforts.

Some programs have a policy detailing their interventions following one or more missed visits: usually one or more phone calls comes first, then a letter to the last known address, and as a last measure, some programs will dispatch personnel to visit the last known address in an attempt to reconnect with a patient who is lost to follow-up. These efforts are more successful when patients are asked for current telephone, address, and other contact information at every clinic visit. Staff members must know to whom a patient has disclosed his or her status; in verbal and written correspondence, staff members must avoid unintended disclosure of the patient's HIV infection.

It is important to document movement of patients to other locations (including correctional facilities) or other care providers whenever the information is known so that these patients are considered transferred rather than lost. Some states provide public lists of incarcerated persons; larger programs may use those lists to find patients who have been missing for some time.

HIV programs can be aggressive in trying to connect with patients who are missing, but also must respect explicit decisions by competent persons to change providers or to forgo medical care.

Outreach encounters to promote participation in care:

A study of seven sites across the United States, funded by the Health Resources and Services Administration (HRSA), found that outreach by health care professionals increased clinic attendance and that frequent outreach by any program staff member increased adherence with antiretroviral therapy (see “References,” below). Outreach by medical professionals included efforts by physicians, nurses, or physician assistants to meet patients outside the HIV clinic setting, often in another part of a medical facility such as an inpatient unit. These encounters were the most expensive type of outreach, but the most effective in engaging new patients in care. Encounters with medical professionals did not increase adherence with medications, however. Other types of outreach, either face-to-face or otherwise (by phone, email, or postal service), by professional, nonprofessional, or paraprofessional staff members, increased adherence with medications, but not with clinic attendance. More frequent encounters of this type were associated with greater improvements in adherence. The results of the study suggest that initial face-to-face contact with medical providers is important for establishing trust that enables new patients to engage in care, and that frequent encounters with other staff members is important for maintaining patients on medications.

Special Population: Women of Color

A 2008 report commissioned by HRSA collected data from the published literature, key informant interviews, and a consultation meeting with Ryan White Care Act (RWCA)-funded providers to provide information on barriers and effective interventions to assist women of color in succeeding with HIV care. Three central themes were extracted from these varied inputs:

1. Development of a responsive care environment that incorporates respect, cultural competency, and flexibility to meet women’s needs;
2. Incorporation of peers into the care system as trained and paid participants in the care teams; and
3. Addressing women’s needs through care coordination, flexibility, health system navigation, and better coordination and communication between medical and social service providers.

HRSA funded a number of clinical sites to test different methodologies applying these principles through the Special Programs of National Significance mechanism; these projects are ongoing and results are not yet available.

Models of Care

Chronic Care Model

Popular in recent years, the chronic care model refers to a mechanism for providing patient-centered care using a variety of staff personnel and interventions to maximize desired health outcomes. This approach has been most highly developed for diabetes care, but it can apply equally well to a wide range of chronic illnesses. In this model, patient training in self-care is key. In contrast to the tradition of teaching patients the pathophysiology of their health condition in lay terms, with this model, training involves focused skills building so that patients can better monitor their health status, use their discretionary medications, and know when and how to contact the professionals for assistance. Frequent contact

between patient and clinical staff, both face-to-face and through other means, both in clinics and in the community, usually are involved. Care is directed toward panels of patients, not just individual patients. Program-wide monitoring of process and outcome variables, such as frequency and results of CD4 cell counts and plasma HIV RNA levels, informs the practice as a whole as well as the quality of care for individuals. These interventions have been shown to improve outcomes, but do not necessarily reduce costs because the staff time required can be substantial.

Patient-Centered Medical Home

The chronic care model concept has been merged with the concept of a home to coordinate care and medical records for children to create the current model of the Patient-Centered Medical Home or PCMH. This concept usually is applied to primary care providers and practices; however, it potentially applies to a specialist who cares for the most prominent or demanding of a patient's health problems as well as other primary care issues. The chronic care model is limited to treatment of one health condition whereas the medical home model supplements such targeted care (e.g., HIV-specific care) with coordination of the other health services the patient may need. HIV programs often act as the primary care provider, especially for patients who do not have insurance and therefore have limited access to other providers, whether the practice is otherwise a primary care or specialty clinic. Many HIV clinics have the capacity to organize and implement a chronic care approach and to coordinate services across other specialties and providers in order to be a true medical home. Several national organizations provide certification of PCMH status to clinicians and practices. One organization is the National Center for Quality Assurance or NCQA (see details on its PCMH certification process on its website (www.ncqa.org). NCQA will certify individual

providers and practices even when they are located within larger institutions. Another organization is the Joint Commission (www.jointcommission.org), which usually certifies PCMH status within an organization that has Joint Commission accreditation for other purposes. General information about the concept and other agencies that provide certification is available online at the National Center for Medical Home Implementation (www.medicalhomeinfo.org). In some states or localities, insurers such as Blue Cross and Aetna have their own certification process. Some health plans provide additional payment to primary care clinicians and practices that are certified as medical home providers, to support the health informatics infrastructure, care coordination, teaching and skill building, and follow-up outside of office visits that are required to manage panels of patients in a proactive manner. The PCMH approach also will provide financial opportunities for practices that become involved in Accountable Care Organizations (ACO), as pay-for-performance models of reimbursement are implemented across the United States. HRSA provides technical assistance to Ryan White grantees interested in being certified as a medical home, and to those interested in learning the lessons of this process even if not seeking certification. Additional information regarding training, resources, and webinars is available on the HRSA Target Center website (careacttarget.org).

PCMH Neighbor

This is a concept for specialty practices who do not wish to or are not able to take up full care coordination for a patient, or who may not be eligible as specialists to become certified as a PCMH (see "References," below). With this concept, a specialist participates in timely and thorough sharing of information and care coordination with a patient's primary care medical home, so that the full array of PCMH services is available without duplication but

with the added expertise of the specialty practice. At this time, there is no additional reimbursement for this status. However, implementing this enhanced level of care coordination with the patient centeredness, proactive approach, and skill building that characterize a PCMH, is expected to improve outcomes and may create opportunities for enhanced reimbursement in the future. This coordination also will be useful for specialist participation in ACOs.

Clinical Services Needed for HIV Care

Optimal array of services provided by an HIV clinic

At a minimum, HIV medical care providers need to offer confirmation of HIV infection, education, recommendations, and management regarding antiretroviral therapy; prevention, diagnosis, and management of HIV-related opportunistic diseases and treatment-related complications; screening and referral for common comorbidities, and linkages to other general health services. Most patients will need additional primary care and specialty health care and support services; it is often more effective and more convenient when these are available on-site rather than by referral. For health interventions to be successful, many patients will need assistance with health behavior change.

The services ideally provided by the HIV clinic include those on the list that follows. Detailed information on most of these topics is available in other chapters in this manual. These standards are derived from the primary care guidelines of the HIV Medicine Association of the Infectious Diseases Society of America (HIVMA/IDSA), the HHS *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, the HHS *Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected*

Adults and Adolescents, the CDC guidelines on prevention services in HIV care programs, as well as U.S. Public Health Service Prevention Task Force and American Cancer Society recommendations (see “References,” below).

- Age-appropriate immunizations including HIV-specific indications for some, including pneumococcal vaccine, influenza vaccine, hepatitis A and B vaccines, quadrivalent human papillomavirus vaccine in appropriate age groups (see chapter *Immunizations for HIV-Infected Adults and Adolescents*).
- Screening for STDs (syphilis, gonorrhea, chlamydia, trichomonas in women, hepatitis B and C) at enrollment and periodically. After the initial screening, new standards promote periodic screening for acquisition of hepatitis C in persons at risk.
- Assessment of ongoing sexual or drug-use behaviors associated with HIV transmission, and counseling or other interventions to reduce transmission behaviors. Interventions regarding sexual transmission behaviors should be linked with family planning.
- General health screening for hypertension, diabetes, dyslipidemia, and cardiovascular risks, and cervical, breast, and colon cancer. The role of anal cytology in screening for anal cancer remains uncertain because of limited data on effective management of anal dysplasia.
- Care of common general medical illnesses including hypertension, dyslipidemia, uncomplicated diabetes, obesity, asthma, and chronic obstructive pulmonary disease. Care of a wider range of disorders, such as congestive heart failure and chronic kidney disease, will vary by practice.
- Evaluation and care of common comorbidities including hepatitis B and C infection and latent and active tuberculosis (TB). Treatment of active TB, including

directly observed therapy, often is provided by public health agencies; treatment of hepatitis may require referral to a specialist (though increasingly HIV providers are likely to manage treatment of HCV in coinfecting patients as additional direct-acting antivirals for hepatitis C become licensed, with their improved efficacy and lower side-effect profile).

- Provision or linkage to oral health care, nutritional services, and other medical specialties including ophthalmology, dermatology, and oncology.
- Provision or linkage to HIV care for pregnant women, adolescents, and infected or perinatally exposed infants.
- Behavior change for general health issues including smoking cessation and other unhealthy substance use, diet for weight control, and exercise.
- Behavioral health services for adaptation to the illness, mental health disorders, and substance-use disorders including unhealthy alcohol use.
- Provision or linkage to social support services, including community-based case management.
- Additionally, clinics should have a system in place to protect the safety of their employees in regard to occupational HIV exposure (see chapter *Occupational Postexposure Prophylaxis*).

Resources required in providing comprehensive HIV care

Patient access is maximized in clinics that can accept Medicare, Medicaid (including Medicaid managed care), and county insurance programs. Clinics with access to Ryan White Treatment Extension Act funding must accept patients regardless of health insurance status or ability to pay. Federally qualified health centers also can accept uninsured patients and have an important role in expanding access to care. Every state receives Ryan White Part B funds for an ADAP to pay for antiretroviral agents and often other drugs for the uninsured or other eligible persons with HIV. Details vary by state and are available at each state's HIV hotline (for phone numbers, see hab.hrsa.gov/gethelp/statehotlines.htm). Clinics should assist appropriate patients to enroll in the ADAP, and to access the drug coverage or other clinical services that vary by state.

Within designated metropolitan areas, Ryan White HIV/AIDS Program Part A funding may be available. Clinics planning to serve a moderate-to-high volume of HIV patients can apply for a Ryan White Part C planning grant. Clinics serving women, pregnant women, youth, and families are eligible to apply for Ryan White Part D funding. Clinics may collaborate with other agencies in seeking Ryan White funding. Smaller programs may become satellites of larger Ryan White-funded programs. Other individual providers or small clinics may be eligible for Part B reimbursement for medical care of uninsured persons, by working with local case management agencies.

The ACA created online insurance marketplaces or exchanges, at which persons and families with incomes between 100% and 400% of the Federal Poverty Level (FPL) can purchase affordable insurance using tax rebates (for 250-400% of FPL) and other subsidies (for 100-250% of FPL). In addition,

many states are expanding Medicaid eligibility, for example to persons and families with annual incomes up to 138% of FPL. Another benefit of the ACA for persons with HIV is the requirement that core health benefits, including evidence-based preventive services, are provided by all health plans. HIV patients will benefit from the fact that preexisting conditions no longer disqualify persons from obtaining individual health insurance at competitive rates, and that more employers are now expected to provide health insurance for employees. Ryan White Part B Drug Assistance Program (DAP) funds may be used to assist patients with the costs of health plans if doing so is less expensive than providing direct benefits to DAP beneficiaries. Details about the plans available on the exchanges, their costs and benefits, the role of DAP, and Medicaid eligibility vary by state. HIV provider organizations will need to contract with some of the new plans available on their state exchanges, and providers will need to educate themselves on details of their plans. Local organizations have been designated as Certified Application Counselors (CACs), which allows trained staff to assist patients with enrollment on the exchanges and to certify that hardcopy documentation provided by patients, if needed in the course of online enrollment, is accurate. Other help may be provided by ACA navigators, who can assist clients with enrollment decisions but are not able to certify clients' documentation. Specific details and mechanisms for this interaction between ACA insurance benefits and Ryan White benefits are still evolving. Updated information on the benefits of the ACA for persons with HIV is available on the HRSA Target Center website (careacttarget.org).

Personnel:

For patients who are self-sufficient or can access community-based services on their own, a lone provider potentially can deliver comprehensive HIV care. In most circumstances, however, patient care needs are met more effectively when multiple team members are available at the clinical site.

Facilities:

In addition to the usual office layout, other facilities are useful. An examination room suitable for gynecologic examinations is important. An apparatus for pulse oximetry is very useful in assessing patients with respiratory symptoms. Easy access to facilities for collecting venous blood, urine, and stool specimens should be available. On-site access to rapid tests that do not require Clinical Laboratory Improvement Amendments (CLIA) certification may be useful, such as urine pregnancy tests, fingerstick blood glucose tests, and perhaps the rapid HIV antibody screening tests. Laboratory certification to perform urine analysis and microscopic examination of vaginal fluid specimens is very useful. Refrigeration to maintain vaccines and material for tuberculin skin testing is necessary. Refrigeration also enables the clinic to provide patients with on-site injection of medications required once a week or less frequently.

Training and technical assistance:

Patients look to nontechnical staff to corroborate information given by physicians and midlevel providers. Further, patients expect the same accepting attitude from all staff members. Thus, all clinic personnel need training in both technical and cultural matters. One important resource is the AETC NRC (www.aidsetc.org) and the local performance sites of the AETCs funded by HRSA to provide training and technical assistance to clinics. The NRC, local AETCs, and the website of the National HIV/AIDS Clinicians' Consultation Center (www.nccc).

ucsf.edu) provide detailed and patient-specific education to assist clinicians in making treatment decisions. Written educational materials for staff, such as national and regional treatment guidelines, may be obtained free of charge via the Internet and are updated regularly. Many regional and national meetings provide training in both clinical care and prevention. Assistance with enhancing and implementing systems of care, including instituting a quality management program, also is available from the AETCs. See chapter *Web-Based Resources* for other resources for training and information. The National HIV/AIDS Clinicians' Consultation Center's Warmline provides expert clinical advice on HIV/AIDS management for health care providers. This telephone consultation service is available Monday through Friday, 9 a.m. to 8 p.m. eastern time, at 800-933-3413.

Implementing interdisciplinary care in the clinic

It is not enough to have staff members from many disciplines on the payroll; rather, systems that allow staff members to function as a team must be created. Training with follow-up by supervisors is essential. Specific tasks for each staff member need to be assigned (see Table 1). Ideally, members of the staff can meet for a few minutes prior to each clinic session to anticipate special needs and allocate personnel resources. Some clinics place a checklist on each chart at each visit to indicate which team members a patient is meant to see that day and to confirm that all intended interactions have occurred.

The team's potential can be best utilized if there is a regular opportunity to meet and discuss patients outside clinic sessions, in multidisciplinary team meetings. When all members participate, the

discussions can range from the selection of antiretroviral regimens for a patient to addressing the patient's adherence issues or chronic mental illness. Services for infected and affected family members also can be coordinated at these meetings.

Table 1. Clinic Personnel Responsibilities

Tasks prior to a clinic visit

- Remind every patient of appointments via phone call or mail.
- Review charts to list items to address during the visit.

Tasks during a clinic visit

- Verify patient's current contact information and current insurance status.
- Orient new patients.
- Assist with insurance gaps (e.g., teaching about need for referrals, help with insurance application or ADAP).
- Assess other barriers to care and psychosocial needs.
- Assess medication adherence.
- Teach and provide behavior change counseling about medications and self-care.
- Assess ongoing transmission behaviors.
- Teach and provide behavior change counseling about transmission behaviors.
- Educate about clinical trial opportunities (if applicable).
- Make referrals for psychosocial services.
- Make referrals/appointments for medical, dental, mental health care

Tasks following clinic sessions

- Make follow-up calls regarding new medication regimens or referrals.
- Call or mail correspondence to patients who missed their visits.
- Help patients overcome barriers to clinic attendance.
- Extract patient data and enter it into the information system, or upload data from an electronic medical record into reporting or data management software.

Support Services and Linkages Needed for HIV Care

Case management and support services enhance clinical care

Case managers assist patients in accessing the range of services and entitlements that can help them succeed in treatment. This may include helping patients apply for insurance; access support groups; access supplemental food, housing, homemaker, and other concrete services; and access mental health and substance abuse services. Excellent case managers also help motivate patients.

Traditionally, case managers should perform periodic assessments of clients' needs and update their comprehensive care plans at least every 6 months. Home visits can be very useful as part of the assessment. Some case managers or their agencies will provide certain direct services themselves; these may include short-term counseling, transportation for clinic visits, accompanying patients to clinic visits, and providing financial assistance for specific emergencies.

In many localities, HIV case management has been a service provided by community-based agencies. With the evolution of the PCMH concept, and a stronger need to have health care coordination for patients with multiple complex medical conditions, the approach to HIV case management is evolving. A new, and perhaps more useful, model is one in which community-based case managers provide linkage and follow-up for community-based services such as health insurance, transportation, housing, food security, income, and psychosocial support generally. These case managers often have training in a psychosocial discipline. At the same time, medical case managers, usually nurses, provide coordination of medical care services, with support for appointment and medication adherence, side-effect management, self-care, and clinical monitoring between office visits.

Close coordination between clinic staff and case management is important for avoiding duplication of efforts and services. Periodic case conferences between clinic staff and case managers are ideal. Written communication, for example, when sharing case management care plans, can be useful. Case management agencies and clinical sites need to obtain written consent from patients to share the information that allows coordination.

Creating useful linkages with community-based services

Clinics can develop relationships with community-based case managers or directly with providers of specific services, such as mental health, substance abuse, or housing services. Personal contact between staff members of clinics and outside agencies is important for establishing the relationship, and ongoing contacts are necessary for coordination. Community organizations often are pleased to give in-service education to clinic staff personnel in order to streamline the referral process. Clinics should make their expectations clear to community-based agencies. Clinics can function as advocates to ensure that their patients receive the attention and services for which they were referred. Periodic interdisciplinary meetings of clinic staff with representatives of community-based agencies, including case managers, are very useful.

Consumer involvement in HIV clinical care

Many clinics have created patient (consumer) advisory groups to participate in planning and quality management. The role these groups take depends on the specific clinic; some advisory boards educate themselves about clinic issues and provide expert input to clinic processes. Other boards act more as social event or support groups. See chapter *Supporting Patients in Care* for further information.

Enhancements to increase the HIV clinic's effectiveness: information and support

Clinics can enable patients to better care for themselves by providing them with information about HIV and by helping to build a community among them.

Much information is available for patients, including publications on medications, side effects, and adherence. Many clinics display HIV-related education materials, including information on safer sex practices and birth control; many also provide male and female condoms with instructions about their use. In some clinics, a separate area for educational materials may help clients maintain confidentiality. Free educational materials are available from federal and state HIV websites, and the pharmaceutical industry also produces some appropriate materials.

Many ASOs and clinics host support groups for interested patients. Participation must be voluntary, and only patients who are comfortable with revealing their status to other patients will be willing to participate. Some support groups target specific populations. Groups may be more effective if an experienced counselor or mental health provider leads them.

Some clinics hold classes on HIV and adherence. Other clinics provide periodic symposia to keep patients up to date on treatment advances. Clinics serving pregnant women and parents may include classes on birth preparation and parenting. For clinics that have a community advisory board, the board can be the organizing force for these community updates. Both public grants and funds from the pharmaceutical industry may be used to support these events.

Some youth-oriented clinics arrange social events and outings for their patients. Programs for children or mothers may provide support

services for both infected and affected children, ranging from formal psychological care to supportive recreational activities after school or during school breaks.

Medical Information Systems: Tools for Enhancing Care

Medical information systems may include Practice Management Software (PMS), Electronic Health Records (EHRs), and Personal Health Records (PHRs). These three types of software may be available as a suite or as separate products that can be linked, although the linkage of separate products sometimes is challenging. Software products may be designed to run on one desktop computer in a small practice or on a computer server that can be accessed by many users simultaneously, or they may be based on the Internet and managed by the vendor. In all instances, backup of the data and maintenance of confidentiality and compliance with *Health Insurance Portability and Accountability Act* (HIPAA) rules and other laws are necessary.

PMS refers to software used principally for scheduling and billing; it includes information on patient demographics, insurance or payer, attendance with appointments, diagnoses, and sometimes other information. This is very useful in tracking clinic productivity and patient adherence with visits, and in developing an overview of a patient population and understanding the finances of a practice. PMS software can provide data regarding some quality measures, because services such as vaccinations and procedures performed within the practice can be tracked easily.

EHR refers to software used for clinical care, as a substitute for or supplement to a paper medical record. Providers enter their notes into these systems, and clinic staff document procedures and interventions performed in the office. With many systems, prescriptions may be written within the system and sent to pharmacies electronically or by fax,

diagnostic tests may be ordered, and test results may be sent electronically into the EHR for clinician review and action. Paper documents often can be scanned into the system so that hard copies of outside reports can be included in the medical record. EHRs that substitute for paper records can reduce issues of storage, retrieval, and access to paper charts once the transition is complete.

EHR refers to software that the patients can access to see part or all of their medical record. These systems are designed to empower patients as members of their health care team, to provide detailed information to them, and to promote interaction between the consumer and provider.

Potential advantages of EHRs

In an era of transformation of the U.S. health care system, much is said about the potential of these software products to increase efficiency and reduce errors. While this potential is real, substantial effort and investment is required to deploy and maintain systems that are useful to clinicians, administrators, and payers. An EHR for a small office or one that is deployed only in an HIV program can be managed fairly easily, and some products developed specifically for HIV care are available. An EHR for a large organization, such as a multispecialty group, is more complex and requires much more planning, training, maintenance, and sometimes customization to meet the needs of all the users.

Success in EHR implementation is greater when the users are involved in the selection and implementation of the system.

Commercially available systems run on servers for large organizations may provide options for customization; however, customization greatly increases the cost and complexity of installing the software updates that are likely to be required.

EHRs may be text based (such as the system used by the Veterans Health Administration) or data based. Text-based systems are often quicker to learn; however data-based systems may provide more information for quality and program management and reporting needs and may be more useful for billing functions. Some EHR software packages are available at no cost (such as the Veterans Health Administration system and other open-source software) whereas others are available commercially and are maintained by vendors.

Once fully implemented, EHRs are expected to improve quality by improving communication and coordination among clinicians, reminding clinicians about standards of care and the timing of health maintenance or monitoring, avoiding errors associated with handwritten notes or prescriptions, documenting prescriptions, and providing warnings on potential drug interactions or hazards associated with specific diagnoses. EHRs are expected to lower costs by reducing the expense of maintaining paper records and by reducing duplication by sharing prescriptions, test orders, and test results among all users. EHRs can provide both process and outcome data for monitoring and for quality improvement activities (see chapter *Quality Improvement*), and data for Ryan White grantee reports. They also may make it easier for practices to fulfill and document adherence with the standards of payers.

Medicare and other payers are currently offering incentives for specific uses of EHRs, for example when at least 75% of prescriptions are sent electronically (because this is thought to reduce prescription errors) and for other types of “meaningful use” that are thought to improve the organization of care and adherence with clinical care standards.

Cautions

These software packages are complex entities that require substantial staff time and effort, hardware purchase and maintenance, training, and modifications in workflow. EHRs are not simply replacements for paper records; effective use involves changes in the work habits of clinicians. Successful implementation of an EHR system requires working with the end users as the system is developed so that reasonable compromises and accommodations can be made. Choices must be made regarding both the software and the hardware to be used (e.g., a laptop computer used by a single clinician in multiple examination rooms versus a fixed desktop computer in each room). An EHR system that must share data with another system such as a hospital EHR or a laboratory reporting system can be very complex and require substantial investment of time and money, even when the different software systems use compatible data standards. Effective implementation often occurs over the course of years. Implementation of EHR systems is not a panacea and will not solve all health care system problems, but use of EHRs is likely to be a necessity for functioning in the evolving systems of health care finance and reimbursement, as well as an essential tool for monitoring and assuring quality of care for the individual patient and at a population level.

Ensuring that patients receive necessary services at clinics without EHRs

At clinics in which paper charts are in use, forms, checklists, and flow sheets can be designed to remind providers of care standards, simplify data collection, and serve other purposes as well. Sample forms for initial and follow-up visits are posted on the HRSA HIV/AIDS Bureau (HAB) website (www.hab.hrsa.gov). They include reminders regarding clinical standards, reminders of services required for billing levels, checklists built around definitions used by Ryan White

HIV/AIDS Program grantees for reporting to HRSA, and other data for quality management. These instruments often can be used to generate reports to individual providers. Staff members may find it challenging to adjust to using new forms; however, using checklists often saves time by listing required elements of the visit and by reducing the amount of writing. Including representatives from clinical, data, and quality management staffs in the process of designing forms increases the acceptability of new forms or procedures.

Effective Management of HIV Programs

Managing a program with all the components described in this chapter is challenging. For enhancing communication and advancing the clinic's objectives, staff meetings are important. Smaller organizations may include the entire staff at monthly meetings, whereas larger organizations may have staff meetings less often, such as on a quarterly basis. Some larger organizations find it useful to have a monthly interdisciplinary meeting of program leadership, with representation of the different disciplines or program components, such as nursing or clinical care, psychosocial support, data and quality management, behavioral health, research, finance, administration, satellite services, and consumers. These coordinating meetings provide an opportunity for personnel from each discipline to update others on current activities, challenges, successes, and initiatives. They also provide a regular forum for updates on fulfilling grant-related work plan tasks and reviews of financial reports. Minutes of the meetings, which include decisions taken and assignments made, should be prepared and circulated to participants; minutes should be reviewed at the subsequent meeting and reports on assigned tasks should be delivered.

These larger organizations also may have monthly meetings by discipline, for example, comprising the nursing or clinical staff, to transmit information from the larger meeting and to coordinate the discipline-specific activities. In smaller programs, quality management may be part of monthly staff meetings whereas in larger programs it is more practical to have a separate quality management committee (see chapter *Quality Improvement*).

HIV programs often are contained within larger health organizations, and may be outliers with regard to the patients they serve and other features. It is important for program leadership to build and maintain support within the host institution. Where applicable, this may involve reminding the host institution of the grant or other funding the program generates. HIV programs often are on the forefront of innovative health care delivery, for example, in adopting quality management approaches and using other data to assist program management, incorporating EMR and PHR systems, implementing interdisciplinary care that integrates medical care with behavioral health, using a chronic care model or providing a medical home for patients, and linking with community-based programs. An important task for HIV program leadership is making the host institution feel proud and supportive of the HIV program itself.

Suggested Resources

- National Resource Center of the AIDS Education and Training Centers (www.aidsetc.org)
- National HIV/AIDS Clinicians' Consultation Center (www.nccc.ucsf.edu) (free and confidential advice from a multidisciplinary team):
 - **National HIV/AIDS Telephone Consultation Service (Warmline):** 800-933-3413 (*Monday-Friday, 9 a.m. to 8 p.m. eastern time*)
 - **National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline):** 888-448-4911 (*9 a.m. to 2 a.m. eastern time/7 days a week*)
 - **National Perinatal HIV Consultation and Referral Service (Perinatal Hotline):** 888-448-8765 (*24 hours a day/7 days a week*)
- New York State AIDS Institute guidelines (www.hivguidelines.org)
- HRSA Target Center website (careacttarget.org)

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Quality Improvement

Bruce D. Agins, MD, MPH

Improving Systems of Care:

“Every system is perfectly designed to achieve exactly the results that it achieves.”

Quality improvement (QI) is an important strategy to improve systems and reduce variation in delivery of care and services so that patients receive the right care every time they visit clinic, increasing the likelihood of their achieving the expected benefits and outcomes of care. As we move forward to end AIDS in the United States and meet the goals of the National HIV/AIDS Strategy, QI becomes an even more important methodology to implement in local systems through evidence-based interventions that can improve care, linkage, and retention.

Quality improvement has become a fundamental component of the HIV service delivery system whether care is provided in dedicated or integrated delivery models. Clinical quality management is a legislative requirement for Ryan White-funded programs. Many clinicians have learned the basics of quality management, which are reinforced through Maintenance of Certification programs directed through medical and specialty boards. Many clinicians not only are participating actively in QI activities, but also are leading improvement efforts in their clinics. Moving beyond the basics, however, remains a challenge for clinicians who have limited time to participate in activities not related to direct patient care. Yet, focusing on quality can reveal important phenomena in the operational processes and delivery systems of the clinic of which the leadership is unaware and may reveal factors that explain why intended outcomes are not always being realized. Additionally, the participation of clinicians in clinic-wide QI improvement activities is often a critical ingredient for their success.

Increasingly, QI work in the HIV field is directed toward achieving important health outcomes such as HIV viral load suppression, retention in care, and reductions in readmissions and emergency department utilization. Simple subanalyses of basic performance data also may reveal disparities in how care is being provided to different patient groups in the clinic, for example, according to age, gender, or race/ethnicity. Careful assessment of the social determinants of health also may show which patients need to be targeted in improvement activities. At the same time, advances in health information technology have made it easier to generate data for performance measurement and to produce simple reports that can be used for improvement activities.

This chapter will review the basics of QI; an appendix at the end of the chapter illustrates concepts with examples of more advanced improvement work. The *Health Resources and Services*

“Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

(Institute of Medicine, 1990)

“All health care organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable.”

(Institute of Medicine, 2001)

“Health care interventions that are known to work and save lives are not being implemented for every patient every time.”

(Salzburg Seminar Statement, 2013)

Administration HIV/AIDS Bureau Performance Measures chapter in this manual presents a national quality initiative developed by the U.S. Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) for Ryan White HIV/AIDS Program-funded clinics; HRSA's Performance Measures can be incorporated into the quality improvement programs of local clinics.

The fundamental concepts of QI have evolved over the past century to include the following:

- QI provides an opportunity to solve problems that are part of the system and do not depend on one individual.
- Reducing variation in performance will allow consistent delivery of the best possible care.
- Improving processes within the health care delivery system will lead to improvements in outcomes.
- Data are the key to identifying problems and measuring change.
- Focusing on performance measurement and improvement usually stimulates employees to maximize their performance.
- Team-based problem-solving techniques lead to better care and promote a positive working environment.
- Testing changes will identify solutions that work and eliminate putting ineffective solutions into practice.
- Consumers play a pivotal role in providing the “end-user” perception of the quality of the services delivered; their active participation in the quality management program strengthens improvement work and leads to better results.

In addition, documentation of QI activities helps to demonstrate institution-wide compliance with accreditation responsibilities and funding requirements. Data generated from the clinic's QI program showing improvements over time demonstrate to constituents that the program is successful and help to justify its funding. These data also build the evidence base for determining which interventions are successful and can be disseminated to achieve large scale change.

Finally, quality management systems that are dependent on single individuals will not last when these key players leave the clinic or are absent for long periods, whereas a fully functioning QI program that involves staff working in teams with a clearly defined infrastructure will keep going when even the most dynamic individuals depart.

This chapter will articulate the core principles of QI and describe activities that can be easily adapted into the HIV ambulatory care setting to implement a sustainable quality management program.

Introduction to Quality Improvement

QI includes regular measurement of processes and outcomes to analyze the performance of the system of care with the ultimate goal of reducing variation in care delivery. It involves the implementation of solutions to improve

care and the monitoring of their effectiveness in achieving optimal health outcomes for patients. Ongoing cycles of change and remeasurement are implemented to test and try different ideas to determine which practices result in improved care. QI activities in clinics can range from a single team focusing on improving one aspect of care to a

comprehensive QI program with many teams working on a wide variety of improvement projects, with a well-established plan and an oversight committee.

The methods of QI are based on core principles that are readily translated into a practical approach and integrated into the clinical care delivery system (see Table 1). Successful implementation of QI involves actions at two levels: the QI activities and the HIV program processes that provide the structural backbone for them.

Table 1. Core Principles of Quality Improvement
• Emphasis on systems of care: improve processes that link to desired outcomes • Focus on the customer: understanding patients' experience in the clinic will identify areas that are important for improving care • Measurement: collect and use data to improve care • Involvement of participants: encourage direct participation in teams by those individuals who implement the processes being evaluated

Measurement and Management
Are Not Sufficient

Although it is the bedrock for improving care, measurement alone is not sufficient to improve quality. A common pitfall in implementing QI programs is to rely solely upon performance data, the medical or program director's interpretation of it, and one person's decisions about how to make changes. Successful improvements occur most often when staff members from the systems being assessed work together in teams. When they are engaged in the process, staff members are more likely to generate ideas for improvement and to accept changes. Staff review of improvement charts (e.g., see Figure 1, below) generates pride and a sense of accomplishment based on members' participation in the QI work. These charts may be posted on bulletin boards in common areas of clinics so that everyone can view them.

QI Personnel

The size of the clinic will determine who participates in quality-of-care activities. In small HIV clinics with a primary care provider, case manager, nurse, and support staff, most of the staff members are involved in all aspects of QI work. Larger institutions usually establish an HIV Quality Committee that includes senior management of the HIV clinic, designated QI staff members if there are any, and other key players who work in the clinic. A member of this committee represents the group in the agency-wide QI committee. The Quality Committee identifies the priorities for improvement or agrees to pursue the priorities identified by staff members or patients in the clinic. The Quality Committee also charters improvement teams and identifies potential members who are key stakeholders in the process under investigation. In a small clinic that has only a handful of staff members, all clinic personnel may participate in the quality management program and in QI activities, although perhaps in a less formal way than in larger clinics.

Team Membership and
Responsibilities

Teams are formed to address the specific care processes or systems that are targeted for improvement. Team members should be selected to represent the different functions involved in these processes or to represent the components of the system under focus. The size of a team varies according to the size of the clinic and the process under study. In small clinics, the few dedicated HIV program staff members may constitute the project teams, with added representation from different departments as needed (such as from the laboratory, or from other medical disciplines). In larger clinics, teams often include 6-10 members. Membership should include representatives from the different groups in the clinic who are involved in the care process. In

addition to the clinical and case management staff, scheduling clerks and medical records personnel are often important participants, especially when follow-up appointments and documentation are components of the care process or have been identified as areas that need to be improved.

Teams sometimes struggle with engaging physicians in their QI activities. Increasingly, physicians have overcome their reluctance to join process improvement teams, especially since more sophisticated data systems and comparative reports have become available to focus interest on improving care that does not meet standards or falls below mean performance rates. Moreover, physicians are now required to directly engage in practice-based learning and improvement to satisfy requirements for maintenance of professional certification. Studies of physician performance have demonstrated that participation in QI activities enhances job satisfaction and reduces work-life stress.

Involving consumers in QI project teams enhances the work of the team. Consumers who are involved in the clinic's community advisory board often are natural leaders and have a good grasp of clinic processes. Their feedback on the experience of care delivery can reveal areas that need improvement. They know the bottlenecks and can inform the staff how long a clinic visit lasts, whether assessments truly occurred, and whether behavioral interventions are effective. Their ideas about what improves care often diverge significantly from those generated by providers and may not even be recognized unless consumers participate directly in discussions about the system.

Teams are expected to analyze clinical processes, identify areas of change, implement tests of the changes, review data assessing the change, and ultimately make recommendations about which improvements should be adopted in the clinic.

Data Collection

Selecting Measures

Evaluating measurable aspects of care can help in determining the extent to which a facility provides a certain element of care. Quality measures should be based on standards or guidelines, meet the primary goals of QI, and reflect priorities specific to the community and the clinic. In addition, they should represent processes where changes are feasible. For example, in HIV clinics where the population consists of a large number of women, indicators may include rates of routine cervical cancer screening, rates of preconception counseling, or other aspects of care specific to women. In clinics that care for a high volume of patients who have been treated with antiretroviral therapy (ART) for a long time, measures may focus on rates of virologic suppression, screening for adverse effects of antiretroviral medications, and resistance testing. As we focus on our strategies to maximize community viral suppression, measures of linkage to care, engagement, and retention in care become priorities.

Some measures should be selected by soliciting input from patients who attend the clinic (see Table 2). Staff members also often know what aspects of care would benefit from being measured and improved, and they should be consulted to determine priorities. If routine data collection systems already exist in the clinic, data should be reviewed to determine which components of care would be prime candidates for improvement.

Table 2. Methods for Obtaining Input from Patients

- | | |
|-------------------|----------------------------------|
| • Suggestion box | • Consumer advisory board |
| • Surveys | • Participation on QI teams |
| • Exit interviews | • Membership on the QI Committee |
| • Focus groups | |

On a national level, the HRSA HIV/AIDS Bureau (HAB) has developed HIV/AIDS Performance Measures for monitoring the quality of care provided in Ryan White HIV/AIDS Program-funded clinics. These measures emphasize important areas of HIV care that are linked to the goals of the National HIV/AIDS Strategy and that are also endorsed by the National Quality Forum, which confers eligibility for inclusion in Meaningful Use criteria and other provisions of the Accountable Care Act that are important for both measuring care and are linked to enhanced reimbursement programs. They form a core package of priority indicators that can be enhanced by those that are identified through analysis of local data, or identified by local stakeholders. See chapter *Health Resources and Services Administration HIV/AIDS Bureau Performance Measures* for these.

Ideally, a balanced set of measures should be selected. Different ways to categorize measures might include the following:

- Structure/process/outcome
- Treatment/care (non-ART)/prevention/nonclinical service
- Provider/consumer/funder driven
- Aspects representing overutilization, underutilization, or misutilization of services

Developing and Quantifying Quality Measures

Three major activities constitute the process of developing performance measures:

- Defining the measurement population
- Defining the measures
- Developing the data collection plan

The measurement population is defined by determining factors such as the location of care being studied, whether both men and women are eligible, the applicability of the measure to various age groups, whether any

clinical conditions are necessary to determine the applicability of the measure, the number of clinic visits by the patient, and amount of time the patient has been in care.

After the population is defined, the measure needs to be defined. The measure should be objective and should address specific aspects of quality care. It also should have a straightforward, dichotomous answer. For each measure, specific criteria must be developed to define the “yes” response and the “no” response (see Table 3). This often involves deciding the time period during which an activity has been performed. For example, a measure that evaluates viral load monitoring must include the frequency with which that test should be performed. One simple way to construct this measure would be to ask, “Was viral load measured within the past 6 months?”

Table 3. Examples of Specific Measures with Definitions of Responses

Measure	Definition of Measure	Yes/No Response
HIV Viral Load Monitoring	Was HIV viral load measured in the past 6 months?	Yes: Viral load testing was performed No: Viral load testing was not performed (or the test was done but results were not documented)
HIV Viral Load Suppression	Was the HIV viral load <200 copies/mL at the most recent test during the past year?	Yes: Viral load was <200 copies/mL No: Viral load was >200 copies/mL

Several elements of care should be measured simultaneously, whether abstracted from medical records or analyzed through administrative databases. Measures reflecting aspects of patient management should be selected, as should those involving different populations. Measures also should be selected to evaluate various components of the health care system, such as the components of the chronic disease model.

Clinical measures should include those that affect a large proportion of the patient population, such as whether comprehensive mental health screening has been performed.

The data collection plan includes determining the source of information (e.g., whether medical records or an electronic database will be used), how the data will be recorded, who will record the data, and how a data sample will be selected. A representative sample will allow inferences to be made about the overall clinic population based on observations of the smaller sample. Some form of random sampling should be used, either by using a random numbers table or by selecting every n th record from the list of eligible patients.

If electronic health records (EHRs) are used, sampling will not be necessary.

Careful planning is required, however, to ensure that the measures are included in the electronic system, and that the EHR database is constructed to contain the elements required in the reports generated by the quality evaluation queries.

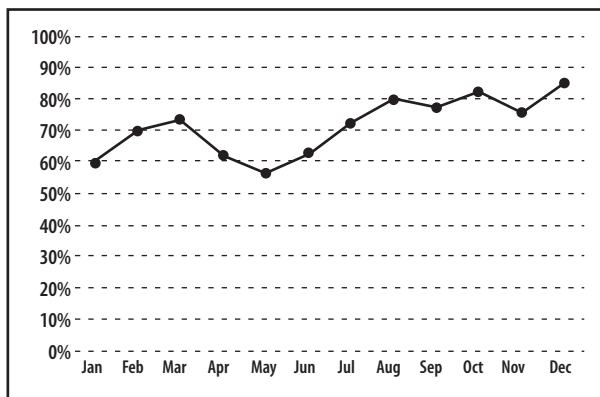
A common pitfall at this point is to think of the measurement sample as a research project. For the purposes of QI, a sample needs only to be current, representative, and readily obtained (i.e., sample size calculations and the achievement of statistically significant results are not necessary).

Analyzing and Displaying Data

Data should be reviewed and distributed to all members of the team and others involved in the care process under evaluation. When possible, data should be displayed in graphic format. After data from multiple time periods have been collected (e.g., percentage of patients with HIV suppression), a simple line graph (run chart) can be constructed with each point representing a performance rate (percentage) for a given period of time. This usually is the simplest and most effective way to show performance data (see Figure 1).

Identifying Targets and Implementing Improvements

Figure 1. Percentage of Patients with HIV Viral Load Suppression, by Month



Adapted from *Measuring Clinical Performance: A Guide for HIV Health Care Providers*. New York: New York State Department of Health AIDS Institute. April 2002.

After the project team has reviewed the data, it must decide where opportunities for improvement exist. The first step in this process is to investigate the care process in greater detail. Several techniques are used to accomplish this goal. The simplest is brainstorming, in which key stakeholders offer their suggestions as to which processes are the best candidates for change. Another easy method is flowcharting, in which the group breaks down the process into its components to identify how it is coordinated and how its parts fit together. A fishbone diagram, or cause-and-effect diagram, may aid in exploring and displaying the causes of a particular problem (Figures 2 and 3). It often helps for staff members to consider factors potentially influencing a process that are not obvious, and to help sort out those factors that are external to the clinic and those that are internal. A *driver diagram* is a visual tool to help understand and prioritize factors that drive desired outcomes, which are called the “primary outcome.” *Primary drivers* are the factors that drive the primary outcome. *Secondary drivers* are subsets of factors that influence the primary drivers.

Figure 2. Sample Fishbone Diagram

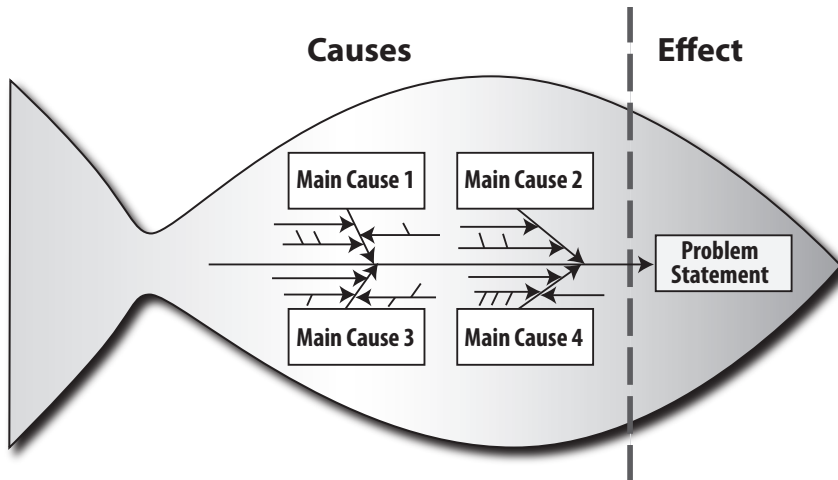
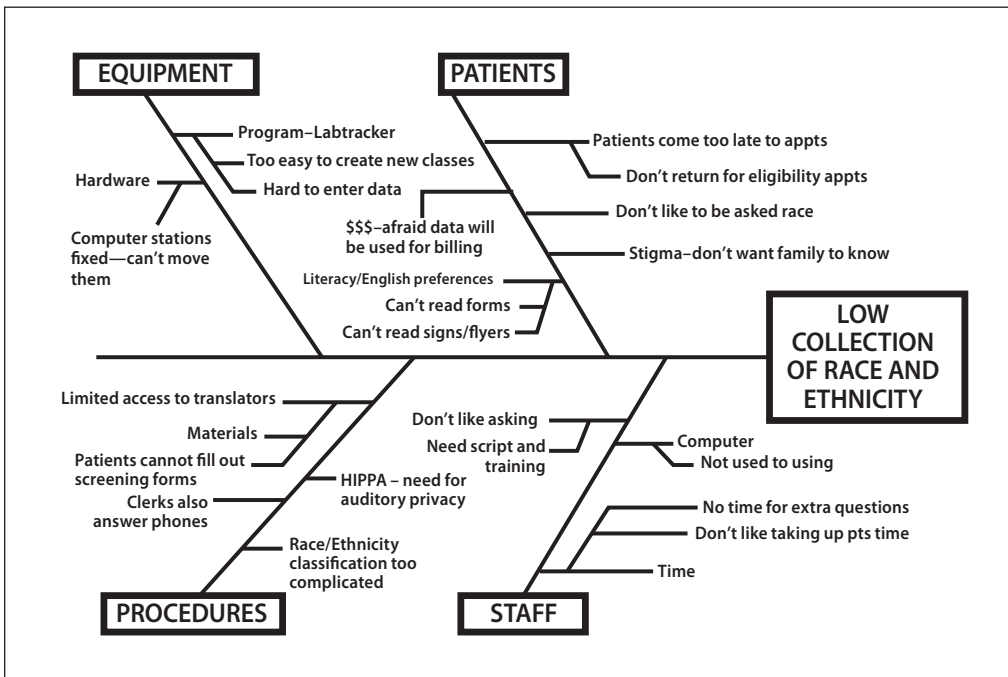


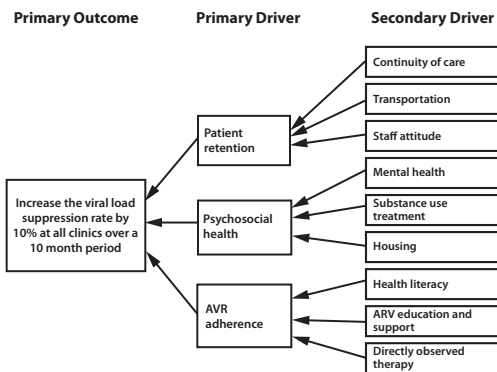
Figure 3. Fishbone Diagram: Low Collection Rates of Race and Ethnicity Patient Data



Used with permission from Kathleen A. Clanon, MD; Low-Income Health Program of Alameda County.

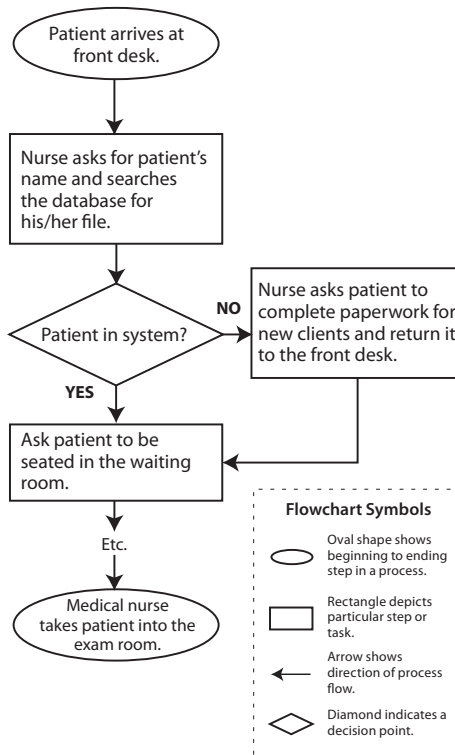
The driver diagram, which can be generated through discussion with stakeholders, is a particularly effective strategy to identify processes that may be key areas to target for improvement goals that will affect the ultimate outcome. For example, if retention in care is the desired outcome, housing status may be a primary driver that, in turn, is affected by access to factors such as entitlements, mental illness, substance use, or health literacy, which then are secondary drivers that, when addressed through QI activities, will affect the primary driver and ultimate outcome. Framing this larger picture of the system that is being improved may be extremely useful for participants at different levels who may be involved in only one aspect of the QI initiative, as well as for those only involved at the macro level who do not recognize the role of the processes being prioritized for ground-level work. An example of a driver diagram focusing on viral load suppression is shown in Figure 4.

Figure 4. Driver Diagram: Viral Load Suppression



Then, the areas that would be most likely to benefit from improvement are selected for change (see Figure 5) and tested in the Plan-Do-Study-Act (PDSA) cycle (see Figure 6). See “Appendix,” below, for examples of QI projects conducted in HIV clinics.

Figure 5. Sample Flow Chart



Source: U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau. *A Guide to Primary Care of People with HIV/AIDS*. Bartlett JG, Cheever LW, Johnson MP, Paauw DS, eds. Rockville, MD: U.S. Department of Health and Human Services; 2004:145.

Figure 6. Plan-Do-Study-Act Cycle

Plan: Plan the change and collect baseline data

Do: Test the change and collect data

Study: Analyze the data

Act: If the change did not improve the process, try another idea. If the change resulted in improvement, adopt the change, monitor the process periodically, and spread the change throughout the clinic



Source: U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau. *A Guide to Primary Care of People with HIV/AIDS*. Bartlett JG, Cheever LW, Johnson MP, Paauw DS, eds. Rockville, MD: U.S. Department of Health and Human Services; 2004:145.

Even if evidence-based criteria on how to improve desired outcomes exist, how they are implemented varies according to the local context. Thinking through the “hows” of an intervention – who will do it, when during the care process it will be done, where it will be done – are important questions to ask as the test of the intervention is planned. After a change has been selected, a test of the change can be quickly implemented and evaluated. A limited implementation of the proposed change can be tested – perhaps with just a few subsequent patients, or those attending on the following day, or those seen by a particular clinician. If the small change does not work, another change can be selected and implemented quickly. If the change is feasible and improvement is noted, it can be adopted more widely, before formal remeasurement occurs, and a regular period of remeasurement can be adopted. If the change was not

successful, then another one can be chosen and tested. Occasionally, multiple changes may be tested simultaneously or on different days of the week.

Many different approaches to QI exist and can be implemented successfully. However, sometimes just stepping back to refocus on the three basic questions of the model for improvement presented by Langley et al. (see “Suggested Resources,” below) can effectively guide QI activities. These are as follows:

- What do we want to accomplish?
- How do we know that a change will result in an improvement – in other words what measure will we use to demonstrate whether our improvements worked?
- What kinds of changes can we test that will result in an improvement?

Establishing Systems to Support QI

The key to sustaining QI in the clinic is development of an infrastructure that supports ongoing QI activities. The central components of this infrastructure include the following:

- A QI plan with goals and a process to prioritize these goals
- A work plan that clearly defines steps, sets timeframes for completion, and identifies responsible parties
- An organizational framework that displays clear lines of accountability for QI in the organization
- Commitment of senior management staff to support the program, allocate resources, and celebrate its successes
- Creation of a culture that supports quality in the program and that values the activities of QI as part of the regular work of the clinic (see Table 4)

Table 4. Tips for Promoting a Culture of Quality Improvement: Integration of Quality into the Regular Work of the Clinic

- Educate staff members about QI and provide them with the skills to participate in QI activities.
- Consistently articulate the values of QI in staff meetings.
- Display QI data and storyboards (simple statements and visual representations that describe a problem, the evaluation process, the proposed changes, and their implementation, and display the results).
- Celebrate successes.
- Provide opportunities for all staff members to participate in QI teams.
- Reward staff members through performance evaluation for their contributions to the QI program.
- Participate in activities with peers to discuss QI activities, share data and learn about successful strategies to improve care.

- Patient participation, to share experiential knowledge and inform QI program development
- Establishment of a formal QI committee to oversee quality activities, monitor the quality plan, and evaluate its effectiveness

The regular, ongoing work of the QI committee, supported by the clinic leadership, constitutes the backbone of the infrastructure that supports ongoing QI activities. The committee oversees the dynamic process of planning, implementation, and evaluation that involves the following:

- Analysis of data from the QI projects
- Solicitation of feedback from participating staff members and from patients
- Decision-making based on the information from its analysis

These contribute to sustaining the QI program and its activities in the clinic.

Sustaining Improvements

Sustainability is probably the biggest challenge that clinics face in the field of QI. All too often, improvements do not last after initial projects are completed, because the structure and culture to support QI are not present or are not supported. The challenge of sustainability therefore is twofold: to maintain the successes of QI work and its clinical outcomes, and to maintain the systems of QI and keep the QI program vital. By asking questions about how care systems can be improved and how QI activities are progressing, clinicians play an important role in both catalyzing and supporting QI activities.

Appendix: Case Examples of Quality Management Initiatives

Using QI to Improve ART Management and Virologic Suppression

In one community health center, nearly 10% of patients on antiretroviral therapy (ART) were not virologically suppressed. The clinic had adopted a strategy of developing a specific ART management plan for each patient being treated. Review of the charts of the 45 patients not suppressed showed that only 40% had a plan in the chart. Only 20% had a plan that was executed. Improvement goals were set for each step, to increase from 40% to 90% for documentation of an ART management plan and from 20% to 75% for execution of the plan. Over the course of a 4-month period, clinicians and support staff were educated about the plan and decision-support tools were created, including an algorithm showing key decision points for plan development and execution with corresponding prompts in the clinic database. Visit forms were revised to incorporate data fields specific to the ART plans. Reminders also were created. All

changes were implemented through small tests of change with formal remeasurement in 6 months; this showed that 100% of patients had a plan in their charts and that 71% of them had it executed. Continued monitoring showed a dip in performance 4 months later to 88% and 60%, respectively, but with gains restored 3 months subsequently to 100% and 65%, respectively. Vigilance and reaffirmation of the main steps have been keys to maintaining performance. The fields are now being added to the new clinic electronic medical record (EMR) system with automatic prompts based on changes in viral load values.

Another clinic focused QI efforts directly on improving rates of virologic suppression. Data on the HIV viral loads of each specific provider were generated to show comparative rates as a stimulus for improved performance on the part of individual providers. ART regimens were reviewed for their appropriateness, and renewed education about antiretroviral drug combinations and resistance monitoring was introduced. The clinicians reviewed their own patient lists each day. Patients who were not virologically controlled were contacted by phone by the clinician or a nurse. Nurses eventually were assigned directly to the primary care team to facilitate communication with patients and ensure that specific issues raised during phone conversations were addressed during clinic visits. Adherence problems were particularly common, and were addressed through these multiple contacts. Reasons for adherence lapses were identified, which allowed for more effective targeting of service interventions with specific patients, including substance use and mental health service referrals, regimen switching, and targeted adherence interventions. The individual providers improved their patients' rates of virologic suppression from 45% to 62%. Review of suppression rates also showed that a subset of patients remained controlled and did not require quarterly monitoring. A decrease in visit frequency was possible for this

group, reducing overutilization of services and unnecessary costs.

Another federally qualified health center with multiple sites struggled with its rates of viral load suppression that ranged from 0% at one small clinic to 47% at another. The medical director was new to the clinic and undertook a thorough investigation of the problem with his team. First, they reviewed the results and matched them with their clinical data and knowledge of the patients. Based on that step, they sent specimens to another lab and found that there had been a major error in the processing of specimens. Once this special cause of their findings was corrected, their rates increased to a range of 50-67%. Then, the team undertook a more thorough investigation of their system and implemented a package of changes based on their analysis and discussions with their patients. Among the improvements the team introduced were the development of a group of adherence educators among their staff, case conferencing *together with the patient* to discuss the results and identify particular issues and concerns that could then be addressed (*managed problem-solving*), biweekly team case conferencing, home visits and phone calls as needed in between visits and preparing provider-specific data results to generate additional incentives for providers to intensify their efforts to work with their patients to decrease viral load. Rates have steadily improved up to the 70-80% range in the short run as the clinic team awaits ongoing measurement results to determine whether it can hold its gains and improve further.

Using QI to Eliminate Disparities

The quality committee in another clinic wanted to determine whether the clinic's performance was consistent across all patient groups and arranged to have the clinic's patient data sorted by race, ethnicity, and primary language spoken. This revealed that data about race, ethnicity, and language spoken were not recorded in a high proportion of

patient records. The team invited patients from their community advisory board to attend a staff meeting where a fishbone diagram was developed to identify potential causes of the poor collection rates of these patient data. Potential reasons were identified in all categories: equipment, patients, procedures, and staff (see Figure 3). A flow chart was developed to identify the sequential steps of data collection. A training program for intake staff was developed, resulting in an improvement in collection of these data to 85%.

Subsequent analysis showed that only 54% of African-American patients and 68% of Latino patients had suppressed HIV RNA whereas white patients had a suppression rate of 75%. A focus group with Spanish-speaking patients revealed that these patients were not getting enough information about medication and its side effects. The QI team decided to aim for an improvement in virologic suppression rates to 75%. A number of changes were implemented and tested throughout the clinic including the addition of peer adherence counseling, using teach-back by nonphysician staff to facilitate adherence problem-solving, along with medication reconciliation. With these new interventions, virologic suppression rates improved to 71% for African-Americans, 80% for Latinos, and 81% for whites. With ongoing QI activities, suppression rates have subsequently increased for all groups and the gaps between groups has narrowed. Ongoing changes aim to narrow these gaps even further.

Finally, in another clinic, analysis showed that major differences in viral load suppression were noted among patients who were stably housed and those who were not. To tackle their low rates, this agency intensified its relationship with their local housing agency and began to investigate other resources in their community to provide transitional housing services.

Suggested Resources

- Chassin and Loeb. *The Ongoing Quality Improvement Journey: Next Stop, High Reliability*. Health Affairs. 2011 30, no. 4:559-568.
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- Quinn M, et. al. *The Relationship Between Perceived Practice Quality and Quality Improvement Activities and Physician Practice Dissatisfaction, Professional Isolation and Work-Life Stress*. Med Care 2009;47: 924-928.
- Scholtes PR, Joiner BL, Streibel BJ. *The Team Handbook (3rd Edition)*. Madison, WI: Oriel; 2003.

Websites

HIV-Specific

- **National Quality Center (NQC)** (www.nationalqualitycenter.org) Provides no-cost, state-of-the-art technical assistance to all Ryan White Program-funded grantees to improve the quality of HIV care nationwide. Website includes training and technical assistance materials
- **The HRSA HIV/AIDS Program: Quality of Care** (hab.hrsa.gov/deliverhivaids/qualitycare.html)
- **HIV Clinical Resources** (HIVGuidelines.org) Quality of Care Section (NY AIDS Institute) (www.hivguidelines.org/quality-of-care)
- **Health Care Improvement Project: HIV/AIDS (USAID)** (www.hciproject.org/improvement_topics/HIVAIDS)

General QI Websites

- **Institute for Healthcare Improvement** (www.ihl.org/Pages/default.aspx)
- **International Society for Quality in Health Care** (www.isqua.org)
- **American Society for Quality (ASQ)** (asq.org/index.aspx)
- **My Tapestry!** (www.mytapestry.com/qlinks.html) (See the “Quality Links” page for extensive resource listing)
- **Agency for Healthcare Research and Quality** (www.ahrq.gov)
- **National Association for Healthcare Quality** (www.nahq.org)
- **Medical University of South Carolina** (academicdepartments.musc.edu/fm_ruralclerkship/curriculum/cqi.htm)
- **Health Quality Ontario** (www.hqontario.ca/quality-improvement)
- **The Health Foundation: Quality Improvement Made Simple** (www.health.org.uk/publications/quality-improvement-made-simple)
- **USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project** (www.usaidassist.org)
- **1000 Lives Plus QI Guide** (www.1000livesplus.wales.nhs.uk/qi-guide)
- **NHS Scotland Quality Improvement Hub** (www.qihub.scot.nhs.uk/knowledge-centre.aspx)

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- Institute for Healthcare Improvement. *HIV/AIDS Bureau Collaborations: Improving Care for People Living with HIV/AIDS Disease*. Boston: Institute for Healthcare Improvement; 2002.
- Institute of Medicine. *Medicare: A Strategy for Quality Assurance, Volume 1*. Washington: National Academies Press; 1990.
- Institute of Medicine. *Crossing the Quality Chasm*. Washington: National Academies Press; 2001.
- Institute of Medicine. *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act*. Washington: National Academies Press; 2004.
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- New York State Department of Health AIDS Institute. *HIVQUAL Workbook*. September 2006. Available at www.hivguidelines.org/quality-of-care. Accessed December 1, 2013.
- U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau. *Case Studies in QI in 9 Community Health Centers*. Rockville, MD: U.S. Department of Health and Human Services; year of publication unknown.

Health Resources and Services Administration HIV/AIDS Bureau Performance Measures

Overview

The HIV/AIDS Bureau has revised its performance measure portfolio. The updated portfolio is more focused on critical areas of HIV care and treatment, and, as of November 6, 2013, it contains fewer performance measures. The revisions include:

- Identifying core performance measures that are most critical to the care and treatment of people living with HIV
- Combining measures to address people of all ages living with HIV
- Aligning measures with U.S. Department of Health and Human Services (HHS) priorities, guidelines, and initiatives
- Promoting relevant performance measures used in other federal programs
- Archiving performance measures

Unlike the previous version wherein the portfolio included three groups of core measures intended for various levels of programs' ability to implement, the updated portfolio features a set of *Core Clinical Performance Measures* and consolidates several of the previous clinical measures into four categories: *All-Age Clinical Performance Measures*, *Adult and Adolescent Clinical Performance Measures*, *HIV-Exposed Children*, and *HIV-Infected Children*. The Core performance measures emphasize the essential aspects of HIV care and treatment and align with the milestones along the HIV care continuum (hab.hrsa.gov/data/reports/continuumofcare/index.html).

The *Medical Case Management Performance Measures* target all clients, and focus on two key issues: care plans and medical visits. Medical case management programs are encouraged to utilize the Core clinical

performance measures as appropriate.

The *Oral Health Performance Measures* target all clients. The measures are intended for use by programs providing direct oral health services.

The *AIDS Drug Assistance Program (ADAP) Measures* are intended for use by the ADAP. Four measures are included and target all clients, regardless of age.

The *Systems-Level Performance Measures* address aspects of access and entry to care and may be utilized by any system or network.

Two sets of measures not reproduced here (*HIV-Exposed Children* and *HIV-Infected Children*) address a range of clinical, social, and system issues for programs that serve pediatric clients. In addition, the archived performance measures are available for reference on the HRSA HAB website at hab.hrsa.gov/deliverhivaids/habperformmeasures.html.

The HIV/AIDS Bureau encourages all organizations providing HIV services to use the Bureau's revised performance measures, including the Core performance measures, and select the appropriate measures for their own portfolio. Measure selection is based on the services that are provided, prominent clinical issues, and patient demographics. The HIV/AIDS Bureau does not promote using every performance measure available because the activities needed to implement performance measurement (e.g., collecting, analyzing, and

reviewing data) can be costly. Individual programs are recommended to consider having some measures that are collected and analyzed more frequently (e.g., every 2 months or quarterly) and others that are collected and reviewed less frequently (e.g., every 6 months or annually). Grantees are not required to use all performance measures. Given the emphasis on using performance measures to improve patient health, grantees may trend performance measures over time and analyze performance measures for disparities in care.

Core Clinical Performance Measures

Measure	Definition
HIV Viral Load Suppression	Percentage of patients, regardless of age, with a diagnosis of HIV with an HIV viral load of <200 copies/mL at last HIV viral load test during the measurement year
Prescription of HIV Antiretroviral Therapy	Percentage of patients, regardless of age, with a diagnosis of HIV who were prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year
HIV Medical Visit Frequency	Percentage of patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits
Gap in HIV Medical Visits	Percentage of patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year
<i>Pneumocystis jiroveci</i> Pneumonia (PCP) Prophylaxis	Percentage of patients, aged 6 weeks or older with a diagnosis of HIV/AIDS, who were prescribed <i>Pneumocystis jiroveci</i> pneumonia (PCP) prophylaxis

All-Age Clinical Performance Measures

Measure	Definition
CD4 Cell Count	Percentage of patients, aged 6 months and older with a diagnosis of HIV/AIDS, with at least two CD4 cell counts or percentages performed during the measurement year at least 3 months apart
HIV Drug Resistance Testing Before Initiation of Therapy	Percentage of patients, regardless of age, with a diagnosis of HIV who had an HIV drug resistance test performed before initiation of HIV antiretroviral therapy if therapy started during the measurement year
Influenza Immunization	Percentage of patients, aged 6 months and older seen for a visit between October 1 and March 31, who received an influenza immunization OR who reported previous receipt of an influenza immunization
Lipid Screening	Percentage of patients, regardless of age, with a diagnosis of HIV who were prescribed HIV antiretroviral therapy and who had a fasting lipid panel during the measurement year
Tuberculosis Screening	Percentage of patients aged 3 months and older with a diagnosis of HIV/AIDS, for whom there was documentation that a tuberculosis screening test was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection
Viral Load Monitoring	Percentage of patients, regardless of age, with a diagnosis of HIV with a viral load test performed at least every 6 months during the measurement year

Adult and Adolescent Clinical Performance Measures

Measure	Definition
Cervical Cancer Screening	Percentage of female patients with a diagnosis of HIV who have a Pap screening in the measurement year
Chlamydia Screening	Percentage of patients with a diagnosis of HIV at risk of sexually transmitted infections who had a test for chlamydia within the measurement year
Gonorrhea Screening	Percentage of patients with a diagnosis of HIV at risk of sexually transmitted infections who had a test for gonorrhea within the measurement year
Hepatitis B Screening	Percentage of patients, regardless of age, for whom hepatitis B screening was performed at least once since the diagnosis of HIV/AIDS or for whom there is documented infection or immunity
Hepatitis B Vaccination	Percentage of patients with a diagnosis of HIV who completed the vaccination series for hepatitis B
Hepatitis C Screening	Percentage of patients for whom hepatitis C screening was performed at least once since the diagnosis of HIV
HIV Risk Counseling	Percentage of patients with a diagnosis of HIV who received HIV risk counseling in the measurement year
Oral Exam	Percentage of patients with a diagnosis of HIV who received an oral exam by a dentist at least once during the measurement year
Pneumococcal Vaccination	Percentage of patients with a diagnosis of HIV who ever received pneumococcal vaccine
Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan	Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen
Preventive Care and Screening: Tobacco Use – Screening and Cessation Intervention	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user
Substance Abuse Screening	Percentage of new patients with a diagnosis of HIV who have been screened for substance use (alcohol and drugs) in the measurement year
Syphilis Screening	Percentage of adult patients with a diagnosis of HIV who had a test for syphilis performed within the measurement year

Medical Case Management Performance Measures

Measure	Definition
Care Plan	Percentage of medical case management patients, regardless of age, with a diagnosis of HIV who had a medical case management care plan developed and/or updated two or more times in the measurement year
Gap in HIV Medical Visits	Percentage of medical case management patients, regardless of age, with a diagnosis of HIV who did not have a medical visit in the last 6 months of the measurement year (that is documented in the medical case management record)
HIV Medical Visit Frequency	Percentage of medical case management patients, regardless of age, with a diagnosis of HIV who had at least one medical visit in each 6-month period of the 24-month measurement period with a minimum of 60 days between medical visits

Oral Health Services Performance Measures

Measure	Definition
Dental and Medical History	Percentage of HIV-infected oral health patients who had a dental and medical health history (initial or updated) at least once in the measurement year
Dental Treatment Plan	Percentage of HIV-infected oral health patients who had a dental treatment plan developed and/or updated at least once in the measurement year
Oral Health Education	Percentage of HIV-infected oral health patients who received oral health education at least once in the measurement year
Periodontal Screening or Examination	Percentage of HIV-infected oral health patients who had a periodontal screen or examination at least once in the measurement year
Phase 1 Treatment Plan Completion	Percentage of HIV-infected oral health patients with a Phase 1 treatment plan that is completed within 12 months

AIDS Drug Assistance Program Performance Measures

Measure	Definition
Application Determination	Percent of ADAP applications approved or denied for new ADAP enrollment within 14 days (2 weeks) of ADAP receiving a complete application in the measurement year
Eligibility Recertification	Percentage of ADAP enrollees who are reviewed for continued ADAP eligibility two or more times in the measurement year
Formulary	Percentage of new antiretroviral classes that are included in the ADAP formulary within 90 days of the date of inclusion of new antiretroviral classes in the HHS <i>Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents</i> during the measurement year
Inappropriate Antiretroviral Regimen Components Resolved by ADAP	Percent of identified inappropriate antiretroviral regimen components prescriptions that are resolved by the ADAP program during the measurement year

Systems-Level Performance Measures

Indicator	Definition
Waiting Time for Initial Access to Outpatient/ Ambulatory Medical Care	Percentage of Ryan White Program-funded outpatient/ambulatory care organizations in the system/network with a waiting time of 15 or fewer business days for a Ryan White Program-eligible patient to receive an appointment to enroll in outpatient/ambulatory medical care
HIV Test Results for PLWHA	Percentage of individuals who test positive for HIV who are given their HIV-antibody test results in the measurement year
HIV Positivity	Percentage of HIV positive tests in the measurement year
Late HIV Diagnosis	Percentage of patients with a diagnosis of Stage 3 HIV (AIDS) within 3 months of diagnosis of HIV
Linkage to HIV Medical Care	Percentage of patients who attended a routine HIV medical care visit within 3 months of HIV diagnosis
Housing Status	Percentage of patients with HIV diagnosis who were homeless or unstably housed in the 12-month measurement period

References

- U.S. Department of Health and Human Services HIV/AIDS Program. *HAB HIV Performance Measures*. Available at hab.hrsa.gov/deliverhivaids/habperformmeasures.html. Accessed December 1, 2013.

HIV Care in Correctional Settings

Minda Dwyer, ANP-C; Douglas G. Fish, MD; Abigail V. Gallucci, BS; and Sarah J. Walker, MS

Background

Caring for HIV-infected patients who are incarcerated is a complex and challenging task. For many of these patients, the prison health service provides their first opportunity for access to consistent health care. This chapter will discuss some of the issues relevant to the HIV-infected population in correctional settings.

Jail vs. Prison Settings

It is important to note the distinction between “jail” and “prison” custodial settings. These terms are often used interchangeably, but doing so can create confusion for health care providers, as the services that an inmate receives while incarcerated may differ greatly according to the type of facility (NYSDOH, 2008).

Jails are locally operated, or managed, institutions that detain individuals who typically are serving short sentences of 1 year or less. They also hold individuals who are awaiting arraignment, trial, or sentencing, or those who have violated terms of their parole (Harrison and Beck, 2006). Because inmates who are detained in jail settings have shorter confinement terms, providers often face time constraints in establishing longer-term treatment plans for chronic conditions such as HIV/AIDS, and for substance use and mental health problems. Opportunities for inmate education also may be more limited. In addition, because jail inmates often are released within days, weeks, or months after initial confinement, establishing continuity of health care may be challenging for providers and administrators (Okie, 2007).

Prisons, in contrast, are operated by state governments or the Federal Bureau of Prisons. Prisons generally detain people who have been convicted of state or federal felonies and are sentenced to terms of longer

than 1 year (Harrison and Beck, 2006). The nature of a person’s crime, namely a state or federal offense, will dictate the type of prison in which he or she will be detained. The length of sentences for inmates in state or federal custody is longer than those for persons serving time in jail, and prison inmates typically have a firm release date in advance. As a result, HIV-infected inmates released from prison may be more likely to have treatment and discharge plans in place (NYSDOH, 2008).

Note that these characteristics may differ from prison to prison and jail to jail.

Epidemiology

Inmates continue to be disproportionately affected by the epidemic, with the estimated overall rate of AIDS among prison inmates at more than 2.5 times the rate in the United States general population. In 2006, there were 21,980 HIV-infected inmates in federal or state prisons, according to a report from the Bureau of Justice Statistics, and there are many more in jails. With the advent of effective combination antiretroviral therapy (ART), AIDS-related mortality as a percent of total deaths in state prisons decreased significantly between 1995 and 2006, from 34.2% to 4.6% (Maruschak, 2006).

Inmates who have drug- or sex-related illegal behaviors that lead to incarceration often are at high risk of becoming infected with HIV,

hepatitis C virus (HCV), and other pathogens through these behaviors. Their risk factors may include unsafe substance use behaviors, such as sharing syringes and other injection equipment, and high-risk sexual practices, such as having multiple sex partners or unprotected sex. Many inmates also may have conditions that increase the risk of HIV transmission or acquisition, such as untreated sexually transmitted diseases (STDs).

The prevalences of chronic viral hepatitis and tuberculosis are much higher among incarcerated persons than among the general public. Depending on the prison system, 13% to 54% of inmates are infected with HCV (Cassidy, 2003). The incidence is 10 times higher among inmates than among non-inmates and is 33% higher among women than among men (Nerenberg et al., 2002). The Centers for Disease Control and Prevention (CDC) recommends that all incoming inmates be screened for HCV, and those who are infected should be evaluated for liver damage and the need for treatment (Cassidy, 2003). Chronic hepatitis B virus (HBV) infection and tuberculosis also are substantially more common among the incarcerated population than among the general public. The presence of any of these conditions should prompt HIV testing (Nicodemus and Paris, 2002).

Incarcerated Women

Women account for almost 7% of the prison population in the United States (West and Sobol, 2009). The HIV epidemic in the United States increasingly affects women of color, and this trend is reflected in HIV rates among the incarcerated. In terms of total numbers, there are more males than females with HIV/AIDS in state and federal prisons nationally (19,809 and 2,135, respectively). However, the percentage of female inmates with known HIV infection in these settings is higher than that for incarcerated males (2.4% and 1.6 percent, respectively) (Maruschak, 2006).

In many cases, incarcerated women are low-income and have limited education and sporadic employment histories. Compared with men, they are less likely to be incarcerated for a violent crime, and more likely to be incarcerated for a drug or property offense. Women's property crimes often are the result of poverty and substance-use histories (National Institute of Corrections, 2003). Numerous studies have shown that the behaviors that lead to incarceration also put women at increased risk of HIV infection. Risk factors that are present in abundance among female inmates include the following (Hammett and Drachman-Jones, 2006):

- History of childhood sexual abuse and neglect
- History of sex work, with increased frequency of forced, unprotected sex
- High rates of STDs
- High rates of mental illness
- History of injection drug use (IDU) or sex partners with IDU history
- Poverty

Among all women entering a correctional facility, 10% are pregnant (De Groot and Cu Uvin, 2005). These women should be offered HIV testing, and HIV-infected pregnant women should be offered combination ART immediately to prevent perinatal HIV transmission. Many incarcerated women will receive their first gynecologic care in prison. Because the incidence of cervical cancer is higher among women with HIV, referrals for colposcopy should be made for any HIV-infected woman with an abnormal Papanicolaou test result.

Testing and Prevention

The correctional facility is an ideal location for identifying individuals already infected with HIV, HCV, or HBV, and for education

interventions that are geared to prevent infection among those at highest risk of these acquiring diseases. For many adults, the prison or jail setting is a rare potential point of contact with the health care system, making it an important avenue for HIV testing and linkage to care. It also may be an effective setting in which to initiate and maintain individuals on ART.

Inmates commonly are hesitant to be tested for HIV because they fear a positive diagnosis and because of the potential stigma involved. They often lack accurate information about HIV, including awareness of behaviors that may have put them at risk and knowledge of means for protecting themselves from becoming infected. Health care providers in correctional settings are in a key position to evaluate inmates for HIV risk factors, to offer HIV testing, and to educate and counsel this high-risk group about HIV.

HIV testing policies in correctional facilities vary from state to state and among local, state, and federal penal institutions. Depending on the setting, policies may require testing of inmates upon entry, upon release, or both, but as of 2010 more than 50% of state prison systems did not require HIV testing at any point. Some prisons may do HIV testing based on clinical indication or risk exposure during incarceration, and this may be voluntary or mandatory. Most prison systems do provide HIV testing for inmates who request it. See Table 1 for an overview of the circumstances under which inmates in state prisons were tested for HIV in 2006 (Maruschak, 2006).

In high-risk settings such as correctional facilities, routine, voluntary HIV testing has been shown to be cost-effective and clinically advantageous (Paltiel et al., 2005). The CDC supports universal opt-out HIV screening in prisons and jails and has produced the *HIV Testing Implementation Guidance for Correctional Settings* (www.cdc.gov/correctional_health/default.htm). This

document serves as a guide for individual institutions in determining and establishing the most appropriate testing strategy for their settings, presents the components of such a testing program, and explains obstacles that may be encountered in the implementation process. It also provides information regarding the following:

- Background statistics on HIV in correctional facilities
- Inmate privacy and confidentiality
- Opt-out HIV screening in correctional medical clinics
- HIV testing procedures
- HIV case reporting

Testing inmates for HIV prior to their release is a critical aspect not only of individuals' own health care needs but also of preventing transmission of HIV to others. Knowledge of their HIV status affects people's HIV risk behaviors: Studies have shown that, after learning they are infected with HIV, many persons take measures to reduce the risk of transmitting HIV to others.

Risk-Reduction Education

Given the high HIV seroprevalence among inmates, the reentry of inmates into the community presents a danger of spreading HIV and other infectious diseases, and it is a public health concern. Thus, inmates need adequate HIV prevention counseling before release, both to protect themselves and to decrease the likelihood of infecting others in their communities with HIV (Gaiter and Doll, 1996). The World Health Organization (WHO) has stated: "All inmates and correctional staff and officers should be provided with education concerning transmission, prevention, treatment, and management of HIV infection. For inmates, this information should be provided at intake and updated regularly thereafter."

Risk-reduction counseling addresses specific ways the inmate can reduce the risk of becoming infected with HIV. If an inmate is already HIV infected, the goal of counseling is to reduce the risk of infecting others or becoming infected with a drug-resistant strain of HIV.

Education should include information about the efficacy of ART in decreasing risk of HIV transmission. In addition, it should focus on the use of latex barriers with all sexual activity. Condoms and dental dams are not available in most jails and prisons; nonetheless, the inmate should receive education regarding their proper use. The state prisons systems that provide condoms to inmates are those of Vermont and Mississippi. The larger metropolitan jails in New York City, such as Rikers Island, as well as those in Los Angeles, San Francisco, Philadelphia, and Washington, also provide condoms. Within the systems that allow condoms, inmates' ability to obtain them may be restricted (e.g., limited to one per week or available only via medical prescriptions or dispensing machines) (Sylla, 2007); see chapter *Preventing HIV Transmission/Prevention with Positives*.

No correctional system in the United States provides clean injection needles as a part of a prevention program (Sylla, 2007). However, inmates with a history of IDU should be educated about the risks of sharing needles and injection equipment, specifically the high risk of transmitting or acquiring HIV, HCV, and HBV. Inmates also should be counseled about the risks of sharing needles and other "sharps," such as those used for tattooing or body piercing. Substance abuse treatment should be provided when appropriate. Recovery from addiction often is a chronic process and relapses are common. In addition to substance abuse treatment, risk-reduction strategies should include planning for support after release from the correctional setting. For example, prior to release, inmates should

be provided with information about syringe exchange or clean needle access programs in their communities. These programs have proved to be quite effective in decreasing the rate of parenteral HIV transmission (CDC, 1999).

Furthermore, overdose prevention should be discussed with inmates leaving correctional systems. Using heroin after a period of abstinence, such as during incarceration, hospitalization, or drug treatment, is a major risk factor for overdose. Former inmates are at highest risk of overdose within the first 2 weeks after release (NYSDOH, 2008). Overdose risk is heightened when someone has a significant medical condition, such as HIV infection (Catania, 2007). The literature documents an increased number of correctional systems that consider including naloxone (Narcan) prescriptions in prerelease planning for inmates with a history of opiate addiction (Wakeman et al., 2009). Naloxone is a prescription medicine that reverses an overdose by blocking heroin (or other opioids) in the brain for 30-90 minutes (NYSDOH, 2008).

Antiretroviral Therapy in Correctional Facilities

In correctional facilities, as in any setting, a consideration of HIV treatment must begin with educating the patient about the benefits and risks of treatment and the need to fully adhere to the entire regimen, and with an assessment of the patient's motivation to take ART (see chapter *Antiretroviral Therapy*).

Correctional facilities have two main methodologies for dispensing medications to those who are on ART. Each has advantages and disadvantages that can impact treatment adherence. These are directly observed therapy (DOT) and keep-on-person (KOP).

Directly Observed Therapy

DOT is the system in which the inmate goes to the medical unit or pharmacy for all medication doses; dosing is observed by staff members. This system offers the advantage of more frequent interaction between the patient and the health care team, allowing for earlier identification of side effects and other issues. In general, patients have better medication adherence in this system, resulting in better control of HIV. For some inmates, however, the need for frequent visits to the medical unit or pharmacy may be a barrier to receiving proper treatment, particularly if they are housed at a distance from the medical unit. Another disadvantage of DOT is the potential loss of confidentiality, as many inmates feel that the frequency of dosing and the large number of pills they may take will reveal clues that they are HIV infected. In addition, this system puts inmates in a passive role in terms of medication treatment and does not foster self-sufficiency.

Keep-on-Person

KOP is the system that allows inmates to keep their medications in their cells and take them independently. Monthly supplies are obtained at the medical unit or pharmacy. This system offers greater privacy and confidentiality regarding HIV status. It also allows inmates to develop self-sufficiency in managing medications, which may facilitate improved adherence upon release. However, as the KOP system involves less interaction with medical staff, problems with adherence can be more difficult to identify (Ruby, 2000). Problems with refills also can occur. For example, inmates usually must initiate the process for obtaining a refill. They may be told that a refill request was made too early or too late, which can result in delays in dispensing medications, and ultimately, treatment interruptions. In addition, many facilities do not have on-site pharmacies, but rely on local pharmacies, or a

regional or central pharmacy in the state; this may further delay refills (NYSDOH, 2008).

In a study comparing DOT in HIV-infected inmates with KOP in nonincarcerated HIV-Infected patients receiving ART as part of a clinical trial, a higher percentage of DOT patients achieved undetectable viral loads compared with the KOP patients (85% vs. 50%) over a 48-week period (Fischl, 2001).

Adherence

Adherence is one of the most important factors in determining the success or failure of ART. For the HIV-infected inmate starting ART, a number of issues can affect medication adherence. These include patient-related factors, factors related to systems of care (including the medication dispensing systems described above), and medication-related factors. The following are suggestions for supporting adherence to ART. (Also see chapter *Adherence*.)

Patient-Related Factors

- Correct misconceptions about HIV and ART that are common among inmates and could affect adherence adversely. Inmates should be educated about the disease process and the role of the medications, along with the benefits and risks of taking ART.
- Use teaching tools that are appropriate in terms of language and reading level. Illiteracy and low-level reading ability are common among inmates. Diagrams and videos may be more effective than reading-intensive material in some cases. Basic HIV education prior to initiation of ART should include the following topics:
 - How the medications work
 - Potential benefits in terms of personal health and reducing transmission risk
 - Consequences of nonadherence

- Names and dosages of all medications
- Potential side effects and strategies for managing them
- Encourage participation in peer support groups. These can be effective ways to foster self-esteem, empower inmates to come to terms with a positive diagnosis, allay fears and correct misconceptions about HIV disease, and aid adherence. Upon release, telephone hotlines may be available to provide follow-up support and linkages to community services. To the extent possible, family and friends should be included in the education process.
- Provide alcohol and substance abuse treatment before, or while, initiating ART. Without appropriate treatment during incarceration, linkages to supports, and follow-up treatment upon discharge, inmates are more likely to resume high-risk behaviors that may interfere with adherence to ART. In 2004, nearly one third of inmates in state facilities and one fourth of inmates in the federal system committed their offenses under the influence of drugs (Mumola and Karberg, 2006).
- Use mental health consultation to identify inmates with psychiatric needs. Treatment for underlying mental health disorders should precede or take place concurrently with the initiation of ART to ensure successful adherence. Depression and other psychiatric illnesses are more prevalent among inmates than among the general population (James and Glaze, 2006).

Factors Related to Systems of Care

- Educate the facility's security staff about the importance of timely medication dosing, and communicate with other facilities in advance of a transfer; this can eliminate or reduce the frequency of missed doses.

- Schedule frequent follow-up medical visits in the early weeks after ART is initiated; these can make the difference in whether or not patients "stay the course."
- Consult with an HIV specialist, if possible. If a facility's medical provider lacks experience in treating patients with HIV, the results may be undertreatment of side effects or errors in prescribing medications. Because caring for HIV-infected patients is complicated, HIV specialists can provide assurance that patients are receiving proper care. Of particular concern are patients whose current ART regimens are failing, those who are declining clinically, and those who are coinfecting with other diseases such as tuberculosis, HCV, and HBV.

Medication-Related Factors

- Aggressively monitor and treat side effects. The most common barrier to proper adherence to ART is side effects from the medications. Inmates should be educated in advance about potential adverse events and urged to observe and report them. In the first weeks after starting a new ART regimen, patients should be assessed frequently for side effects. For treating gastrointestinal toxicities, antiemetics and antidiarrheals should be available on an as-needed basis. As with all patients on ART, inmates should have appropriate laboratory monitoring.
- Be aware of food requirements. Various food requirements must be considered carefully when administering ART. That can be especially challenging in the correctional environment, particularly in facilities that do not allow inmates to self-administer medications. Make arrangements with prison authorities to provide food when inmates are taking medications that require administration with food.
- Avoid complex regimens and regimens

with large pill burdens, if possible. Simple regimens with fewer pills appear to help improve adherence.

- Avoid drug-drug interactions. Some antiretroviral medications have clinically significant interactions with other drugs (e.g., methadone, oral contraceptives, cardiac medications, antacids). These interactions may cause failure of either the antiretroviral drug or the other medication, or they may cause additional toxicity. Consult an HIV specialist or pharmacist for information on drug interactions.
- Question patients about medication adherence at each appointment.
- ART regimens need to fit into each patient's schedule and lifestyle. This becomes a bigger issue when an inmate is close to release. Education about HIV management, including ART adherence, should begin well before the inmate is discharged back to the community.

Transition to Community Care

It is estimated that 630,000 individuals are released from jails and prisons in the United States each year (Bonczar, 2003; Travis, 2005), and many of these individuals are HIV infected. Many will have difficulty managing even the most basic elements for successful reintegration into their communities. Inmates living with HIV face many challenges when reentering the community, such as finding stable housing, employment, adequate medication supply, follow-up medical care, and psychiatric and substance use treatment services (Hammett et al., 1997).

Ideally, the discharge process at the correctional facility will maximize the likelihood that the person being released will have continuous medical care. At the time of discharge from the correctional facility, all HIV-infected inmates should have a discharge plan that addresses the following:

- Housing
- Health insurance
- 30-day supply of HIV medications
- Follow-up appointments for medical care and, if necessary, psychiatric and substance abuse care

As discussed, inmates in prisons generally serve longer sentences than do those incarcerated in jails, and they have a release date that is known in advance. Thus, HIV-infected inmates in prisons may be more likely than HIV-infected inmates in jails to have treatment and discharge plans in place before their release. However, because the extent of discharge planning resources varies among correctional systems of care, it is important for care providers to discuss the scope of services their clients received while incarcerated to learn of any service gaps upon reentry to the community (NYSDOH, 2008).

The need to find housing often is the greatest challenge for an HIV-infected inmate leaving a correctional facility. In many correctional systems, inmates must document a physical address at which they intend to reside in order to be released. However, problems with housing availability, stability, and location can create significant stressors for an HIV-infected person being released and can compromise the likelihood that he or she will access HIV health care and adhere to an HIV medication regimen (NYSDOH, 2008).

Medication Continuity Issues

HIV-infected individuals leaving correctional settings have a variety of experiences with ARV medication continuity. A short confinement period, for example, can prevent the development of a solid transition plan. Jail inmates may be released without their medications and have no choice but to call or walk into community health centers or clinics for their medications and ongoing

care. Being released from jail after business hours, such as on a Friday night, can result in treatment interruptions over the weekend (NYSDOH, 2008). Depending on the state system, HIV-infected inmates leaving prison are more likely than jail releasees to have a medication supply in hand when they reenter the community. For example, in the New York State Department of Correctional Services, inmates will leave prison with a 30-day supply of HIV medications as well as a prescription for another 30-day supply (NYSDOH, 2008).

For some individuals, interruptions in treatment occur during their time in jail or prison. For example, many inmates choose not to disclose their HIV infection while they are incarcerated. Particularly if the sentence is short, an inmate may feel it better not to mention HIV status and instead plan to resume taking medications upon release. Such treatment interruptions can result in adverse health outcomes (NYSDOH, 2008).

It is important that clinic staff and community-based organizations develop the capacity to work with clients in real time as they present for care in order to help them maintain continuity with their medications.

Strategies for Supporting Inmates upon Release

- A clear way to support clients is to intervene immediately and directly upon their release, such as by meeting them as they step off a bus or exit a facility.
- Engage clients by:
 - Hearing their stories; listening to concerns, wishes, history, perceptions, feelings, and so forth
 - Asking open-ended questions, affirming strengths, listening reflectively, and summarizing discussions and plans
 - Understanding their backgrounds, goals, and motivations (understand “where they are coming from”)

- Avoiding getting caught up in issues about the crimes they committed
- Identifying perceived needs by asking how services can be beneficial to them
- Acting honestly by providing a full disclosure of one’s role as a provider (e.g., what you can or cannot do)
- Provide material assistance by giving clients something tangible such as a meal ticket, condoms, bleach kit, or hygiene kit.
- Provide information and referrals to short-term and survival services for clients to help improve their immediate situation.
- If possible, accompany clients to support them in obtaining short-term and survival services such as health care, food, shelter, and clothing.
- Respond to emergency situations.
- Support clients in meeting parole or probation requirements to avoid reincarceration. Based on their individual histories, anticipate circumstances that may result in them breaking parole. For example, if a client confides that he or she has anxiety regarding meeting the parole officer, initiate and practice role plays to better prepare the client for this encounter.
- Be culturally competent.
- Link to services (e.g., medical care, mental health, substance use, domestic violence).
- Diversify clinic staffing, and use a multidisciplinary approach, including peer support.
- Think outside the box! (NYSDOH, 2008)

A number of HIV education resources for inmates and correctional health care providers are cited on the Albany Medical College website at www.amc.edu/Patient/services/HIV/index.cfm (go to the section on correctional education).

Table 1. HIV Testing in Prisons: Circumstances Under Which Prison Inmates Were Tested for HIV (by Jurisdiction)

Jurisdiction	All Inmates			Random	High-risk	Inmate request	Court order	Clinical indication	Involvement in incident	Other
	Entering	In Custody	Upon Release							
Federal					X	X	X	X	X	
Northeast										
Connecticut					X	X	X	X	X	
Maine						X	X	X		
Massachusetts						X			X	
New Hampshire	X						X	X		
New Jersey						X	X	X	X	
New York				X	X	X	X	X	X	
Pennsylvania						X	X	X	X	
Rhode Island	X					X	X	X	X	
Vermont						X		X	X	
Midwest										
Illinois					X	X	X	X	X	X
Indiana	X				X	X	X	X	X	
Iowa	X	X				X	X	X	X	
Kansas					X	X	X	X	X	X
Michigan	X					X	X		X	
Minnesota	X					X	X	X	X	
Missouri	X	X	X		X		X	X	X	
Nebraska	X					X	X	X	X	
North Dakota	X	X				X	X	X	X	
Ohio	X					X	X	X	X	
South Dakota						X	X	X	X	X
Wisconsin					X	X	X	X	X	

Jurisdiction	All Inmates			Random	High-risk	Inmate request	Court order	Clinical indication	Involvement in incident	Other
	Entering	In Custody	Upon Release							
South										
Alabama	X		X	X		X	X	X	X	X
Arkansas	X		X	X	X	X	X	X	X	X
Delaware						X	X	X	X	
Florida			X			X	X	X	X	
Georgia	X					X	X		X	
Kentucky					X			X	X	
Louisiana						X	X	X	X	
Maryland					X	X	X	X	X	X
Mississippi	X				X	X	X	X	X	
North Carolina						X	X	X		X
Oklahoma	X					X	X	X	X	X
South Carolina	X					X	X	X	X	X
Tennessee					X	X	X	X	X	
Texas	X		X		X	X	X	X	X	
Virginia						X	X	X	X	X
West Virginia						X				
West										
Alaska					X	X		X	X	
Arizona					X	X	X	X		
California						X	X	X	X	
Colorado	X					X	X	X	X	
Hawaii						X		X	X	
Idaho	X	X			X	X	X	X	X	
Montana						X	X	X	X	
Nevada	X	X	X			X	X	X	X	
New Mexico						X		X		
Oregon						X	X			
Utah	X				X			X	X	
Washington	X				X	X	X	X	X	
Wyoming	X					X		X		

Adapted from Maruschak L. *HIV in Prisons*, 2006. Bureau of Justice Statistics Bulletin. Washington: U.S. Department of Justice, Office of Justice Programs; revised April 2008. Publication NCJ 222179.

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Patient Education

Background

Informed and empowered patients are better able to achieve healthy outcomes as a result of improved communication and development of trust with their care providers. HIV patient education provides patients with knowledge about HIV infection, including prevention, treatment, and other aspects of care, along with tools that enable them to participate more actively in decisions regarding their medical care. Given the complexity and the rapid evolution of HIV information, education and skills-building should be an ongoing activity and a key aspect of the clinical care of HIV patients. This chapter provides a brief review of the areas that should be addressed in patient education and discusses some strategies for integrating patient education into HIV care; additional information on patient education is found in many other chapters, particularly *Supporting Patients in Care*, *Preventing HIV Transmission/Prevention with Positives*, *Smoking Cessation*, and *Adherence*, as well as in the “Patient Education” sections found at the end of most of the clinical chapters.

S: Subjective

A newly diagnosed patient presents to clinic after being referred from a testing center in the community. The patient received the positive HIV test results more than a year ago, but has not been ready to seek care until now. The patient feared hearing that he/she was “going to die.” Now, he/she is ready to consider facing this “terminal” illness. The patient received some information about HIV infection at the testing center, but that was months ago.

O: Objective

See chapters *Initial History*, *Initial Physical Examination*, and *Initial and Interim Laboratory and Other Tests* for information on the initial clinic evaluation.

A/P: Assessment and Plan

The patient will need extensive information and education about HIV infection in general, his/her individual health status and prognosis, and the support and care systems that are available. Below are some suggestions about specific areas to review with a new patient.

Topics for Patient Education

Patient education should cover the following topics:

- What is HIV?
- How is HIV transmitted?
- Progression of HIV; prognosis
- Interpretation of laboratory results
- Treatment information
 - General information regarding the benefits of treatment
 - Indications for treatment, goals of treatment
 - General information regarding potential side effects and risks of treatment
 - Access to medication
 - Insurance information
- Treatment options
- Prevention for positives
- Support services and support groups available to the patient

Patient Educators

In most clinics, a number of different personnel may take on the responsibilities of providing health education to patients. They may include primary care providers, nurses, social workers, case managers, and pharmacists. Some clinics have designated health educators whose role is to provide this type of support for patients. Even when a formal health educator is available, a collaborative, multidisciplinary approach to patient education serves both patients and providers optimally. However, it is important to ensure that patient education messages are coordinated and that patients are receiving consistent information.

Patient education must be provided in a language and at a literacy level appropriate for the patient. Patient education should be conducted in the patient's primary language, if possible; otherwise, skilled medical interpreters should be involved.

Conducting Patient Education

Rarely are patients able to absorb all of the necessary information in a single session. Attention and comprehension levels are optimal during the first 15-20 minutes of a visit, after which an individual's ability to absorb and retain information declines. Therefore, clinics should consider strategies to integrate brief patient education messages throughout the course of patient care and to engage patients in this process. Support groups, case managers, and peer educators can be invaluable in this process of engagement.

It is important to keep the medical information specific to the patient. Although there are some areas of education that should be considered for all patients (see above), patients should not be required to have a high level of understanding in each area. Patients should be given the opportunity to learn as much about an area as they would like, and should be encouraged to gain a working knowledge of the information that is necessary to keep them healthy and safe. Patients vary widely in terms of their interest level in mastering the details of their illness. For example, in the area of "What is HIV?" there may be some patients who want to know details about the basic science and immunologic impact of HIV. With this information, these patients might then want to take the lead in making treatment and care decisions for themselves, in consultation with their care providers. Other patients, however, would feel overwhelmed by this volume of information and involvement and may be best engaged in participating in their care by knowing how HIV is transmitted, how to keep themselves healthy, and how to access more information if they want it. Some patients would prefer for their care providers to "just tell them what to do" rather than take the lead in making their own treatment decisions.

There are a number of websites that provide HIV information for patients (see chapter *Web-Based Resources*). Many patients may prefer this form of self-education. Encourage patients to convey any information they discover to their care providers for further discussion. Reminding patients that they can be teachers as well as students can be a useful strategy for engaging patients in this process. In addition, patients may learn of novel tools and information sources that could be useful to others.

The following are some useful suggestions that providers can convey to their patients:

- Define your goals for each visit; please let your provider know your concerns and what you hope to learn in the course of the visit.
- Write down questions and concerns as they arise, and take that list with you to your appointments.
- Meet all the members of your care team and learn their areas of expertise and what they might be able to offer you.
- Ask about support groups and other peer groups that might be able to provide support/education.
- Review brochures and websites that provide additional information.
- Ask supportive friends or family members to accompany you to clinic visits. They may be able to obtain information that is helpful for their role in supporting your health or reminding you of information discussed at visits.

Initial History

Background

Conducting a thorough initial history and physical examination is important even if previous medical records are available. This is the best opportunity to get a complete picture of the patient’s HIV disease status, comorbid conditions, and his or her physical and emotional condition, as well as to establish the basis for an ongoing relationship with the patient. Many of the conditions that put immunocompromised patients at risk of disease can be detected early, by means of a thorough assessment.

The information gathered through the initial history and physical examination will provide a comprehensive standardized database for the assessment and treatment of HIV-related problems, including acute intervention and ongoing prevention services and supportive care.

This chapter includes essential topics to cover during the clinic intake and examples of questions that can be used to elicit important information (the questions should be tailored to the individual patient). This can be completed during the initial visit or divided over the course of two or three early visits. For essential aspects of the physical examination to cover in an initial clinic intake visit, see chapter *Initial Physical Examination*.

HRSA HAB Performance Measures

Percentage of patients with a diagnosis of HIV who had at least **one medical visit in each 6-month period** of the 24-month measurement period with a minimum of 60 days between medical visits

(Core measure)

Percentage of patients with a diagnosis of HIV who received **HIV risk counseling** in the measurement year

(Adult and Adolescent measure)

Percentage of new patients with a diagnosis of HIV who have been screened for **substance use** (alcohol and drugs) in the measurement year

(Adult and Adolescent measure)

Percentage of patients aged 12 years and older **screened for clinical depression** on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen

(Adult and Adolescent measure)

S: Subjective

Initial History		
Category / Topics to Cover	Sample Questions	
History of Present Illness		
HIV Testing	- What was the date of your first positive HIV test? - Did you have a previous HIV test? If so, when was the last negative result?	
Treatment Status	- Where do you usually receive your health care? - Have you ever received care for HIV? - What was the date of your last HIV care visit? - What is your current CD4 (T-cell) count?	- Do you know what your first CD4 count was? - What was your lowest CD4 count? - What was your highest CD4 count? - Do you know what your first viral load count was? - What is your current viral load count?

Category/Topic to Cover	Sample Questions
History of Present Illness (continued)	
HIV-Related Illnesses	- What opportunistic infection(s) have you had, if any? (PCP, MAC, cryptococcal meningitis, TB, etc.) - What year(s) were you diagnosed with these infections? - Have you had cancer(s)? - What other HIV-related illnesses have you had? Have you had zoster (shingles), oral thrush, pneumonia?
Active TB and TB Testing History	- Have you ever had tuberculosis (TB)? - When was your last TB test? - Was it a TB skin test (TST) or interferon-gamma release assay (IGRA)? - What were the results of this test? - Have you ever had a positive TB result? - What year and what health care setting? - What medications did you take and for how long?
Antiretroviral Therapy (ART) History	- Are you taking HIV medications now? - If so, please name them or describe them, and tell me how many times a day you take them. - How many doses have you missed in the past 3 days? - The past week? - The past month? - What side effects, if any, do you have now? In the past? - What HIV medicines have you taken in the past (names or descriptions)? - When did you start and stop taking them (dates)? - Do you know why you stopped taking these medications? - Do you know what your HIV viral load or your CD4 counts were while you were taking your medications? - Have you ever had a resistance test? - Did you have any side effects to past HIV medications?
Past Medical and Surgical History	
Chronic Diseases	Do you have any chronic conditions, such as the following? - Diabetes - High blood pressure - Heart disease - Cholesterol problems - Asthma or emphysema - Sickle cell disease - Ulcers, acid reflux, or irritable bowel syndrome - Thyroid disorders - Kidney or liver problems - Mental health disorders If so, do you receive medical care for these conditions?
Previous Illnesses	- Have you had any hospitalizations? Where, when, and for what reason? - Have you had any surgeries? When and where? - Have you had any major illnesses, including mental health conditions?
Hepatitis	- Have you ever had hepatitis? What type (A, B, C)? - Do you have chronic hepatitis? - Do you know whether you are immune to hepatitis A or hepatitis B? Have you been vaccinated?

Category/Topic to Cover	Sample Questions		
Past Medical and Surgical History (continued)			
Gynecologic and Women's Health	• When was your last cervical Papanicolaou (Pap) test? • What were the results? • Have you ever had an abnormal Pap test? • When was your last menstrual period? • What is the usual length of your cycle? Is it regular or irregular? • Have you noticed changes in your menstrual cycle? • When was your most recent breast examination? • Have you had a mammogram? When? • Have you ever had an abnormal breast examination or mammogram? • Do you get yeast infections? How often? • Do you get urinary infections? • Have you ever had kidney stones?		
Obstetric	• How many pregnancies have you had? • How many live births? Ages of children now? • How many miscarriages or therapeutic abortions? • Were you tested for HIV during any pregnancy? What year? • Did you deliver an infant while you were HIV infected? • Was HIV medication given during pregnancy and delivery? • Do you have children? What is their HIV status? • Do you intend to become pregnant?		
Anorectal History	• Have you ever had an anal Pap test? • What were the results? • Have you had anal warts? Other abnormalities?		
Urologic History	Have you ever had: • Kidney stones • Urinary tract Infections • Prostate infection or enlargement • Have you had a prostate-specific antigen (PSA) test? (What were the results?)		
Sexually Transmitted Diseases	Have you ever had any of the following infections? If yes, when was last episode? <table border="0"> <tr> <td> • Syphilis (If yes, ask about stage, treatment and date of treatment, titer follow-up, and date and result of last titer.) • Vaginitis • Genital herpes • Nongonococcal urethritis (NGU) </td><td> • Gonorrhea (If yes, ask about sites of infection: oral, anal, urethral, vaginal.) • Chlamydia (If yes, ask about sites of infection: oral, anal, urethral, vaginal.) • Genital warts (HPV) • Proctitis • Pelvic inflammatory disease (PID) • Trichomoniasis </td></tr> </table>	• Syphilis (If yes, ask about stage, treatment and date of treatment, titer follow-up, and date and result of last titer.) • Vaginitis • Genital herpes • Nongonococcal urethritis (NGU)	• Gonorrhea (If yes, ask about sites of infection: oral, anal, urethral, vaginal.) • Chlamydia (If yes, ask about sites of infection: oral, anal, urethral, vaginal.) • Genital warts (HPV) • Proctitis • Pelvic inflammatory disease (PID) • Trichomoniasis
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Category/Topic to Cover	Sample Questions
Past Medical and Surgical History (continued)	
Dental/Oral Care	• When was your last oral health examination? • Do you have all your natural teeth? • Do you have partials or dentures?
Eye Care	• When was your last vision examination? • When was your last dilated retinal examination? • Do you wear glasses or corrective lenses?
Medications	• What (non-ARV) medications do you take? • What herbs, vitamins, nutritional supplements, or over-the-counter (OTC) medications, do you take?
Allergies; Medication Intolerance	• Have you had an allergic reaction to any medications? What type of reaction, how severe? • Have you had allergic reactions to other types of exposures? • Have you had severe side effects from any medications?
Immunizations	When was your last vaccination for the following: • Streptococcal pneumonia (Pneumovax; PPV23, PCV13) • Tetanus/Pertussis (Tdap) • Influenza • Hepatitis A • Hepatitis B Did you have chickenpox as a child, or were you vaccinated against chickenpox? What about measles, mumps, and rubella?
Health-Related Behaviors	Tobacco use: • Do you smoke? How many cigarettes per day? How long have you smoked? How much have you have smoked in the past? • Besides tobacco, what do you smoke? • Do you chew tobacco? Alcohol use: • How often do you have a drink containing alcohol? How many drinks do you have on a typical day? How many per week? • Have you ever had a problem fulfilling work, social, or school obligations because of alcohol use? • Have you ever sought treatment for alcohol-related problems? Drug use: • Do you use any recreational or street drugs we haven't covered in earlier questions? Any prescription drugs or medications that were not prescribed to you? • If so, what drugs and how do you use them (inject, smoke, inhale, etc.)? Drug use (continued): • How often do you use substances? • Have you shared drug-use equipment with another person? • What pain relievers do you use on a regular basis? • Are you interested in treatment for alcohol or drug use? • Have you ever sought treatment? Exercise: • What kind of exercise do you participate in? How frequently? Diet: • What do you eat during a typical day? • Do you consume raw (unpasteurized) milk, raw eggs, raw or rare meat, deli meats, soft cheeses, or raw fish? • How much water do you drink during a typical day? • What is your source of water? • How much caffeine do you drink during a typical day?

Category/Topic to Cover	Sample Questions
Sensitive Sexual and Gender History Questions	
Gender Identity	- Do you consider yourself male or female? - Have you had or considered treatment for sex change? - Are you presently taking hormone therapy? - Have you had hormone therapy in the past? - Have you had any gender confirmation (sex reassignment) surgery?
General Sexual	- Do you have sex with men, women, or both? - In the past, have you had sex with men, women, or both? - In the past 2 months, how many sex partners have you had? - In the past 12 months, how many sex partners have you had?
Sexual Practices	- Do you have anal sex? Vaginal? Oral? - How do you protect yourself from sexually transmitted diseases, or HIV reinfection? - For men who have sex with men: - Are you the receptive or insertive partner, or both? - How often do you use alcohol or drugs before or during sex?
HIV Prevention	- Do you know the HIV status of your partner(s)? - Do you take measures to protect your partners from HIV? What measures? - In what situations do you or your partner use condoms or some other barrier? - Are there situations in which you do not use barrier protection?
Sex Trading	Have you ever exchanged sex for food, shelter, drugs, or money?
Contraception	- What birth control measures do you use, if any? - How often do you use condoms or other latex barriers? - Do you have plans for you or your partner to become pregnant?
Family History	
	Do you have a family history of: - Heart disease? Heart attacks or strokes? - Cholesterol problems? Diabetes? - Cancer? - Mental health conditions (e.g., depression, bipolar disorder, anxiety, phobias)? - Addictions? Which family member(s), and what is their health status currently?
Social History	
Relationship Situation	- What is your relationship status (single, married, partnered, divorced, widowed)? - Do you have children? - Does your partner (and/or children) know about your HIV status?
Living Situation	- Do you live alone or with others? With whom? - How long have you lived in your residence?
Support System	- Who knows about your HIV status? - Which individual has been the most supportive since your HIV diagnosis? - Who has been the least supportive? - Have you used any community services such as support groups?

Category/Topic to Cover	Sample Questions
Social History (continued)	
Employment	• Are you currently employed? • Where do you work? • Describe your job task(s). • What setting do you work in on a daily basis? • Does your employer provide health insurance? • Does your employer know of your HIV status? • If on disability: How long have you been on disability? • What medical condition has made you disabled?
Incarceration History	• Have you ever been incarcerated? When was the last time?
Pets	• What kind of pets do you have, and who cleans up after them?
Travel	• Where have you traveled outside the United States? • When did travel take place?
Mental Health	
Coping	• How do you handle your problems/stresses? • What do you do to relax?
History	• Have ever been diagnosed with depression, anxiety, panic, bipolar disorder, schizophrenia, etc.? • Have you taken or are you taking any medications for these conditions? • Are you seeing a therapist or mental health professional? • Have you had any previous counseling or mental health problems? • Have you ever been hospitalized for a psychiatric condition? • Have you ever thought about hurting yourself? (If yes, probe for previous suicide attempts: Are you feeling that way now?) (See chapter <i>Suicide Risk</i> and prepare for immediate referral if necessary.)
Violence	• Have you ever been sexually abused, assaulted, or raped? • Has an intimate partner ever forced you to do something you did not want to do? • Has a partner, family member, or other person ever physically hurt you? • Have you lived in any situation with physical violence or intimidation? • When has this occurred? • Are you afraid for your safety now? • (If yes) Did you seek legal help, therapy, or other type of assistance?
Childhood Trauma	• Was there any alcoholism or drug abuse in your household when you were a child? • Did you experience or observe violence; physical, sexual, or emotional abuse; or neglect?

Review of Systems

For each positive answer, ask about location, characteristics, duration of symptoms, exacerbating and alleviating factors, previous diagnostic workup, and treatments tried.	
General	Do you ever wake up feeling tired?
Fever	Do you have fevers? How high, and for how long? How often?
Night Sweats	Do you ever sweat so much at night that it soaks your sheets and nightclothes?
Anorexia	How is your appetite?
Weight	- What was your weight 1 year ago? - What is a normal weight for you? - Have you lost or gained weight unintentionally?
Body Changes	- Have you noticed any changes in the shape of your body (describe)? For example, has there been an increase in your waist, collar, or breast size or a decrease in your arm, leg, or buttocks size? - Have you noticed increased visibility of veins in your arms and legs? - Have you noticed thinning of your face, especially around the cheeks?
Head, Ears, Eyes, Nose, and Throat	
Vision	- Have you noticed any changes in your vision, especially blurred vision or vision loss, double vision, new "floaters" or flashes of light? - Have you noticed this problem in one or both eyes? - When did you first notice these changes?
Mouth, Ears, Nose, Throat	- Have you noticed any white spots in your mouth or a white coating on your tongue (thrush, oral hairy leukoplakia)? - Do you ever get sores in your mouth or the back of your throat? Gum problems? - Any nosebleeds? - Do you ever experience hearing loss, ringing in your ears, or ear pain?
Cardiovascular	
Cardiac	- Any chest pain or pressure? Palpitations? - Any shortness of breath during activities or while you are lying down? - How far can you walk or run before you get short of breath? - Any swelling in your feet or legs?
Pulmonary	
Cough	- Do you have a cough? - Can you describe it? Dry or productive, amount, color, odor, presence of blood in sputum? When is it the worst?
Dyspnea	- Do you ever feel short of breath? - Does that happen when you are sitting still, lying down, or moving around? - How severe is your shortness of breath? - What does it prevent you from doing? - Do you ever wheeze??

Gastrointestinal	
Dysphagia	• Do you have any problems with food sticking in your throat or being difficult to swallow? • Do you gag or get nauseated when trying to eat? • Do you notice it is easier to swallow liquids or solids? • Do you have difficulty swallowing pills?
Odynophagia	• Do you have pain in your throat, esophagus, or behind your breastbone when you swallow?
Dyspepsia/Reflux	• Do you ever have heartburn (or a burning feeling rising from the stomach to behind the breastbone)? • When does it happen – after eating, lying down, on an empty stomach? • Do you get the taste of stomach acid in your mouth?
Nausea/Vomiting	• Do you have nausea or vomiting? • When? Are there specific things that cause this?
Diarrhea	• Do you have diarrhea, or more than 3-5 unformed stools a day? • Stool characteristics: bloody, pus, mucus? • Pain or cramping with diarrhea? Tenesmus?
Bowel Habits	• How frequently do you have bowel movements? • Do you have problems with constipation, blood in the stools, or other? • Do you have problems with flatulence or belching after eating?
Genitourinary	
Genital	• Do you have any lesions or sores on your genital area now, or have you in the past? • Have you ever had genital herpes? If yes, how often do you have outbreaks? • When was the most recent outbreak?
Women	• Have you had any lower abdominal pain? • Have you noticed a vaginal discharge or odor? • Do you have any burning or pain on urination? • Frequent urination? • Do you lose control of your urine or have problems getting to the bathroom before you start to urinate?
Men	• Have you noticed any swelling or testicular pain? • Do you have difficulty starting your stream of urine? • Are you getting up at night to urinate? • Have you had burning or pain on urination? • Do you lose control of your urine or have problems getting to the bathroom before you start to urinate? • Do you have any difficulty developing or maintaining an erection? • Any discharge from your penis?

Musculoskeletal	
	• Do you have any muscle aches or pains? Joint pain or swelling? • Back pain? • Have you ever broken any bones? • Do you have chronic pain? • Describe the pain – location, duration, rating (scale of 1-10), alleviating factors.
Skin	
Skin Lesions	• Have you noticed any rash or skin problems? If so, where? • Have you noticed any new moles, bruises, or bumps on your skin? • Do you have any moles that have changed shape, size, or color?
Tinea	• Do you have fungal infections on your skin, especially groin, fingernails, toenails, or feet?
Folliculitis	• Do you have any itchy bumps on your face, back, or chest?
Seborrhea	• Do you have flaking or itching on your skin or scalp?
Neurologic	
Headache	• How often do you get headaches? • Describe the headaches – location, timing, duration, alleviating or aggravating factors. • Do they cause nausea or vomiting? • Does sensitivity to light lead to headaches?
Neuropathy	• Do you have any numbness, tingling, burning, or pain in your hands or feet?
Weakness	• Do you have or have you had any weakness in your arms or legs?
Gait	• Have you noticed any changes in the way you walk?
Memory	• Do you have difficulty with your memory or ability to concentrate? If so, describe.
Seizures	• Have you ever had a seizure or “fit”? • If so, describe the seizure – When? How long did it last? Did you experience loss of consciousness? Did you receive medical care?
Endocrine	
Diabetes	• Have you had any increase in thirst, hunger, or urination?
Thyroid	• Have you noticed changes in your energy level? • Do you have intolerance to heat or cold? • Have you noticed changes in your hair (thinning, coarse texture)?
Sex Steroids	• Have you noticed any changes in your libido? In your energy level, mood?
Hematologic/Lymphatic	
Adenopathy	• Do you have swollen glands? • If so, describe – location, pain, size.
Bruising or Bleeding	• Have you noticed easy bruising or prolonged bleeding after injury? • Nosebleeds or bleeding gums?

Psychiatric	
Mood	• Depression screening: Have you experienced a decrease in your interest or pleasure in your activities? Have you felt depressed, down, or hopeless? • Do you feel more angry, sad, depressed, numb, irritable, or anxious than usual? • Have any major life events have occurred to cause you to feel sad or depressed? • When did these events occur?
Sleep	• How is your sleep? • How many hours do you sleep each night? • What is your sleeping schedule – time to bed and time to rise? • Do you take naps?

HIV Research

Sample Questions	
	• Have you participated in any research protocols? What studies, and when? • Would you be interested in participating in research studies (if available)?

O: Objective

- Conduct a physical examination, focusing on subjective findings elicited in the history. (See chapter *Initial Physical Examination*.)
Note: If significant time has elapsed between the review of symptoms (ROS) and the physical examination, perform another ROS.

A/P: Assessment and Plan

- Arrange for baseline/intake laboratory work. (See chapter *Initial and Interim Laboratory and Other Tests*.)
- Compose a problem list. Initiate a medication list (if appropriate).
- Refer the patient to social services, mental health care, local health department partner services, community and other resources, or other clinic services as needed.

During the current visit or a future visit:

- Perform immunizations for pneumonia (Pneumovax), influenza (as appropriate), and other immunizations as indicated. (See chapter *Immunizations for HIV-Infected Adults and Adolescents*.)
- Provide counseling on prevention of HIV transmission (e.g., safer sex and injection practices), as appropriate. See chapter *Preventing HIV Transmission/Prevention with Positives*.

Patient Education

A very important aspect of caring for HIV-infected individuals is educating patients about HIV infection, including goals of care and ways of achieving those goals.

Review the following with each patient:

HIV disease

- Disease course
- Significance of CD4 cell count and HIV viral load
- Possible treatment approaches, including initial discussion about the importance of ART for the patient's own health and for reducing risk of HIV transmission
- Disclosure (e.g., whom the patient may need to tell about HIV status, relevant legal requirements, approaches to disclosure)

HIV transmission prevention and risk reduction for HIV-infected individuals

(see chapter *Preventing HIV Transmission/Prevention with Positives*)

- Strategies to prevent transmission of HIV to uninfected partners and to prevent acquisition of sexually transmitted diseases, hepatitis, and other infections
- Safer-sex approaches, including the use of condoms or other latex barriers during sexual contacts
- Safer use of recreational drugs

Nutrition

- Maintaining a healthy weight
- Nutritional support resources, if appropriate
- Importance of including a nutritionist in medical care

Mental health

- Stress reduction
- Rest and exercise to enhance a healthy mental state

Adherence

- Importance of keeping medical appointments
- Need for adhering to any medication regimen and the consequences of missed HIV medication doses

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Initial Physical Examination

Background

Many of the conditions that put immunocompromised patients at risk of disease can be detected early, by means of a thorough history and physical evaluation.

HRSA HAB Performance Measures

Percentage of female patients with a diagnosis of HIV who have a **Pap screening** in the measurement year

(Adult and Adolescent measure)

S: Subjective

See chapter *Initial History*.

O: Objective

Assess the patient’s general appearance, affect and demeanor in answering questions, body language, and other relevant characteristics. Measure vital signs; perform a physical examination.

Table 1. Vital Signs	
(These measurements establish a baseline against which future measurements can be compared.)	
Vital Sign	Recommendation/Notes
• Height • Weight • Temperature • Blood pressure • Heart rate • Respiratory rate • Oxygen saturation • Waist, hip circumferences	• Should be measured at baseline and annually. • Record at each visit. • Record at each visit. • Record at each visit. The BP cuff size should be appropriate for the patient’s arm circumference. • Record at each visit. • Record at each visit. • Record at each visit. • Waist and hip circumference should be measured at baseline for comparison in case the patient later develops obesity or lipoaccumulation related to antiretroviral therapy (ART); repeat as indicated. Abdominal circumference: >102 cm (39”) in men = abdominal obesity >88 cm (35”) in women = abdominal obesity Waist-hip ratios: >0.95 in men = increased risk of coronary heart disease (CHD) >0.85 in women = increased risk of CHD

Body mass index (BMI)	BMI can be helpful in assessing underweight or overweight conditions, HIV/AIDS-related weight loss, and ART-related weight gain. Perform at baseline and upon changes in weight. BMI calculation: $\frac{\text{(weight in pounds)}}{\text{(height in inches)} \times \text{(height in inches)}} \times 703$ or, $\frac{\text{(weight in kilograms)}}{\text{(height in meters)} \times \text{(height in meters)}}$ BMI: <table border="0"> <tr> <td><18.5 = underweight</td> <td>25-29.9 = overweight</td> </tr> <tr> <td>18.5-24.9 = normal range</td> <td>≥30 = obese</td> </tr> </table>	<18.5 = underweight	25-29.9 = overweight	18.5-24.9 = normal range	≥30 = obese
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Table 2. Physical Examination

Regions	Recommendation/Notes																					
General	• State of nourishment, physical appearance, well or ill appearing																					
Eyes	• Examine visual acuity by Snellen chart, visual fields by confrontation. • Test extraocular movements and pupillary size and reactivity. • Perform funduscopic examination, with or without mydriatics. Note any retinal lesions, white or yellow retinal discoloration, infiltrates, or hemorrhages (could indicate cytomegalovirus retinitis, retinal necrosis, or ocular toxoplasmosis). • Referral to ophthalmologist for retinal examination every 6 months if the CD4 count is <50 cells/μL. • Refer immediately if the patient has retinal lesions or new visual disturbances.																					
Ears/Nose	• Examine ear canals and tympanic membranes. • Visualize nasal turbinates. • Palpate frontal and maxillary facial sinuses.																					
Oral Cavity	• Good lighting is essential for this examination. • Examine: • Gingiva and teeth (note loss of teeth, decay, or inflammation) • Mucosal surfaces (with dentures removed) (note any lesions or discolorations) • Posterior tongue • Tonsils (note absence or presence; any abnormality in tonsil size) • Pharynx (note lesions or exudate) • Refer to oral health specialist for examination.																					
Endocrine	• Check thyroid for enlargement, tenderness, nodules, and asymmetry.																					
Lymph Nodes	• Document site and characteristics of each palpable node. <table><thead><tr><th colspan="2">Node Sites:</th><th>Characteristics:</th></tr></thead><tbody><tr><td>• Posterior cervical chain</td><td>• Supraclavicular</td><td>• Size (two dimensions, in millimeters)</td></tr><tr><td>• Anterior cervical chain</td><td>• Submental</td><td>• Consistency (hard, fluctuant, soft)</td></tr><tr><td>• Submandibular</td><td>• Axillary</td><td>• Tenderness</td></tr><tr><td></td><td>• Epitrochlear</td><td>• Mobility</td></tr><tr><td></td><td>• Inguinal</td><td>• Definition (discrete, matted)</td></tr><tr><td></td><td>• Femoral</td><td>• Symmetry</td></tr></tbody></table>	Node Sites:		Characteristics:	• Posterior cervical chain	• Supraclavicular	• Size (two dimensions, in millimeters)	• Anterior cervical chain	• Submental	• Consistency (hard, fluctuant, soft)	• Submandibular	• Axillary	• Tenderness		• Epitrochlear	• Mobility		• Inguinal	• Definition (discrete, matted)		• Femoral	• Symmetry
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Table 2. Physical Examination (continued)

Regions	Recommendation/Notes
Lungs	- Inspect, auscultate, and percuss. - Note any abnormal sounds including crackles or wheezes (e.g., signs of infections, asthma, and congestive heart failure). - Note any absence of air movement (e.g., pneumothorax, pleural effusion).
Heart	- Examine for jugular venous distention (JVD). - Palpate for point of maximal impulse (PMI). - Note rate and rhythm, heart sounds, murmurs, extra heart sounds.
Breasts	- Palpate for breast masses in both men and women. - Check for symmetry, nipple discharge, dimpling, and masses.
Abdomen	- View: examine for distention, obesity, undernutrition, vascular prominence, petechiae. - Auscultate; note bowel sounds. - Percuss; record liver size. - Palpate for hepatomegaly, splenomegaly, masses, tenderness or rebound tenderness.
Genitals / Rectum	- Inspect the genitalia and perirectal area; note lesions, warts, etc. - Look for discharges, ulcerative lesions, vesicles, or crusted lesions; take samples for diagnostic studies (e.g., for chlamydia, gonorrhea, herpes simplex virus, syphilis, chancroid, as appropriate).
Female Patients	- Perform speculum examination; note any lesions on vaginal walls or cervix. - Obtain a Papanicolaou (Pap) test. - Obtain endocervical swab for gonorrhea and chlamydia, and a posterior pool swab for wet mount evaluation for trichomoniasis, candidiasis, and bacterial vaginosis. - Consider anal Pap test, especially if the patient has a history of an abnormal cervical Pap test or genital warts (perform before introduction of lubricant).* - Bimanual examination; note size of uterus and ovaries, shape, and any tenderness or pelvic pain. - Rectal examination (e.g., for anorectal lesions, warts) and evaluation of posterior uterine abnormalities.
Male Patients	- Examine external genitalia; note whether patient is circumcised; note any lesions, discharge, or other abnormalities, as above. Perform testicular examination for masses, tenderness. - Consider anal Pap test (perform before introduction of lubricant).* - Digital rectal examination to evaluate rectal tone, discharge or tenderness, masses, or lesions; perform prostate examination if appropriate.
Extremities / Musculoskeletal	- Joints; note any enlargement, swelling, or tenderness. - Muscles; for the major muscle groups, evaluate muscle bulk (normal or decreased), tenderness, or weakness. - Look for evidence of peripheral fat atrophy. - Consider measuring baseline arm, thigh, and chest circumferences for later comparison. - Note nail changes (clubbing, cyanosis, thickening, discoloration). - Assess for pedal or leg edema.
Habitus	- Look carefully for signs of lipoatrophy or lipohypertrophy, wasting, or obesity. - Subcutaneous fat loss (face, extremities, buttocks). - Central fat accumulation (neck, dorsocervical area, breasts, abdomen).

Table 2. Physical Examination (continued)	
Regions	Recommendation/Notes
Skin	- Examine the entire body, including scalp, axillae, palms, soles of feet, and pubic and perianal areas. - Describe all lesions (e.g., size, borders, color, symmetry/asymmetry, distribution, raised/flat, induration, and encrustation). - Note evidence of folliculitis, seborrheic dermatitis, psoriasis, Kaposi sarcoma, fungal infections, prurigo nodularis, etc. - Note any tattoos or body piercings.
Neurologic	Assess the following: - Mental status, including orientation, registration, recent and remote memory, and ability to calculate (serial subtraction) - Cranial nerves - Peripheral sensory examination, including pinprick, temperature, and vibratory stimuli - Extremity strength and gait to discern myopathy, neuropathy, and cerebellar disease - Fine motor skills such as rapid alternating movements (often abnormal in dementia) - Deep tendon and plantar reflexes
Psychiatric	- Assess the patient's general mood (e.g., depressed, anxious, hypertalkative). - Note verbal content (e.g., whether the patient answers questions appropriately; unusual or odd content). - Note inappropriate or unusual behavior, such as extremes of denial, hostility, or compulsiveness. - See section <i>Neuropsychiatric Disorders</i> for more complete information on common pathologies. - If the possibility of an emergency situation exists (e.g., potential suicide or violence), refer to crisis mental health services for immediate evaluation.

* Anal Pap test: Consider this test if follow-up evaluation of an abnormal Pap test result is available. Rates of anal dysplasia and anal cancer are higher in HIV-infected women and men than in HIV-uninfected individuals; see chapter *Anal Dysplasia*.

A/P: Assessment and Plan

After completing the initial history and physical examination, do the following:

- Enter the information garnered through the history and physical examination into the patient's chart or database.
- Continue to develop the problem list, assessment, and plan for patient care.
- Complete follow-up or laboratory studies suggested by the history and physical examination. (See chapter *Initial and Interim Laboratory and Other Tests*.)
- Prescribe opportunistic infection prophylaxis as appropriate. (See chapter *Opportunistic Infection Prophylaxis*.)
- Arrange for any appropriate vaccinations. (See chapter *Immunizations for HIV-Infected Adults and Adolescents*.)
- Refer for dental, nutrition, and social services, as well as case management and mental health care, as appropriate.
- Refer for any additional specialty care needs identified in the history or physical examination.
- Make follow-up appointment with health care provider.
- Answer the patient's questions.

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Initial and Interim Laboratory and Other Tests

Background

This chapter discusses the laboratory tests and other monitoring that should be performed for HIV-infected individuals. This involves testing for staging HIV infection, screening for comorbidities, establishing baselines before treatment with antiretroviral (ARV) medications, and monitoring responses to ARV therapy (ART).

Note that documentation of HIV infection by laboratory testing is essential for each patient, and it should be included in the patient’s chart.

HRSA HAB Performance Measures

Percentage of patients, aged 6 months and older with a diagnosis of HIV/AIDS, with at least two **CD4 cell counts or percentages** performed during the measurement year at least 3 months apart

(All-Age measure)

Percentage of patients, regardless of age, with a diagnosis of HIV who had an **HIV drug resistance test** performed before initiation of HIV antiretroviral therapy if therapy started during the measurement year

(All-Age measure)

Percentage of patients, regardless of age, with a diagnosis of HIV with a **viral load test** performed at least every 6 months during the measurement year

(All-Age measure)

Percentage of patients aged 3 months and older with a diagnosis of HIV/AIDS, for whom there was documentation that a **tuberculosis screening test** was performed and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection

(All-Age measure)

Percentage of patients for whom **hepatitis C screening** was performed at least once since the diagnosis of HIV

(Adult and Adolescent measure)

Percentage of patients, regardless of age, for whom **hepatitis B screening** was performed at least once since the diagnosis of HIV/AIDS or for whom there is documented infection or immunity

(Adult and Adolescent measure)

Percentage of patients, regardless of age, with a diagnosis of HIV who were prescribed HIV antiretroviral therapy and who had a fasting **lipid panel** during the measurement year

(All-Age measure)

Percentage of adult patients with a diagnosis of HIV who had a **test for syphilis** performed within the measurement year

(Adult and Adolescent measure)

Percentage of patients with a diagnosis of HIV at risk of sexually transmitted infections who had a **test for gonorrhea** within the measurement year

(Adult and Adolescent measure)

Percentage of female patients with a diagnosis of HIV who have a **Pap screening** in the measurement year

(Adult and Adolescent measure)

O: Objective**Table 1. Laboratory Evaluations for HIV-Infected Patients**

Test	Rationale	Result		Frequency and Comments
HIV Confirmation, Staging and ART Monitoring				
HIV Antibody	Confirm diagnosis, if not documented previously			At entry to care
CD4 Count	- For HIV staging and prognosis - Helps guide urgency of ART initiation - Indicates risk of opportunistic illnesses and guides initiation of prophylaxis against opportunistic infections - Used to monitor immune reconstitution during ART	Reported in cells/μL		- Perform at baseline (twice). - Repeat every 3-6 months for stable patients on or off ART; may repeat every 6-12 months if stable and suppressed viral load. - Repeat if results are inconsistent with the clinical picture or with previous trends. - See chapter <i>CD4 and Viral Load Monitoring</i>.
CD4 Percentage	- Used in addition to the absolute CD4 count for monitoring trends; may be discrepant with absolute CD4 <i>Pneumocystis pneumonia</i> prophylaxis is indicated for CD4 percentage <14% regardless of absolute count	CD4 Count (cells/ μ L)	Expected CD4 Percentage	Usually obtained with absolute CD4 count.
		>500	>29%	
		200-500	14%-28%	
		<200	<14%	
Quantitative Plasma HIV RNA (HIV Viral Load)	- Estimates level of HIV replication - Used to monitor effect of ART - May be used to identify acute HIV infection; has high sensitivity in setting of acute infection, when antibody may be negative	- Reported in copies/mL - In untreated patients, detectable (with rare exceptions) and measured to the upper limit of detection (usually >500,000 copies/mL) - For patients taking ART, ideally suppressed to undetectable levels (usually <40 or <75 copies/mL)		- Perform at baseline (twice). - For patients on new or modified ART regimen: perform 2-8 weeks after initiation or change in ART, then every 4-8 weeks until viral load is suppressed. - For patients on stable ART: perform every 3-4 months (if stable and viral load suppressed >2-3 years, consider every 6 months). - For patients not taking ART: perform every 3-6 months; more frequently if CD4 count is low. <i>Factors that may temporarily increase viral load:</i> - Immunizations - Active infections

Test	Rationale	Result	Frequency and Comments
Predicting Safety and Efficacy of ARVs			
Drug Resistance Testing (Genotype, Phenotype)	To assess whether the patient's HIV virus is likely to be resistant to specific ARV medications	- Genotype: detects specific mutations to ARV medications - Phenotype: measures HIV viral replication in the presence of ARVs	- Genotype is recommended for all ARV-naïve patients. For greatest accuracy, should be done as early as possible in the course of HIV infection. - Acute or primary infection: recommended (genotype). - Chronic infection and treatment naïve: recommended before initiation of ART. (genotype). If resistance test was performed at entry, consider repeat testing. - Pregnancy: recommended before initiation of ART (repeat if done earlier) or for patients with detectable HIV RNA while taking ART. - Virologic failure: recommended. - Obtain genotype for integrase mutations if integrase inhibitor resistance is a concern. (See chapter <i>Resistance Testing</i> for more information.)
Coreceptor Tropism Test	Determine coreceptor tropism	If CXCR4-tropic (or dual/mixed tropic) virus is detected, CCR5 antagonist is not likely to be effective and should not be used	- Test before making decision to treat with CCR5 antagonist, or if virologic failure occurs while on a CCR5 antagonist (phenotypic assay preferred). - For standard assay, HIV RNA must be >1,000 copies/mL (a proviral DNA test is available for samples with HIV RNA below limits of detection; has not been clinically validated).
HLA-B*5701	Establish risk of hypersensitivity reaction to abacavir	If positive, high risk of abacavir hypersensitivity reaction; abacavir should not be used	Test before starting treatment with abacavir.

Test	Rationale	Result	Frequency and Comments
Baseline and Subsequent Hematologic, Renal, Hepatic, and Metabolic Screening			
Complete Blood Count (CBC) with Differential and Platelets	• Detects anemia, thrombocytopenia, leukopenia	• Normal	• Perform at baseline. • Repeat every 3-6 months.
		• Abnormal	• Requires follow-up evaluation as indicated; may influence choice of ARVs. • Repeat more frequently if the patient's results are abnormal or if the patient is taking bone marrow suppressive drugs (including zidovudine).
Chemistry Profile Electrolytes, Creatinine, eGFR (Estimated Glomerular Filtration Rate), Blood Urea Nitrogen Liver Transaminases, Bilirubin (Total and Direct)	• Detects electrolyte abnormalities, kidney disease, liver disease	• Normal/abnormal	• Perform at baseline; before starting ART. • Repeat 2-8 weeks after starting or modifying ART, then every 3-6 months if stable. • May influence ARV selection. • May be useful in monitoring drug toxicities. • Abnormalities should prompt evaluation of cause.
Urinalysis with Urine Protein and Creatinine	• Used to screen for kidney disease	• Normal/abnormal	Screen at baseline and before initiation or change of ART regimen. Repeat every 12 months. Repeat every 6 months for patients on tenofovir, more frequently if indicated. Abnormalities should prompt evaluation of cause. See chapter <i>Renal Disease</i>.

Test	Rationale	Result	Frequency and Comments
Baseline and Subsequent Hematologic, Renal, Hepatic, and Metabolic Screening (continued)			
Lipid Profile (Total Cholesterol, LDL, HDL, Triglycerides); fasting	Detects dyslipidemia, identifies risk factors for cardiovascular disease	Normal/abnormal	- Baseline; before starting ART. - Consider repeating 4-8 weeks months after starting or changing ART. - Repeat annually if normal (on or off ART), or more frequently (e.g., every 6 months) if abnormal or risk of cardiovascular disease. - May influence ARV selection. - May be useful in monitoring drug toxicities. See chapter <i>Dyslipidemia</i>.
Glucose (preferably fasting) or hemoglobin A1C	Detects diabetes and hyperglycemia	Normal/abnormal	- Baseline; before starting ART. - Repeat every 3-6 months if abnormal, every 6 months if normal on ART; every 12 months if normal and not on ART. - May influence ARV selection. - May be useful in monitoring drug toxicities. See chapter <i>Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy</i>.
Hepatitis A, B, and C Screening			
Hepatitis A Serology			
Hepatitis A Antibody (HAV IgG)	Screen for immunity to hepatitis A; vaccinate those not immune	Negative	Offer hepatitis A vaccine if indicated. (See chapter <i>Immunizations for HIV-Infected Adults and Adolescents</i>.)
		Positive	Immune; no vaccine necessary.

Test	Rationale	Result	Frequency and Comments
Hepatitis A, B, and C Screening (continued)			
Hepatitis B Serology (See chapter <i>Hepatitis B Infection</i>.)			
Hepatitis B Surface Antigen (HBsAg)	Indicates active hepatitis B	sAg negative	- Most likely, no chronic infection (may be falsely negative). - Vaccinate if HBsAb negative (not immune).
		sAg positive	Indicates chronic or acute hepatitis B infection; requires further evaluation (check HBV DNA). (See chapter <i>Hepatitis B Infection</i>.)
Hepatitis B Core Antibody (Anti-HBc, IgG)	Indicates past infection or ongoing infection	Anti-HBc negative	The patient most likely has not been infected with hepatitis B; consider vaccination if HBsAb negative and HBsAg negative.
		Anti-HBc positive	- The patient most likely has been infected with hepatitis B; this test alone does not distinguish past exposure and active infection. - In rare cases, may be falsely negative in some patients with chronic infection. - If sAb negative and sAg negative, check HBV DNA to rule out active infection; vaccinate if HBV DNA is not detected. - If sAb is positive, patient is immune.
Hepatitis B Surface Antibody (Anti-HBs)	Indicates immunity status	Anti-HBs negative	The patient is not immune to hepatitis B; consider vaccination, unless patient has active hepatitis (sAg positive or HBV DNA positive).
		Anti-HBs positive	The patient is immune to hepatitis B either by previous infection or by immunization; may be negative in acute hepatitis B infection.

Test	Rationale	Result	Frequency and Comments
Hepatitis A, B, and C Screening (continued)			
Hepatitis C Serology (See chapter <i>Hepatitis C Infection</i> .)			
Hepatitis C Antibody (HCV IgG)	Hepatitis C status	HCV negative	- Patient is not infected with hepatitis C. - Screen at baseline; consider annual screening for high-risk patients, and if clinically indicated.
		HCV positive	Patient has chronic hepatitis C infection or past infection with spontaneous clearance (no protective immunity); confirm positive results with HCV RNA.
Other Opportunistic Infection Screening Tests			
<i>Toxoplasma gondii</i> IgG	Detects past exposure; if positive, patient has increased risk of developing CNS toxoplasmosis if CD4 count <100 cells/μL	Negative	Repeat if patient becomes symptomatic or when CD4 count drops to ≤100 cells/μL.
		Positive	- Note as baseline information. - Start toxoplasmosis prophylaxis if CD4 count drops to ≤100 cells/μL.
Tuberculosis (TB) Screening TST (Tuberculin Skin Test) or IGRA (Interferon-Gamma Release Assay) (if no history of TB or positive TB screening test in the past)	Detects latent TB infection (LTBI)	Normal	- Repeat every 12 months if high risk of repeated or ongoing exposure. - Repeat if CD4 count was <200 cells/μL on initial test but increases to >200 cells/μL on ART.
		Abnormal (TST induration ≥5 mm or positive IGRA)	Evaluate for active TB. (See chapter <i>Latent Tuberculosis Infection</i>.)
Chest X-Ray (if pulmonary symptoms are present or positive LTBI test)	Detects latent or active diseases	Normal	Repeat as indicated for pulmonary symptoms or positive LTBI test.
		Abnormal	Evaluate for TB, PCP, or other pathology.

Test	Rationale	Result	Frequency and Comments
Other Opportunistic Infection Screening Tests (continued)			
Papanicolaou Test (cervical for women; consider anal for women and men)	• Detects abnormal cell changes, dysplasia	• Normal	• Cervical: Repeat in 6 months, then annually if negative on two tests and no ongoing risk factors. • Anal: No national guidelines; consider screen at baseline. Follow-up interval has not been determined; consider same as in cervical Pap screening.
		• Abnormal	• Perform workup, treat (see chapters <i>Cervical Dysplasia</i> and <i>Anal Dysplasia</i>) and follow up as indicated by condition.
Pregnancy Screening			
Pregnancy Test	• Indicates pregnancy status	• Positive/negative	• Perform before starting efavirenz (given risk of teratogenicity). • If positive, consider ART initiation; avoid efavirenz in first trimester (see chapters <i>Reducing Perinatal HIV Transmission</i> and <i>Care of HIV-Infected Pregnant Women</i>).
Sexually Transmitted Disease Testing			
Serum VDRL (Venereal Disease Research Laboratory) or RPR (Rapid Plasma Reagin) (some centers screen using a treponemal test)	• Screen for syphilis at least annually in sexually active persons who are at risk; for men who have sex with men (MSM) with multiple partners: every 3-6 months	• Negative/nonreactive	• Counsel about safer sex and avoiding STDs. • Repeat every 3-12 months, depending on risk factors.
		• Positive/reactive: confirm with treponemal test	• Treat patient; refer partner(s) for evaluation and treatment; counsel about safer sex. (See chapter <i>Syphilis</i>.) • Perform serial testing if monitoring active disease. (See chapter <i>Syphilis</i>.)

Test	Rationale	Result	Frequency and Comments
Women			
Gonorrhea (GC) and Chlamydia (CT) Testing	Screen for STDs in sexually active women at risk according to CDC and USPSTF guidelines; screen all ≤25 years of age at baseline and at least annually; more frequently if risk factors Screen all sites of possible exposures: • Pharynx (recommended for GC screening) • Cervix/vagina • Rectum	• Negative	• Counsel about safer sex and avoiding STDs. • Repeat every 6-12 months; more frequently if at high risk (e.g., adolescents).
		• Positive	• Treat patient; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex. • Retest at 3 months.
Trichomoniasis Testing	• Wet mount (insensitive), culture or nucleic acid amplification test (NAAT) of vaginal secretions • Screen HIV-infected women annually	• Negative	• Counsel about safer sex and avoiding STDs. • Repeat every 12 months.
		• Positive	• Treat patient; refer partner(s) for evaluation and treatment; counsel about safer sex. • Retest at 3 months.
Men			
Gonorrhea (GC) and Chlamydia (CT) Testing	• Screen for STDs in sexually active men who are at risk according to CDC guidelines, especially MSM • Screen all MSM at baseline and at least annually; frequency of subsequent testing depends on risk factors • Screen sites of possible exposures: • Pharynx, if receptive oral sex (recommended for GC screening) • Rectum, if receptive anal sex • Urethra for MSM, if insertive oral or anal sex	• Negative	• Counsel about safer sex and avoiding STDs. • Retest every 3-12 months, depending on risk factors.
		• Positive	• Treat; refer partner(s) of previous 60 days for evaluation and treatment; counsel about safer sex. • Retest at 3 months.

Test	Rationale	Result	Frequency and Comments
Consider/Optional			
G6PD Level	Prevent hemolytic reactions to certain medications by screening higher-risk patients (African, Mediterranean, Asian, Sephardic Jewish descent); some would recommend screening all patients	• Normal range	• No intervention is necessary beyond documentation.
		• Abnormal range	• Avoid oxidant drugs such as dapsone, primaquine, and sulfonamides, if possible.
Cytomegalovirus (CMV) Antibody (anti-CMV IgG) (for those at low risk of CMV, especially those who are not MSM or injection drug users)	Detects exposure; may reveal future disease risk	• Negative	- Avoid exposure by practicing safer sex. - If blood transfusion is required, use CMV-negative or leukocyte-reduced blood.
		• Positive	• Be aware of disease risk in advanced HIV infection, when CD4 count is <50 cells/ μ L.
Varicella zoster (Varicella IgG) (for those without history of chickenpox or shingles)	Detects exposure	• Negative	• Consider vaccination, if CD4 count is >200 cells/ μ L.
		• Positive	• No intervention is necessary.
Dilated Retinal Examination	Detects CMV, ophthalmic toxoplasmosis, or HIV retinopathy	• Normal	- If CD4 count is >100 cells/μL, repeat annually. - If CD4 count is <50 cells/μL or symptoms of retinal changes are present, repeat every 6 months.
		• Abnormal	• Follow up immediately with ophthalmologist.

Patient Education

- Discuss safer sex (review specifics appropriate to the patient's sexual practices and infections) to prevent the patient's exposure to herpes, hepatitis B, hepatitis C, and other STDs, and to prevent the patient from exposing others to HIV or other pathogens. In addition, remind the patient that safer sex practices will limit the risk of reinfection with HIV. (See chapters *Preventing HIV Transmission/Prevention with Positives* and *Preventing Exposure to Opportunistic and Other Infections*.)
- If *Toxoplasma* IgG test result is negative, see chapter *Preventing Exposure to Opportunistic and Other Infections*.
- If CMV test result is negative, counsel the patient that CMV is shed in semen, vaginal and cervical secretions, saliva, and urine of infected people. Latex condoms will help reduce risk. For women considering childbearing, CMV should be avoided to prevent severe disease and even death of the neonate. (See chapter *Preventing Exposure to Opportunistic and Other Infections*.)
- For patients who are hepatitis C negative and are using injection drugs, offer referral to a drug treatment program or a clean needle exchange program. (See chapters *Preventing HIV Transmission/Prevention with Positives* and *Preventing Exposure to Opportunistic and Other Infections*.)

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Interim History and Physical Examination

Background

This chapter shows the suggested frequency and follow-up intervals of the history and physical examination for monitoring HIV-infected patients, as well as specific areas to assess in an ongoing manner. With this information, the clinician can track disease progression and formulate and maintain an appropriate care plan. Note that information gathered in the history or physical examination may indicate a need for additional directed explorations.

It is important to document new or ongoing symptoms and functional limitations at each visit. This information is particularly useful when outside agencies must determine the patient's disability status. (See chapter *Karnofsky Performance Scale*.)

See chapter *Initial and Interim Laboratory and Other Tests* for recommended screening tests.

HRSA HAB Performance Measures

Percentage of patients, regardless of age, with a diagnosis of HIV who had at least **one medical visit in each 6-month period** of the 24-month measurement period with a minimum of 60 days between medical visits
(Core measure)

Percentage of female patients with a diagnosis of HIV who have a **Pap screening** in the measurement year
(Adult and Adolescent measure)

Percentage of patients with a diagnosis of HIV who received **HIV risk counseling** in the measurement year
(Adult and Adolescent measure)

Percentage of new patients with a diagnosis of HIV who have been **screened for substance use** (alcohol and drugs) in the measurement year
(Adult and Adolescent measure)

Percentage of patients aged 12 years and older **screened for clinical depression** on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen
(Adult and Adolescent measure)

Table 1. History and Physical Examinations

History	Physical Examination
Every visit (at least every 3-4 months)	
• New symptoms • Medications • HIV-related medications • Medications for other conditions • Over-the-counter medications • Herbs or vitamins • Adherence to medications and clinical care visits • Antiretroviral (ARV) doses missed in the past 3 days, in the past month • Knowledge of HIV regimen • HIV transmission risk behaviors and risk reduction methods • Sexual history (risk factors for STDs) • Mood • Alcohol and recreational drug use • Tobacco use • Allergies • Pain • Social supports • Housing • Insurance • Intimate partner violence	• Vital signs (temperature, blood pressure, heart rate, respiratory rate, and oxygen saturation) • Weight • General appearance and body habitus (including evaluation for lipodystrophy) • Skin • Oropharynx • Lymph nodes • Heart and lungs • Abdomen • Neurologic • Psychiatric (e.g., mood, affect, and attention)
Every 6 months	
As above	As above, plus: • Vision and funduscopic examination (if CD4 count <100 cells/μL) • Ears/nose
Every 6 months (twice), and, if both are normal, annually thereafter (see chapters <i>Cervical Dysplasia</i> and <i>Anal Dysplasia</i>)	
As above	• Women: pelvic examination; cervical Papanicolaou (Pap) test; consider anorectal examination, anal Pap test • Men: consider anal examination, anal Pap test
Annually	
Update initial history: HIV-related symptoms, hospitalizations, major illnesses, and family history	Complete physical to include: • Genitorectal examination • Testicular examination • Prostate examination • Breast examination

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HIV Classification: CDC and WHO Staging Systems

Background

HIV disease staging and classification systems are critical tools for tracking and monitoring the HIV epidemic and for providing clinicians and patients with important information about HIV disease stage and clinical management. Two major classification systems currently are in use: the U.S. Centers for Disease Control and Prevention (CDC) classification system and the World Health Organization (WHO) Clinical Staging and Disease Classification System.

The CDC disease staging system (most recently revised in 1993) assesses the severity of HIV disease by CD4 cell counts and by the presence of specific HIV-related conditions. The definition of AIDS includes all HIV-infected individuals with CD4 counts of <200 cells/ μL (or CD4 percentage $<14\%$) as well as those with certain HIV-related conditions and symptoms. Although the fine points of the classification system rarely are used in the routine clinical management of HIV-infected patients, a working knowledge of the staging criteria (in particular, the definition of AIDS) is useful in patient care. In addition, the CDC system is used in clinical and epidemiologic research.

In contrast to the CDC system, the WHO Clinical Staging and Disease Classification System (revised in 2007) can be used readily in resource-constrained settings without access to CD4 cell count measurements or other diagnostic and laboratory testing methods. The WHO system classifies HIV disease on the basis of clinical manifestations that can be recognized and treated by clinicians in diverse settings, including resource-constrained settings, and by clinicians with varying levels of HIV expertise and training.

S: Subjective

When a patient presents with a diagnosis of HIV infection, review the patient's history to elicit and document any HIV-related illnesses or symptoms (see chapter *Initial History*).

O: Objective

Perform a complete physical examination and appropriate laboratory studies (see chapters *Initial Physical Examination* and *Initial and Interim Laboratory and Other Tests*).

A: Assessment

Confirm HIV infection and perform staging.

P: Plan

Evaluate symptoms, history, physical examination results, and laboratory results, and make a staging classification according to the CDC or WHO criteria (see below).

CDC Classification System for HIV Infection

The CDC categorization of HIV/AIDS is based on the lowest documented CD4 cell count and on previously diagnosed HIV-related conditions (see Table 1). For example, if a patient had a condition that once met the criteria for category B but now is asymptomatic, the patient would remain in category B. Additionally, categorization is based on specific conditions, as indicated below. Patients in categories A3, B3, and C1-C3 are considered to have AIDS.

Table 1. CDC Classification System for HIV-Infected Adults and Adolescents

CD4 Cell Count Categories	Clinical Categories		
	A Asymptomatic, Acute HIV, or PGL	B* Symptomatic Conditions, not A or C	C# AIDS-Indicator Conditions
(1) ≥ 500 cells/ μ L	A1	B1	C1
(2) 200–499 cells/ μ L	A2	B2	C2
(3) <200 cells/ μ L	A3	B3	C3

Abbreviations: PGL = persistent generalized lymphadenopathy

* Category B Symptomatic Conditions

Category B symptomatic conditions are defined as symptomatic conditions occurring in an HIV-infected adolescent or adult that meet at least one of the following criteria:

- They are attributed to HIV infection or indicate a defect in cell-mediated immunity.
- They are considered to have a clinical course or management that is complicated by HIV infection.

Examples include, but are not limited to, the following:

- Bacillary angiomatosis
- Oropharyngeal candidiasis (thrush)
- Vulvovaginal candidiasis, persistent or resistant
- Pelvic inflammatory disease (PID)
- Cervical dysplasia (moderate or severe)/cervical carcinoma in situ
- Hairy leukoplakia, oral
- Herpes zoster (shingles), involving two or more episodes or at least one dermatome
- Idiopathic thrombocytopenic purpura
- Constitutional symptoms, such as fever ($>38.5^{\circ}\text{C}$) or diarrhea lasting >1 month
- Peripheral neuropathy

Category C AIDS-Indicator Conditions

- Bacterial pneumonia, recurrent (two or more episodes in 12 months)
- Candidiasis of the bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical carcinoma, invasive, confirmed by biopsy
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month in duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcers (>1 month in duration), or bronchitis, pneumonitis, or esophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 -month in duration)
- Kaposi sarcoma
- Lymphoma, Burkitt, immunoblastic, or primary central nervous system
- *Mycobacterium avium* complex (MAC) or *Mycobacterium kansasii*, disseminated or extrapulmonary

- *Mycobacterium tuberculosis*, pulmonary or extrapulmonary
- *Mycobacterium*, other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis jiroveci* (formerly *carinii*) pneumonia (PCP)
- Progressive multifocal leukoencephalopathy (PML)
- *Salmonella* septicemia, recurrent (nontyphoid)
- Toxoplasmosis of brain
- Wasting syndrome caused by HIV (involuntary weight loss >10% of baseline body weight) associated with either chronic diarrhea (two or more loose stools per day for ≥ 1 month) or chronic weakness and documented fever for ≥ 1 month

WHO Clinical Staging of HIV/AIDS and Case Definition

The clinical staging and case definition of HIV for resource-constrained settings were developed by the WHO in 1990 and revised in 2007. Staging is based on clinical findings that guide the diagnosis, evaluation, and management of HIV/AIDS, and it does not require a CD4 cell count. This staging system is used in many countries to determine eligibility for antiretroviral therapy, particularly in settings in which CD4 testing is not available. Clinical stages are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS (see Table 2). These stages are defined by specific clinical conditions or symptoms. For the purpose of the WHO staging system, adolescents and adults are defined as individuals aged ≥ 15 years.

Table 2. WHO Clinical Staging of HIV/AIDS for Adults and Adolescents

Primary HIV Infection	
• Asymptomatic	• Acute retroviral syndrome
Clinical Stage 1	
• Asymptomatic	• Persistent generalized lymphadenopathy
Clinical Stage 2	
• Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis) • Herpes zoster	• Angular cheilitis • Recurrent oral ulceration • Papular pruritic eruptions • Seborrheic dermatitis • Fungal nail infections
Clinical Stage 3	
• Unexplained severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhea for >1 month • Unexplained persistent fever for >1 month (>37.6°C, intermittent or constant) • Persistent oral candidiasis (thrush) • Oral hairy leukoplakia • Pulmonary tuberculosis (current)	• Severe presumed bacterial infections (e.g., pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia) • Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis • Unexplained anemia (hemoglobin <8 g/dL) • Neutropenia (neutrophils <500 cells/μL) • Chronic thrombocytopenia (platelets <50,000 cells/μL)

Clinical Stage 4	
• HIV wasting syndrome, as defined by the CDC (see Table 1, above) • <i>Pneumocystis</i> pneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital, or anorectal site for >1 month or visceral herpes at any site) • Esophageal candidiasis (or candidiasis of trachea, bronchi, or lungs) • Extrapulmonary tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous system toxoplasmosis • HIV encephalopathy • Cryptococcosis, extrapulmonary (including meningitis)	• Disseminated nontuberculosis mycobacteria infection • Progressive multifocal leukoencephalopathy • Candida of the trachea, bronchi, or lungs • Chronic cryptosporidiosis (with diarrhea) • Chronic isosporiasis • Disseminated mycosis (e.g., histoplasmosis, coccidioidomycosis, penicilliosis) • Recurrent nontyphoidal <i>Salmonella</i> bacteremia • Lymphoma (cerebral or B-cell non-Hodgkin) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy • Symptomatic HIV-associated cardiomyopathy • Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)

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CD4 and Viral Load Monitoring

Background

The CD4 cell count and HIV viral load (RNA level) are closely linked to HIV-related illness and mortality. They give prognostic information on HIV progression and on response to therapy.

HRSA HAB Performance Measures

Percentage of patients, aged 6 months and older with a diagnosis of HIV/AIDS, with at least two **CD4 cell counts or percentages** performed during the measurement year at least 3 months apart

(All-Age measure)

Percentage of patients, regardless of age, with a diagnosis of HIV with a **viral load test** performed at least every 6 months during the measurement year

(All-Age measure)

CD4 Monitoring

CD4 lymphocyte cells (also called T-cells or T-helper cells) are the primary targets of HIV. The CD4 count and the CD4 percentage mark the degree of immunocompromise. The CD4 count is the number of CD4 cells per microliter (μL) of blood. It is used to stage the patient's disease, determine the risk of opportunistic illnesses, assess prognosis, and guide decisions about the urgency of starting antiretroviral therapy (ART) (see chapters *Risk of HIV Progression/Indications for ART* and *Antiretroviral Therapy*). The CD4 percentage is the percentage of the lymphocyte population that is CD4+; it is measured directly by flow cytometry. A CD4 percentage of <14% is considered to correspond to the same degree of immunosuppression as an absolute CD4 count of <200 cells/ μL . The absolute CD4 count is calculated from the CD4 cell percentage and the total white blood cell count.

The normal values for CD4 count vary considerably among different laboratories. The mean normal value for most laboratories is approximately 500-1,300 cells/ μL . This calculated value is subject to more fluctuations than the CD4 cell percentage. Illness, vaccination, diurnal variation, laboratory error, and some medications can result in transient CD4 cell count changes, whereas

the CD4 percentage remains more stable. Because CD4 counts may vary, treatment decisions generally should not be made on the basis of a single CD4 value. When results are inconsistent with previous trends, tests should be repeated, and treatment decisions usually should be based on two or more similar values. A change between two test results is considered significant if it is a 30% change in absolute CD4 count or 3 percentage point change in CD4 percentage.

In persons with untreated HIV infection, the CD4 count declines by approximately 50-80 cells/ μL per year, on average. The pattern of decline may be slow and steady, or the CD4 count may level off for an extended period of time (as in long-term nonprogressors) and then decrease. Although it takes an average of 10 years for a newly infected person to progress to AIDS, there is great variation among patients. For some patients, disease progression occurs within a year or two. For others, it takes more than 20 years, and a small number of patients appear to maintain high CD4 counts and undetectable HIV RNA levels without ART (aviremic or “elite” controllers).

Among asymptomatic individuals, the CD4 count until recent years was the major factor that guided the decision to initiate therapy, and it remains so in resource-limited areas of

the world. Current United States guidelines recommend treatment for all HIV-infected individuals regardless of CD4 count. The CD4 count, though, can help clinicians and patients decide how quickly to start therapy. Clinical status, viral load, pregnancy, comorbidities, patient adherence to medications, and risk of HIV transmission are among the other factors that should be taken into consideration (see chapters *Risk of HIV Progression/Indications for ART* and *Antiretroviral Therapy*).

Prophylaxis against opportunistic infections is based on CD4 count, and sometimes on CD4 percentage. For example, a CD4 count of <200 cells/ μ L or a CD4 percentage of <14% is an indication for prophylaxis against *Pneumocystis jiroveci* pneumonia; a CD4 count of <50 cells/ μ L is an indication for prophylaxis against *Mycobacterium avium* complex. (See chapters *Opportunistic Infection Prophylaxis* and *Risk of HIV Progression/Indications for ART*.) The CD4 count also guides decision making in determining when to stop prophylaxis against opportunistic infections with patients whose CD4 counts rise in response to ART.

Effective ART typically results in CD4 count increases of >50 cells/ μ L within weeks after viral suppression, and increases of 50-100 cells/ μ L per year thereafter. For some patients, CD4 counts may not increase that quickly or steadily, even with durable viral load suppression. Patients who are older (age >50) and those with lower baseline CD4 cell counts are more likely to have blunted CD4 count responses. For monitoring purposes, the CD4 count should be repeated approximately every 3-6 months both in stable untreated patients and in patients on ART. For patients on ART with persistently suppressed HIV RNA and CD4 counts solidly above thresholds for opportunistic infection risk, current guidelines suggest monitoring every 6-12 months, and some data demonstrate that even less frequent CD4 checks in such patients is safe. The CD4

count should be checked more often if clinically indicated (e.g., switching therapy, ART failure, rapidly declining CD4 count) (see Table 1).

Viral Load Monitoring

The HIV-1 viral load measurement indicates the number of copies of HIV-1 RNA per milliliter of plasma. Although HIV ultimately resides within cells, the plasma measurement is an accurate reflection of the burden of infection and the magnitude of viral replication. It is used to assess the risk of disease progression and can help guide initiation of therapy. It is critical in monitoring virologic response to ART.

There are several commercially available HIV-1 viral load assays and numerous institution-specific assays. The range of detectable virus differs somewhat with each test, but the lowest level of detection generally is 20-75 copies/mL. A viral load below this “undetectable” level indicates the inability of the assay to detect HIV in the plasma, but does not indicate absence or clearance of the virus from the body. The highest levels of detection of the viral load assays typically are between 500,000 copies/mL and 750,000 copies/mL. Viral loads higher than these levels are reported, for example, as >500,000 copies/mL. Note that commercially available assays may not detect HIV-2, and they do not accurately quantify it.

After initial infection with HIV, the viral load quickly peaks to very high levels, usually >100,000 copies/mL (see chapter *Early HIV Infection*). During the period of acute infection, when HIV antibody testing may indicate negative results, the viral load test may be used to detect HIV infection. Generally, 3-6 months after primary infection, the viral load declines and then levels off, remaining in a steady state. Among patients who are not taking ARV medications, a small number maintain a low or even undetectable viral load (aviremic or “elite” controllers), but the vast majority of those patients have relatively high HIV RNA levels.

Higher plasma viral loads are associated with more rapid declines in CD4 cells and with increased risk of progression to symptomatic disease and AIDS; they also are associated with higher risk of HIV transmission (see chapter *Risk of HIV Progression/Indications for ART*). In untreated persons, the CD4 cell count is more useful in determining the urgency of ART initiation, but once a patient has started ART, the viral load is used to monitor the response to therapy. A key goal of ART is to achieve a viral load that is below the level of quantitation (e.g., <40 copies/mL). Because CD4 and clinical responses may lag behind changes in viral load, viral load testing is essential for detecting virologic failure in a timely manner. With an effective ARV regimen, a decline of at least 10-fold (1 logarithm) is expected within the first month, and suppression to undetectable levels should be achieved within 3-6 months after initiation of therapy. Isolated low-level elevations (typically <400 copies/mL) in viral load may occur in patients on ART; these “blips” generally do not predict subsequent virologic failure. (Additionally, some viral load assays appear to produce low-level positive results [<200 copies/mL] more commonly

than others; as with blips, these do not in general appear to increase the risk of virologic failure.) To avoid confusing virologic failure with blips or test variability, current guidelines define virologic failure as repeated HIV RNA levels >200 copies/mL. If the viral load does not reduce to an undetectable level (or at least <200 copies/mL), or if it rebounds after suppression, virologic failure has occurred, and possible causes should be investigated (e.g., poor ARV adherence, resistance to ARVs, or reduced drug exposure).

The HIV viral load should be checked at least twice at baseline, before the patient starts an ART regimen. Follow-up viral load measurement should be performed at regular intervals, depending on the patient’s clinical situation (see Table 1). For stable patients, viral load usually should be monitored every 3-4 months; for highly adherent and stable patients with suppressed viral loads for at least several years, monitoring every 6 months is adequate. With new therapy or changes in therapy, significant change in viral load or CD4 count, or declining clinical status, the viral load should be measured at more frequent intervals.

Table 1. CD4 and HIV Viral Load Monitoring Schedule

	Baseline	Follow-Up Before ART Initiation	At ART Initiation or Switch	After ART Initiation or Switch	Follow-Up on Effective ART	Treatment Failure or Clinical Indications
CD4 Count	√	Every 3-6 months	√	3-6 months	Every 3-6 months*	√
HIV Viral Load	√	Every 3-6 months	√	2-8 weeks, then every 4-8 weeks until HIV RNA is undetectable	Every 3-4 months**	√

* Clinically stable patients on ART with sustained viral suppression and CD4 counts above threshold for opportunistic infection risk: may monitor every 6-12 months.

**Adherent patients on stable ART with viral suppression and stable immunologic status for >2-3 years: can consider monitoring every 6 months.

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Viral loads, like CD4 counts, are affected by laboratory variation, assay fluctuations, and patient variables such as acute illness and recent vaccinations. Variations of $<0.5 \log_{10}$ copies/mL (threefold) usually are not clinically significant. Viral load results that are inconsistent with previous trends should be repeated, and treatment decisions usually should be based on two or more similar values. Recent illnesses or vaccinations can transiently increase viral load. If a patient has had a recent illness or vaccination, the viral load measurement should be deferred for 4 weeks, if possible.

Patient Education

- The CD4 cell count is the best indicator for gauging the strength of the immune system and for determining whether a person is at risk of infection with certain organisms. The higher the CD4 count, the stronger the immune system.
- CD4 counts are variable. Caution patients not to pin emotions and hopes to a single laboratory result. A change of $<30\%$ may not be significant.
- The HIV viral load is the best indicator of the level of HIV activity in the patient's body.
- The CD4 count and HIV viral load may be used to help determine how urgently therapy is needed (note, though, that current guidelines recommend ART for all persons with HIV infection, regardless of CD4 or viral load).
- A key goal of therapy is to suppress the viral load to below the level of detectability by laboratory tests. An undetectable viral load does not mean HIV has been completely eradicated or that the patient is not infectious to others.

- For most patients on effective ART, the CD4 count will rise as the virus is suppressed. This indicates an improvement in the immune system.
- In stable patients on ART, the CD4 count and HIV viral load usually should be monitored every 3-6 months.

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Risk of HIV Progression/ Indications for ART

Background

The CD4 cell count and HIV viral load (RNA level) are closely linked to HIV-related illness and mortality, and are the laboratory measures that are followed in clinical practice. They are the primary markers that give prognostic information on disease progression and on response to antiretroviral therapy (ART) (see chapter *CD4 and Viral Load Monitoring*). However, it is increasingly recognized that a number of other factors are involved in HIV disease progression. These include individual HIV-specific immune responses, immune activation, viral factors, host genetics, and age. The role of these factors and their interplay is complex and incompletely understood.

CD4 Count

The CD4 count (and CD4 percentage) marks the degree of immunocompromise. The CD4 count is used to stage the patient's disease progression, determine the risk of opportunistic illnesses, and assess prognosis (see chapter *CD4 and Viral Load Monitoring*). The CD4 count also helps to determine the urgency and the timing of ART initiation, and the need for prophylaxis against opportunistic infections. It also helps in formulating differential diagnoses for symptomatic patients

(see Table 1, Figure 1, and chapters *CD4 and Viral Load Monitoring* and *Opportunistic Infection Prophylaxis*).

Persons with HIV infection are at increased risk of complications at lower CD4 counts. A CD4 count of <200 cells/ μ L (or CD4 percentage of <14%) indicates severe immunosuppression, and is an AIDS-defining condition. Persons with CD4 counts below this level are at greater risk of a number of opportunistic illnesses and death, increasingly so at lower CD4 counts (see Table 1).

Table 1. Correlation Between CD4 Cell Counts and Complications of HIV Infection

CD4 Count* (cells/ μ L)	Infectious Complications	Noninfectious Complications [#]
>500	- Acute retroviral syndrome - Candidal vaginitis	- Persistent generalized lymphadenopathy (PGL) - Guillain-Barré syndrome - Myopathy - Aseptic meningitis
200-500	- Pneumococcal and other bacterial pneumonias - Pulmonary tuberculosis - Herpes zoster - Oropharyngeal candidiasis (thrush) - Cryptosporidiosis (self-limited) - Kaposi sarcoma (cutaneous) - Oral hairy leukoplakia - Herpes simplex (oral/genital)	- Cervical intraepithelial neoplasia - Cervical cancer - B-cell lymphoma - Anemia - Mononeuropathy multiplex - Idiopathic thrombocytopenic purpura - Hodgkin lymphoma - Lymphocytic interstitial pneumonitis - Fatigue
<200	<i>Pneumocystis jiroveci</i> pneumonia (PCP) - Disseminated histoplasmosis and coccidioidomycosis - Miliary/extrapulmonary tuberculosis - Progressive multifocal leukoencephalopathy (PML)	- Wasting - Peripheral neuropathy - HIV-associated dementia - Cardiomyopathy - Vacuolar myelopathy - Progressive polyradiculopathy - Non-Hodgkin lymphoma
<100	- Disseminated herpes simplex virus - Toxoplasmosis - Cryptococcosis - Cryptosporidiosis, chronic - Microsporidiosis - Candidal esophagitis - Kaposi sarcoma (visceral/pulmonary)	
<50	- Disseminated cytomegalovirus (CMV) - Disseminated <i>Mycobacterium avium</i> complex (MAC)	Central nervous system (CNS) lymphoma

* Most complications occur with increasing frequency at lower CD4 cell counts.

[#] Some conditions listed as “noninfectious” are associated with transmissible microbes. Examples include lymphoma (Epstein-Barr virus) and anal and cervical cancers (human papillomavirus).

Adapted from Bartlett JG, Gallant JE, Pham P. 2012 *Medical Management of HIV Infection*. Baltimore: Johns Hopkins University School of Medicine; 2012. Used with permission.

Increasing evidence suggests that the risk of complications from HIV infection occurs across a broad spectrum of CD4 counts, and that patients with relatively high counts (those with counts of >350 cells/ μ L and even those with counts of >500 cells/ μ L) also have increased rates of morbidities compared with HIV-uninfected persons. The complications

in persons with higher CD4 counts typically are not the classic AIDS-related opportunistic illnesses but are “non-AIDS” illnesses such as cardiovascular disease, neurocognitive decline, and non-AIDS-associated cancers.

In asymptomatic individuals, CD4 count has been used as the main indicator of need for ART. It is well established that ART is extremely effective

at reducing HIV-related illness in persons with lower CD4 counts. In recent years, accumulating data have suggested that ART also is beneficial for persons with high pretreatment CD4 counts.

Randomized trials have shown that starting ART for asymptomatic patients with pretreatment CD4 counts of 200-350 cells/ μ L results in decreased morbidity and mortality compared with starting therapy for persons with CD4 counts of <200 cells/ μ L. For patients with pretreatment CD4 counts of >350 cells/ μ L, data from several randomized controlled studies and cohort studies have found decreased rates of complications and death among persons who initiated ART at CD4 counts of $\geq$ 350 cells/ μ L, compared with persons who initiated treatment at lower CD4 counts. Additionally, some (though not all) observational evidence suggests a mortality benefit of ART even among persons with pretreatment CD4 counts of >500 cells/ μ L. These cohort studies are complemented by a

number of investigations that demonstrate ongoing and adverse effects of HIV and associated inflammation on various organ systems. A randomized controlled trial to evaluate the strategy of starting treatment at CD4 counts >500 cells/ μ L is under way.

These lines of evidence, along with studies showing a substantial impact of ART in decreasing HIV transmission, and the availability of ARVs that generally are safe, tolerable, and effective, support the rationale for earlier initiation of treatment. The current U.S. Department of Health and Human Services (HHS) adult and adolescent treatment guidelines recommend starting ART for all HIV-infected persons regardless of CD4 count, both to enhance the health of the infected individual and to prevent transmission of HIV. The strength of this recommendation is greater if the CD4 count is lower or the clinical status is poorer, and according to transmission risk groups (see Table 2 and chapter *Antiretroviral Therapy*).

Table 2. HHS Recommendations on Initiation of Antiretroviral Therapy

The HHS guidelines state that, "*Antiretroviral therapy (ART) is recommended for all HIV-infected individuals to reduce the risk of disease progression.*" The strength and evidence for this recommendation vary by pretreatment CD4 cell count, as follows:

CD4 Criteria	Strength of Recommendation*
- CD4 count <350 cells/μL - CD4 count 350-500 cells/μL - CD4 count >500 cells/μL	- Strongly recommended (AI) - Strongly recommended (AII) - Moderately recommended (BIII)

Additionally, the guidelines state that, "*ART also is recommended for HIV-infected individuals for the prevention of transmission of HIV.*" The strength and evidence for this recommendation vary by transmission risk, as follows:

Transmission Risk Group	Strength of Recommendation*
- Perinatal transmission - Heterosexual transmission - Other transmission risk groups	- Strongly recommended (AI) - Strongly recommended (AI) - Strongly recommended (AIII)

* **Rating of recommendation:** A = strong; B = moderate; C = optional

Rating of evidence: I = data from randomized controlled trials; II = data from well-designed nonrandomized trials or observational cohort studies; III = expert opinion

Considerations
Patients starting ART should be willing and able to commit to treatment and understand the benefits and risks of therapy and the importance of adherence (AIII). Patients may choose to postpone therapy, and providers, on a case-by-case basis, may elect to defer therapy on the basis of clinical and/or psychosocial factors.

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

A number of factors and coexisting conditions signal the need for speedier initiation of therapy, if possible. According to the HHS guidelines, these include the following:

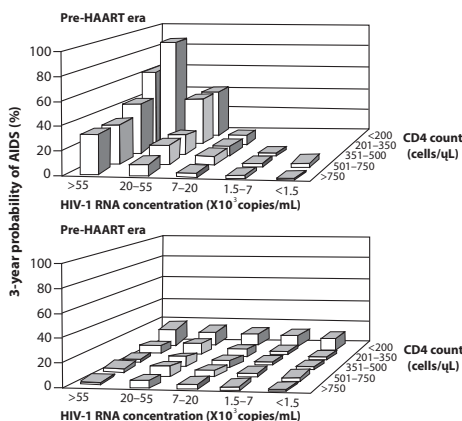
- Pregnancy
- History of AIDS-defining illness
- Acute opportunistic infection
- Lower CD4 cell count
- Acute/recent HIV infection
- HIV-associated nephropathy
- Hepatitis B coinfection
- Hepatitis C coinfection
- Rapidly declining CD4 counts (e.g., >100 cells/ μ L per year)
- Higher HIV RNA (e.g., >100,000 copies/mL)

HIV Viral Load

Whereas the CD4 count is an indicator of immune system function, the HIV viral load (RNA level) gives prognostic information on how quickly the CD4 count is likely to decline and, consequently, the risk of disease progression. Patients with high HIV viral loads generally demonstrate a faster decline in CD4 count and progression to AIDS-related illnesses; they also may have a higher rate of non-AIDS-related events even with relatively high CD4 counts (e.g., >350 cells/ μ L). Those with low viral loads usually have higher CD4 counts and remain asymptomatic for prolonged periods. A small percentage of persons with HIV infection may have very low or undetectable viral loads for extended periods of time.

By themselves, CD4 count and HIV viral load are useful, albeit rough, prognostic indicators. When considered together, they constitute a finer tool to estimate the risk of progression (see Figure 1).

Figure 1. Prognosis According to CD4 Cell Count and Viral Load in the Pre-ART and ART Eras: Kaplan-Meier Estimates of the Probability of AIDS at 3 Years



Abbreviations: HAART = highly active antiretroviral therapy
 Egger M, May M, Chene G, Phillips AN, Ledergerber B, Dabis F, Costagliola D, D'Arminio Monforte A, de Wolf F, Reiss P, Lundgren JD, Justice AC, Staszewski S, Leport C, Hogg RS, Sabin CA, Gill MJ, Salzberger B, Sterne JA; ART Cohort Collaboration. *Prognosis of HIV-1-infected patients starting highly active antiretroviral therapy: a collaborative analysis of prospective studies*. Lancet. 2002 Jul 13;360(9327):119-29. Reprinted with permission from Elsevier.

Other Factors Associated with HIV Progression

Although the CD4 count and HIV viral load are the most important predictors of HIV progression, it is increasingly recognized that a number of other factors, and likely others that remain unknown, contribute to disease progression in HIV infection.

Viral factors

Variations in the HIV genome have been associated with an altered rate of disease progression. For example, deletions in the *nef* gene have been associated with a slow rate of progression. On the other hand, virus that uses the CXCR4 protein as a coreceptor for entry (termed X4 virus or syncytia-inducing virus) has been associated with accelerated progression. As another example, drug-resistance mutations may

affect how efficiently the virus replicates (viral fitness). Patients who have virus with decreased fitness have slower immune deterioration than those with wild-type virus.

Host immune factors

Host genetic factors have been shown to alter the rate of HIV progression. Various human leukocyte antigen (HLA) alleles have been associated with faster or slower progression rates. Genetic polymorphisms also play a role. For example, CCR5 is a chemokine receptor that can serve as a coreceptor for HIV entry into the CD4 cell. A naturally occurring variant allele for CCR5 has a 32 base pair deletion. Individuals who are heterozygous for this allele have slower progression of HIV disease.

Increased immune activation and elevated markers of inflammation, such as IL-6 and D-dimer, also have been associated with risk of disease progression and death. They also may be involved in the ongoing damage seen in a number of end organs. Although T-cell activation and levels of inflammation decrease with ART, they often do not return to normal.

Age

Several studies have shown a higher risk of morbidity and mortality in older patients. When followed from seroconversion, older patients demonstrate faster disease progression compared with younger patients (see Table 3). Older patients also are found to have a less robust increase in the CD4 count in response to ART and may have a higher rate of non-AIDS-related morbidities.

Table 3. Median Survival and Time to AIDS by Age at Seroconversion

Age at Seroconversion (years)	Median (95% CI) Survival (years)	Median (95% CI) Time to AIDS (years)
15-24	12.5 (12.1-12.9)	11.0 (10.7-11.7)
25-34	10.9 (10.6-11.3)	9.8 (9.5-10.1)
35-44	9.1 (8.7-9.5)	8.6 (8.2-9.0)
45-54	7.9 (7.4-8.5)	7.7 (7.1-8.6)
55-64	6.1 (5.5-7.0)	6.3 (5.5-7.2)
≥65	4.0 (3.4-4.6)	5.0 (4.0-6.2)

Adapted from *Concerted Action on SeroConversion to AIDS and Death in Europe. Time from HIV-1 seroconversion to AIDS and death before widespread use of highly-active antiretroviral therapy: a collaborative re-analysis. Collaborative Group on AIDS Incubation and HIV Survival including the CASCADE EU Concerted Action. Lancet.* 2000 Apr 1;355(9210):1131-7.

Patient Education

- The CD4 cell count and HIV viral load are the two markers that provide information on the degree of current immunocompromise and the risk of disease progression.
- The lower the CD4 count, the higher the risk of AIDS-related illness.
- Current United States guidelines recommend ART for all HIV-infected individuals. In areas where treatment resources are limited, the CD4 count is the major indicator for initiation of ART.
- A low HIV viral load is associated with slower immune deterioration; a high viral load is associated with quicker immune deterioration.
- Older individuals may have a poorer response to therapy; earlier initiation of therapy may be considered for older patients.

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Early HIV Infection

Background

Acute HIV infection refers to the very early stages of HIV infection, or the interval from initial infection to the time that antibody to HIV is detectable; early HIV infection usually includes the first 6 months of infection. During the acute stage of HIV infection, patients typically have symptoms of acute retroviral illness, very high HIV RNA levels (>100,000 copies/mL) and detectable p24 antigen, and negative or indeterminate HIV antibody test results.

Diagnosing patients with acute HIV infection is a clinical challenge. The symptoms of acute HIV are nonspecific, and although many patients seek medical care for symptoms of acute retroviral syndrome, the diagnosis commonly is missed at initial presentation. The difficulties involve recognizing the clinical presentation of acute HIV infection and testing patients appropriately. In HIV treatment facilities, clinicians generally do not see patients with primary HIV infection unless they are referred with the diagnosis already established. In other health care settings, clinicians may not be familiar with the signs and symptoms of acute HIV infection and often do not consider this diagnosis. Despite the difficulties, recognizing early HIV infection in symptomatic patients is essential. Early diagnosis provides an opportunity for early linkage to HIV care and treatment and may decrease future HIV transmission by newly identified patients, who are particularly infectious during early untreated HIV infection.

After infection with HIV, it takes a median of about 25 days before the HIV antibodies are detectable in most people; in some individuals, it may be several months before seroconversion occurs. HIV RNA may be detectable within 10 days of infection and p24 antigen in about 15-20 days. Persons with known exposures to HIV, whether occupational or not, should be monitored closely beginning at about 3 weeks after exposure (routine monitoring at 6 weeks, 3 months, and 6 months after exposure to HIV is likely to result in delayed diagnosis of HIV infection). For information on postexposure prophylaxis, see chapters *Nonoccupational Postexposure Prophylaxis* and *Occupational Postexposure Prophylaxis*.

S: Subjective

Approximately two thirds of patients infected with HIV develop symptoms of acute HIV infection, a condition known as acute retroviral syndrome. Symptoms typically appear 2-6 weeks after exposure to HIV and generally include several of the following:

- Fever (present in 80-90%)
- Rash, often erythematous and maculopapular
- Fatigue
- Pharyngitis (with or without exudate)
- Generalized lymphadenopathy
- Urticaria

- Myalgia/arthralgia
- Anorexia
- Mucocutaneous ulceration
- Headache, retroorbital pain
- Neurologic symptoms (e.g., aseptic meningitis, radiculitis, myelitis, cranial nerve palsies)

This symptomatic phase usually persists for 2-4 weeks or less, although lymphadenopathy may last longer. Symptoms and signs are similar to those of many other illnesses, including other viral syndromes, influenza, and mononucleosis. However, generalized lymphadenopathy, rash, thrush, and mucosal ulceration are sufficiently uncommon in most adult febrile illnesses that, when present, they

should trigger suspicion of acute HIV infection. It is important to obtain a history of recent risk behaviors from all patients who present with symptoms consistent with acute HIV infection and to have a low threshold for testing for acute HIV infection. Common laboratory findings include leukopenia, thrombocytopenia, and mild transaminase elevations.

O: Objective

The 3rd-generation assays may detect HIV infection within 4 weeks, but new 4th-generation HIV antigen/antibody tests usually show positive results within 2-3 weeks after an infection occurs. During the symptomatic phase of HIV seroconversion, HIV antibody tests may still indicate negative or indeterminate serostatus. For patients who have negative or indeterminate antibody results but symptoms consistent with seroconversion illness and a recent risk history for HIV exposure, an HIV RNA (viral load) test should be performed. Patients with negative or indeterminate antibody test results but detectable HIV viral loads (particularly >10,000 copies/mL) can be considered to be infected with HIV, although the antibody test should be repeated later to confirm seroconversion. A low viral load (<10,000 copies/mL) may indicate a false-positive result, because viral loads typically run very high (i.e., >100,000 copies/mL and, often, millions of copies/mL) during the acute infection stage. For patients who have negative or indeterminate HIV antibody test results and low positive HIV viral loads, the HIV RNA test should be repeated on a different blood specimen.

The 4th-generation HIV tests do not distinguish between antigen positivity and antibody positivity. Patients with a positive result should be retested with an antibody test; if the result is negative or indeterminate and acute HIV is suspected, an HIV RNA test should be sent, as above (see chapter *Expedited HIV Testing*).

A/P: Assessment/Plan

Patients with early HIV infection will need additional medical evaluation, baseline laboratory testing, and intensive support, counseling, and education about HIV infection. See chapters *Initial History*, *Initial Physical Examination*, and *Initial and Interim Laboratory and Other Tests* for detailed information on the initial evaluation of HIV-infected patients.

Laboratory

The initial laboratory work should include the following:

- CD4 cell count and HIV viral load.
- A baseline HIV genotype test for all patients with early HIV infection, even those who do not choose to start antiretroviral treatment (ART). In some cities in the United States and Europe, 6-16% of infected individuals have acquired HIV virus strains with mutations that confer resistance to antiretroviral medications. These resistance mutations may be identified by early resistance testing, but may not be detectable later. (See chapter *Resistance Testing*.)
- Patients diagnosed on the basis of HIV RNA should have an HIV antibody test repeated in 3-6 months to document seroconversion.

Treatment

ART is recommended for all persons with HIV, including those with early HIV infection. Some limited evidence suggests that treatment initiated during primary HIV infection may have particular benefits, including preserving HIV-specific immune function that would otherwise be lost as the infection progresses, limiting the size of the HIV viral reservoir, and decreasing the loss of gastrointestinal lymphoid tissue. In addition, early treatment is expected to decrease rates of HIV transmission during a time of heightened infectiousness.

The potential advantages of ART for primary infection must be weighed against

the possibility of short- and long-term toxicities, the possibility of developing drug resistance, and the adherence challenges associated with starting ART quickly for newly diagnosed patients. Issues concerning the possible treatment of primary HIV infection are reviewed in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (available at aidsinfo.nih.gov/guidelines).

For pregnant women with acute or recent HIV, the risk of perinatal HIV transmission is very high; thus, ART should be started as early as possible to try to prevent infection of the infant (see chapter *Reducing Perinatal HIV Transmission*).

For patients who opt to start therapy during primary HIV infection, the choice of agents and the recommendations for monitoring are the same as those for the treatment of patients with chronic HIV infection (see chapter *Antiretroviral Therapy*). The initial goal of therapy in primary HIV infection is to suppress the HIV viral load to undetectable levels.

Patient Education

- Patients with early HIV infection need support and counseling, as do all newly diagnosed patients.
- Intensive education about HIV infection, the course of disease progression, prognosis, and the benefits and risks of ART must be undertaken.
- Counseling patients about safer sex and drug injection techniques, as indicated, is especially important because these patients may have ongoing high-risk behaviors for HIV transmission and because they may be highly infectious during the primary infection period. (See chapter *Preventing HIV Transmission/Prevention with Positives* for more information about patient support and counseling in these areas.)

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Expedited HIV Testing

John Nelson, PhD, CPNP

Background

According to the U.S. Centers for Disease Control and Prevention (CDC), about 1.15 million people are living with HIV in the United States, and it has been estimated that about 18% of these individuals are unaware of their HIV serostatus. Additionally, it is estimated that 50,000 new HIV infections occur in the United States each year. It is important to identify persons who are infected with HIV as soon as possible after infection, in order both to link them to health care services and to reduce the risk that they will unknowingly transmit HIV to others.

In order to identify those with HIV infection, the CDC recommends routine voluntary HIV screening for all adults, adolescents, and pregnant women. Nevertheless, many people are reluctant to be tested, and many clinics do not offer routine testing. With expedited HIV testing, clients can be tested and receive their preliminary results during a single visit. The goals of expedited testing are to identify HIV infection as early as possible after initial infection and to do so in as little time as possible (negative results, indeterminate results, and confirmed positive test results are available during the same visit that testing is done). This makes it possible to link persons testing HIV positive to HIV medical care and other supports as quickly as possible. Expedited testing also allows for the efficient management of clients in need of urgent medical treatment (such as pregnant women) and situations requiring quick clinical decision making (such as assessment for postexposure prophylaxis).

Expedited HIV tests include both traditional nonlaboratory-performed rapid tests and antigen/antibody (Ag/Ab) laboratory-based tests. The Ag/Ab 4th-generation tests detect both HIV p24 antigen and anti-HIV antibodies (for HIV-1 and/or HIV-2). The 4th-generation tests are more sensitive during the acute phase of HIV infection than are the previous-generation screening immunoassay tests (including nonlaboratory-based rapid tests), so they are capable of diagnosing HIV infection at an earlier stage (as early as 2-3 weeks after infection). One laboratory-based 4th-generation test is capable of delivering the preliminary results within 1 hour.

Because of the greater sensitivity of 4th-generation laboratory-based immunoassays in identifying HIV at earlier stages of infection, it is now recommended that these tests be done whenever possible for HIV screening. Interestingly, 4th-generation testing is less expensive per test than the point-of-care (POC) rapid tests in the United States.

Clients and Settings for Expedited Testing

Expedited HIV testing is important in settings in which the availability of HIV test results would influence medical care immediately, or in routine screening in settings where HIV prevalence is high or clients are not likely to return for the test results. Settings in which the use of highly sensitive 4th-generation HIV Ag/Ab testing from a laboratory is preferable include labor and delivery facilities (where

identification of HIV infection is critical in preventing perinatal transmission), prenatal care facilities, hospital emergency departments, urgent care and acute care clinics, sexually transmitted disease clinics, drug treatment clinics, hospitals, and other clinical care or testing sites in communities with a high prevalence of HIV. In high-risk jurisdiction settings such as jails and mobile health service vans, and in community outreach programs where access to an on-site laboratory does not exist, nonlaboratory-based rapid testing is still recommended.

Expedited HIV Tests

The U.S. Food and Drug Administration (FDA) has approved three 4th-generation HIV Ag/Ab tests for use in the United States (see Table 1). Federal regulations under the Clinical Laboratory Improvement Amendments (CLIA) program categorize tests as waived, moderate complexity, or high complexity. Many rapid tests are approved as CLIA-waived tests (see Table 2), meaning that they may be performed at the POC after appropriate staff training and with procedures in place to ensure quality control. These tests use whole blood or oral fluid and require a few simple steps to perform.

Other rapid tests are “nonwaived” tests and must be performed in laboratories. Results for rapid tests performed at the POC are available in less than 30 minutes; results for expedited tests done in a laboratory should be available within 1 hour.

As mentioned above, 4th-generation laboratory-based tests are recommended for HIV screening. In cases wherein laboratory-based 4th-generation HIV testing is not available, then 2nd- or 3rd-generation antibody POC rapid testing may be done with the knowledge that a person in seroconversion may test falsely negative.

Table 1. FDA-Approved 4th-Generation HIV Tests for Laboratory Use Only (CLIA Moderate- or High-Complexity Tests)

Test Name	Time to Test Result	Target Analyte (Test Generation)	Sensitivity for Established HIV-1 Infection & Sensitivity for HIV-2 Infection (%) (95% Confidence Interval)	Specificity for Established HIV-1 Infection (%) (95% Confidence Interval)	Approved Specimen Types & Volume	Assay Format
Abbott Architect HIV Ag/Ab Combo Assay (fully automated CLIA moderate-complexity assay) (Expedited)	<30 min	HIV-1 p24 antigen and antibodies to HIV-1/2 (4th generation)	Plasma/Serum HIV-1 p24: 100 (94.3-100)/HIV-1: 100 (99.63-100) HIV-2: 100 (98.2-100)	Plasma/Serum 99.8 (99.6-99.9)	Plasma/Serum 150 µL	Chemiluminescent micro-particle immuno-assay
Bio-Rad GS HIV Combo Ag/Ab EIA (manual or semi-automated CLIA high-complexity assay)	>3 hours	HIV-1 p24 antigen and antibodies to HIV-1/2 (4th generation)	Plasma/Serum HIV-1: 100 (99.7-100); HIV-2: 100 (98.1-100)	Plasma/Serum 99.87 (99.76-99.93)	Plasma/Serum 75 µL	Enzyme immuno-assay micro-well format
Alere Determine HIV-1/2 Ag/Ab Combo	20 minutes	HIV p24 antigen and antibodies to HIV-1 and/or HIV-2 (4th generation)	Whole Blood 99.9 (99.4-100)	Whole Blood 99.6 (99.2-99.8)	Plasma/Serum Whole Blood	Immuno-assay
MultiSpot HIV-1/HIV-2 Rapid Test	15 minutes	Antibodies to HIV-1 and HIV-2 (detection and differentiation) (3rd generation)	100% (99.9-100)	99.9% (99.8-100)	Plasma/Serum	Immuno-assay

Adapted from U.S. Food and Drug Administration. *Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays*. September 17, 2013.

Table 2. FDA-Approved HIV Rapid Screening Assays for Point-of-Care Testing

Test Name	Time to Test Result	Target Analyte (Test Generation)	Sensitivity for Established HIV-1 Infection & Sensitivity for HIV-2 Infection (%) (95% Confidence Interval)	Specificity for Established HIV-1 Infection (%) (95% Confidence Interval)	Approved Specimen Types	Assay Format
SURE CHECK HIV 1/2 ASSAY (Clearview Complete HIV 1/2)	<15 minutes	Antibodies to HIV-1 and/or HIV-2; point-of-care test	99.7 (98.9-100)	99.9 (99.6-100)	Fingerstick & Whole Blood (Venipuncture, Fingerstick)	Rapid Immuno-assay
Clearview HIV 1/2 STAT-PAK ASSAY	15 minutes	Antibodies to HIV-1 and/or HIV-2; point-of-care test	99.7 (98.9-100)	99.9 (99.6-100)	Fingerstick & Whole Blood (Venipuncture, Fingerstick)	Rapid Immuno-assay
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 minutes	Antibodies to HIV-1 and/or HIV-2; point-of-care test	99.3 (98.4-99.7) Oral Fluid 99.6 (98.5-99.9) Whole Blood	99.8 (99.6-99.9) Oral Fluid 100 (99.7-100) Whole Blood	Oral Fluid, Whole Blood (Venipuncture, Fingerstick)	Rapid Immuno-assay
Chembio DPP HIV 1/2 Assay	<40 minutes	Antibodies to HIV-1 and/or HIV-2; point-of-care test	98.9 (98-99.4) Oral Fluid 99.8 (99.2-99.9) Fingerstick Whole Blood	99.9 (99.7-99.9) Oral Fluid 100 (99.8-100) Fingerstick Whole Blood	Oral Fluid, Whole Blood (Venipuncture, Fingerstick)	Rapid Immuno-chromatographic Assay
Uni-Gold Recombigen HIV-1/2	10 minutes	Antibodies to HIV-1 and/or HIV-2; point-of-care test	100 (99.5-100)	99.7 (99.0-100)	Whole Blood (Venipuncture, Fingerstick)	Rapid EIA
bioLytical INSTI HIV-1 Ab Test	60 seconds	Antibodies to HIV-1; point-of-care test	99.8 (99.3-99.9)	100 (99.7-100)	Whole Blood (Fingerstick)	Rapid Flow-Through Immuno-assay

Adapted from U.S. Food and Drug Administration. *Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays*. September 17, 2013.

Interpreting Test Results

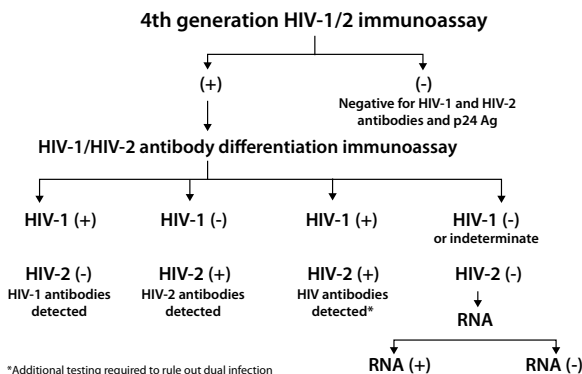
All FDA-approved tests are highly sensitive and specific. As previously mentioned, 4th-generation HIV Ag/Ab tests have significantly greater sensitivity to very recent (acute) HIV infection. The negative predictive value of all rapid and expedited HIV tests is close to 100%. That means a client who receives a negative rapid test result almost assuredly is not infected, barring recent exposures (e.g., sexual contact or needle sharing with an infected person within the past 1-3 months, depending on the test used).

For clients who test reactive (positive) on a rapid or expedited test, the result is considered preliminary and must be confirmed. Traditionally, confirmation has been done by use of either a Western blot (WB) or immunofluorescence assay (IFA). However, neither of these confirmatory tests is expedited, and neither is able to differentiate HIV-1 and HIV-2 infections simultaneously. The confirmatory test currently recommended by the CDC is one that is able to differentiate HIV-1 and HIV-2 antibodies and is expedited (e.g., MultiSpot HIV-1/HIV-2 Rapid Test). If the confirmatory test result is positive, the client is considered to be infected with HIV. If the confirmatory test result is negative (no HIV Ab bands with a WB test or no visible reaction on the MultiSpot in the HIV-1 and/or HIV-2 Ab areas) or indeterminate (with the WB test, greater than 0 bands but too few bands to be considered positive), then an HIV RNA-1 test should be done immediately to check for early infection (Figure 1). In this case, a detectable HIV RNA (unless very low) will indicate early HIV infection – the client is most likely HIV infected and is seroconverting from antibody negative to positive status. The HIV-1 RNA test should be done regardless of the original HIV screening test (4th-generation Ag/Ab or earlier-generation Ab). With detectable HIV RNA, the client

should be considered infected, but an HIV confirmatory (WB or IFA) antibody test should be repeated in roughly 2-4 weeks to determine HIV antibody status. In the case of possible HIV-2 infection, consultation with an HIV specialist is recommended.

The positive predictive value of a single positive rapid or expedited HIV test result depends on the specificity of the test and the HIV prevalence in the community. The high specificity of the rapid or expedited tests means that, if a test result is positive, the likelihood that a client is truly HIV infected depends on the local HIV prevalence. In a population with a high HIV prevalence, a positive test result is likely a true positive, but in a population with a low HIV prevalence, that result has a greater chance of being a false positive.

Figure 3. 4th-Generation HIV Testing Algorithm



Centers for Disease Control and Prevention. *Detection of acute HIV infection in two evaluations of a new HIV diagnostic testing algorithm – United States, 2011–2013.* MMWR Morb Mortal Wkly Rep. 2013 Jun 21;62(24):489–94.

Information for the Client

Educating the Client Before Testing

It is important to offer expedited HIV testing as part of a broader health screening, to educate clients about HIV infection and about the test, and to give them an opportunity to ask questions and to decline testing. The provider should emphasize that a second test is always performed in order to confirm a positive preliminary screening (laboratory or POC) test result. When possible, expedited or rapid testing should be made available during a regular visit so that clients do not face additional waiting time, and so that HIV infection can be detected as early as possible.

Giving Reactive (Preliminary Positive) Rapid Test Results

Example of simple language to use outside labor and delivery settings

The following wording is suggested when the client's rapid (nonconfirmed) test result is positive (or the expedited confirmatory testing is negative [and therefore the final result is "indeterminate"]):

"Your preliminary screening test result was positive, but we won't know for sure if you are infected with HIV until we get the results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus. This means protecting all sex partners from possible exposure (using condoms, for example), not sharing needles or syringes for any purpose, and not sharing razors."

Emphasize the importance of a confirmatory test, arrange for the confirmatory test to be done immediately. If an expedited, confirmatory test is available (MultiSpot Rapid), the client should not leave until that test has been completed and the result given. If an expedited confirmatory test is not available, then schedule a return visit for the client to receive the test result. It is important to develop a plan for follow-up with

this client during this waiting period (by phone or in-person) and to reinforce the importance of following up. (Be sure to have the client's contact information in case he or she does not return for confirmatory results.)

Example of language to use in labor and delivery settings

The following wording is suggested when the client's nonconfirmed expedited or rapid test result is positive:

"Your preliminary HIV screening result was positive. You may have HIV infection. We need to do confirmatory tests to verify this first result, but it is important to start medication immediately to reduce the risk of passing HIV to your baby while we wait for the result. It is important to delay breast-feeding until we have the confirmatory test results."

Follow-Up for Results of Confirmatory Tests

Clinical sites that offer expedited or rapid HIV testing should have a protocol for conveying the results of preliminary and confirmatory positive HIV test results to clients. With rapid tests and expedited laboratory-based testing, the client may be given the confirmatory results on the same day tested. If expedited laboratory-based confirmatory testing (MultiSpot Rapid), is not available, blood for confirmatory WB or IFA must be collected. In this case, results generally will not be available the same day, but appropriate specimen collection and test ordering should be done before the client leaves on the day the preliminary positive result is given.

If the confirmatory result is negative or indeterminate (after a positive preliminary result), testing for HIV-1 RNA must be done.

Sites should either provide confirmatory notification services in-house or have mechanisms in place for notifying clients of

their test results. All clients with confirmed positive HIV test results should be referred immediately for HIV care, community-based HIV services, or health department disease intervention specialists (who are trained to link people to care). Testing sites should establish reliable referral pathways to qualified HIV care providers with follow-up policies and procedures in place to make sure that linkage to care actually occurred.

Client Education

In general settings and in situations not involving labor and delivery, advise clients of the following:

- Expedited laboratory and rapid nonlaboratory HIV testing is an important component of health screening. Learning early that they have HIV infection can help clients better maintain their health.
- Knowing that they have HIV infection can help clients start treatment as soon as possible, and to take precautions to prevent transmission of HIV to others.
- Clients can refuse an HIV test, and it will not affect the care they receive.
- The results from expedited or rapid tests are available at the same visit, usually in less than 1 hour.
- The expedited 4th-generation Ag/Ab tests are very accurate and are better at identifying newly infected persons than the 2nd- and 3rd-generation rapid and laboratory screening tests.
- If the expedited or rapid test result is positive, a second, confirmatory test always is done in order to provide assurance that the screening test result was accurate; and, if the confirmatory test is either negative or indeterminate, a third test (HIV viral load) needs to be done to determine whether the client is infected.
- It is important that clients return for the results of all confirmatory tests.
- If a client's expedited or rapid test result is negative, that client is most likely not infected with HIV, *unless* the infection occurred within the past month – the test may not detect very recent infection.
- Test results are kept confidential. However, if a confirmatory test result is positive, most state laws require that information to be reported to the health department.
- There are clinics and other resources to help clients obtain more information as well as counseling, care, or treatment. The provider should provide specific referrals to these as well as assist the client in linkage to the referral site as soon as possible.

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Resistance Testing

Background

Genotype and phenotype testing for resistance currently is commercially available for all nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and integrase inhibitors that have been approved by the U.S. Food and Drug Administration (FDA). In addition, standardized genotype testing is commercially available for enfuvirtide (a fusion inhibitor).

Neither genotype nor phenotype predicts which antiretroviral (ARV) drugs will be active in a particular patient, only ARVs that are not likely to be active. Nevertheless, studies comparing the use of resistance testing with expert opinion alone have shown that resistance testing can improve virologic control of HIV. Resistance testing is used to guide subsequent treatment for patients whose antiretroviral therapy (ART) is failing and for those whose viral load is not completely suppressed after starting therapy. It also is used to select an initial regimen that is likely to be effective for patients who have never been treated, and it is recommended for all patients with HIV infection (both acute and chronic) upon entry into care, whether or not ART is to be initiated. In addition, resistance testing is recommended for pregnant women who are not on ART and for those who are on ART but have a detectable HIV viral load.

HRSA HAB Performance Measures

Percentage Percentage of patients, regardless of age, with a diagnosis of HIV who had an **HIV drug resistance test** performed before initiation of HIV antiretroviral therapy if therapy started during the measurement year

(All-Age measure)

Genotype Tests

Genotype testing works by amplifying and sequencing HIV taken from a patient to look for mutations in the HIV reverse transcriptase, protease, integrase, or envelope genes that are known to correlate with clinical resistance to ARV drugs. Genotype tests generally can detect mutations in plasma samples with HIV RNA levels of >1,000 copies/mL, but sometimes are successful with viral loads of 500-1,000 copies/mL. Species representing 20% or more of the amplified product usually can be detected by current techniques, but minor species may not be detected. Resistance mutations that developed in the past during treatment with certain ARV medications may be archived as minor species and become invisible to genotype testing (as early as 4-6 weeks) after the drug is discontinued. These resistance mutations may reemerge and cause drug failure, however, if the previous drug is used again. By contrast, mutations acquired at the time of infection (from a transmitted virus

that was already resistant) appear to persist for years, although the duration is not known precisely and may vary by mutation.

A genotype test takes 1-2 weeks to complete. The results are reported as a list of the mutations detected; most reports also include an interpretation that indicates the drug resistance likely to be conferred by those mutations (see “Limits of Resistance Testing,” below).

Note that the standard genotype tests detect only mutations that may affect reverse transcriptase inhibitors and PIs; a specific genotype for the integrase inhibitor (or fusion inhibitor) class must be ordered if there is concern for resistance to this class. Resistance to CCR5 antagonists is uncommon; a change in coreceptor tropism is a more likely cause of virologic failure for patients taking maraviroc. For such patients, a coreceptor tropism assay should be obtained. Afterwards, if resistance to CCR5 antagonists is still suspected, a resistance test can be obtained.

Genotype results must be interpreted carefully. Because mutations can become invisible to the genotype testing process when the selective pressure of a drug is removed, a thorough ARV history, a review of any past resistance tests, and expert clinical assessment are necessary to put the results of a genotype test in proper perspective and to identify options for further treatment (see “Limits of Resistance Testing,” below). A compilation of the most common HIV mutations selected by the three classes of antiretroviral agents is available at www.hiv.lanl.gov/content/index. Other resources useful in understanding resistance testing and interpreting test results include the information compiled by the International Antiviral Society-USA and the Stanford University HIV Drug Resistance Database (hivdb.stanford.edu).

A “virtual phenotype” is a genotype that is compared with a databank of patient samples that have been analyzed by paired genotype and phenotype testing. The patient’s genotype is matched to a banked genotype, and the patient’s phenotype is then predicted on the basis of the phenotypes paired to the banked genotype. A virtual phenotype can be completed in the same amount of time as a genotype. Results are reported as a genotype (listing the mutations detected) as well as a predicted fold change in the 50% inhibitory concentration (IC50) of each drug to the patient’s virus (see “Phenotype Tests,” below). The predicted susceptibility of the patient’s virus to each drug is then reported, based on biologic and clinical cutoffs.

Phenotype Tests

Phenotype testing works by splicing the HIV reverse transcriptase and HIV protease genes from a patient’s virus into a standardized laboratory strain, which is then grown in the presence of escalating concentrations of ARV drugs. The test measures the IC50 of each drug against the virus in vitro. Results are reported as fold change in IC50, as compared with a drug-susceptible control strain or with a previous test of the same patient’s blood. The predicted susceptibility of the patient’s virus to each drug is then reported, based on what is known about the correlation between fold change in IC50 of that drug and clinical resistance. As with genotype testing, the phenotype may not be able to detect resistance if the HIV RNA level is low (<1,000 copies/mL) and may not detect minor species. Therefore, a thorough history of ARV use and resistance tests, as well as expert interpretation, are essential for determining the significance of the results (see “Limits of Resistance Testing,” below). A phenotype takes 2-3 weeks to complete.

Choosing Between Genotype and Phenotype

Genotype testing is faster and cheaper than phenotype testing, and it can detect emerging resistance, that is, virus with a mixture of strains of which some may be sensitive and some may be resistant to a given drug, as long as they are present in sufficient quantity. It is therefore generally recommended (including by the U.S. Department of Health and Human Services [HHS]) for ART-naïve patients and for patients whose first or second ART regimens are failing. Additionally, in some instances it is very important to know the exact viral mutation pattern in order to predict the virus's response to subsequent therapy, particularly in patients with virologic failure on a regimen containing an NNRTI or integrase inhibitor. HHS recommends phenotype testing when patients are suspected of having complicated or multidrug resistance patterns (for example, in the setting of extensive prior ART), or when patients are found to have such patterns on genotype testing (especially resistance to PIs).

Using Genotype and Phenotype Tests at the Same Time

Genotype and phenotype tests have a few complementary properties that may, in some circumstances, make it desirable to use both tests at the same time. This strategy is especially advantageous when trying to devise a regimen for patients who have been exposed to many ARV agents and have few remaining treatment options, and for whom the development of additional resistance could be particularly dangerous. For example, early mutations may appear on a genotype before increases in inhibitory concentrations are detectable on a phenotype. Phenotype testing can detect loss or gain of drug efficacy caused by complex interactions of mutations that, by themselves, would not be predictive. In some cases, results of the genotype and the phenotype may be discordant; in these cases, consultation with an expert is recommended.

Recommendations for Resistance Testing

An overview of when genotype and phenotype testing is and is not recommended is presented in Table 1.

Table 1. Resistance Testing Recommendations

Clinical Setting/Recommendation	Rationale
Recommended	
Acute HIV infection Genotype	- Determine whether drug-resistant virus was transmitted, to help design an initial regimen or to change a regimen accordingly. - If ART is deferred, consider repeating genotype at the time of ART initiation.
Chronic HIV infection before starting ART - Genotype - Coreceptor tropism assay	- Determine whether drug-resistant virus was transmitted to help design an initial regimen. - Perform upon entry to care (as close to the time of infection as possible), because transmitted drug-resistant virus is more likely to be detected earlier in the course of HIV infection. - If ART is deferred, consider repeating genotype at the time of ART initiation. - Consider integrase genotypic resistance assay if integrase inhibitor resistance is a concern. - Perform coreceptor tropism assay if use of a CCR5 antagonist is being considered.
Virologic failure during ART - Genotype if failure of 1st or 2nd regimen - Both phenotype and genotype if multiple prior regimens, suspicion of mutations to multiple ARVs (especially PIs), or evidence of such mutations on genotype - Coreceptor tropism assay	- Determine the role of resistance in drug failure and optimize the selection of active drugs for the new regimen, if indicated. - Perform while patient is taking ARVs, or ≤ 4 weeks after discontinuing ARVs. - If virologic failure on integrase inhibitor or fusion inhibitor, obtain specific genotypic testing for resistance to these to determine whether to continue them. - Perform coreceptor tropism assay if use of a CCR5 antagonist is being considered.
Suboptimal suppression or viral load Genotype or phenotype, depending on clinical situation (as above)	Determine role of resistance: identify active drugs for new regimen.
Pregnant women Genotype or phenotype, depending on treatment history (as above)	- Perform before initiation of ART or prophylaxis. - Perform for all on ART with detectable HIV RNA levels. - Optimize the selection of active drugs for ARV regimen.
Not Usually Recommended	
After discontinuation (>4 weeks) of ARVs	- Assist in selecting optimal regimen to achieve maximal viral suppression. - Drug-resistance mutations may decrease in number and become undetectable on assays.
Plasma viral load <500 HIV RNA copies/mL	Resistance assays are likely to be unsuccessful in patients with HIV RNA <500 copies/mL, because of the low number of RNA copies. In those with levels >500 but $<1,000$ copies/mL, testing may fail but can be considered.

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Antiretroviral-Naive Patients

With treatment-naive patients, resistance testing may reveal resistance mutations that were acquired at the time of infection, through infection with a strain of HIV that had already developed ARV resistance. Current guidelines recommend genotype testing for recently infected patients and for ARV-naive, chronically infected patients before initiation of therapy. It is important to test as early as possible in the course of HIV infection, to increase the likelihood of detecting transmitted mutations. The rationale for resistance testing in ARV-naive patients is twofold: 1) The prevalence of primary resistance is substantial, particularly in locations with a high prevalence of persons taking ART; and 2) Unknowingly starting a patient on ARV medications to which his or her virus is already resistant may risk failure of the initial regimen, rapid acquisition of additional resistance mutations, and curtailment of future treatment options.

Limits of Resistance Testing

As discussed above, drug-resistant HIV evolves in response to selective pressure applied by the ARV drugs in the patient's system. Specific resistance mutations develop in response to the pressure exerted by specific drugs (M184V, for example, evolves in response to lamivudine or emtricitabine). The presence of viral resistance suggests that a particular drug (and drugs with similar resistance patterns, or cross-resistance) is unlikely to be successful in suppressing viral replication.

In contrast, the absence of resistance to a drug on a genotype or phenotype test does not necessarily indicate that the drug will be effective, particularly if that drug (or drugs sharing cross-resistance) has been used previously. If a particular drug is discontinued, the viral strains harboring the mutations that confer resistance to that drug may decrease below the threshold of detection by the resistance assay, so the resistance test may not reveal certain resistance mutations. In such situations, minority populations of resistant viruses may exist in reservoirs and may emerge rapidly under selective pressure if that drug is restarted, or if drugs with similar or overlapping resistance patterns are used. The implications of archived mutations are twofold: 1) Resistance tests are most reliable when the patient is still taking the failing regimen; and 2) Resistance testing should be interpreted in the context of both the drugs that the patient was taking at the time of the test and the drugs that the patient had been exposed to previously (i.e., the patient's ARV history). In addition, it is important to review any previous resistance tests, which may show resistance mutations that were not revealed on subsequent testing.

Resistance Testing in Patients with Virologic Failure

As discussed in the chapter *Antiretroviral Therapy*, factors other than resistance may cause failure of ART; these include nonadherence, drug-drug interactions, and malabsorption. Therefore, before assuming drug failure, it is important to assess the causes of ARV regimen failure. If resistance is suspected, resistance testing should be done while the patient is taking the failing regimen, for the reasons noted above.

Patient Education

Advise patients of the following:

- Resistance testing can improve the likelihood of virologic control of HIV.
- Most treatment guidelines recommend resistance testing in certain circumstances.
- Both genotype and phenotype testing can detect resistance only if it exists in at least 20% of the viral species present in a patient (known as the dominant species). Minor species may harbor resistance that remains undetected by either test.
- In general, a patient's viral load must be at least 1,000 copies/mL for either test to be reliable, although samples with >500 copies/mL sometimes can be analyzed.
- Resistance tests are most reliable when performed while a patient is still taking a failing regimen, or within 4 weeks after stopping.
- Neither test predicts which drugs will be active in a particular patient, only drugs that are not likely to be active.

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Karnofsky Performance Scale

Background

The Karnofsky Performance Scale is an assessment tool intended to assist clinicians and caretakers in gauging a patient’s functional status and ability to carry out activities of daily living.

It is important to assess a patient’s performance on a regular basis, especially as the effects of HIV progress. Documentation of Karnofsky scores over time may be very useful in following a patient’s course of illness, and can help a disabled patient in his/her application for disability benefits. It also is used for some research applications.

The Karnofsky Performance Scale

Description	Percent (%)
Normal; no complaints; no evidence of disease	100
Able to carry on normal activity; minor signs or symptoms of disease	90
Normal activity with effort; some signs or symptoms of disease	80
Cares for self; unable to carry on normal activity or do work	70
Requires occasional assistance, but is able to care for most personal needs	60
Requires considerable assistance and frequent medical care	50
Disabled; requires special care and assistance	40
Severely disabled; hospitalization indicated although death not imminent	30
Very sick; hospitalization necessary; requires active support treatment	20
Moribund; fatal processes progressing rapidly	10
Dead	0

Occupational Postexposure Prophylaxis

Background

Health care personnel (HCP) and other individuals working in medical, public safety, sanitation, and laboratory settings are at risk of occupational exposure to HIV. Although avoiding exposure to HIV is the only reliable way of preventing HIV infection, postexposure prophylaxis (PEP), can reduce the risk of HIV infection in exposed HCP. PEP is defined as antiretroviral (ARV) therapy that is initiated soon after exposure to HIV with the intention of preventing HIV infection.

This chapter examines the general issues involved with PEP in occupational settings. The information is based on 2013 U.S. Public Health Service (USPHS) guidelines for occupational PEP (see “References,” below). For information on PEP for *nonoccupational* HIV exposures (such as sexual exposure), see chapter *Nonoccupational Postexposure Prophylaxis*. Note that other bloodborne pathogens, particularly hepatitis B virus (HBV) and hepatitis C virus (HCV), also may be transmitted through occupational exposure; it is important to consider these potential infections when assessing occupational exposures. For information on the management of occupational exposures to HBV and HCV, refer to the 2001 USPHS PEP guidelines (see “References,” below). In addition, the National Clinicians’ Post-Exposure Prophylaxis Hotline (PEPline) is available for telephone consultation at 888-HIV-4911 (888-448-4911).

The risk of HIV infection after exposure depends on several factors that are related to the exposure itself and to the source patient (see below). To make sound PEP recommendations, the clinician must assess the risk of HIV infection from the particular exposure. After this, the clinician and the exposed worker must discuss the possible benefit of PEP (given the risk of HIV transmission from the injury) in relation to the willingness of the exposed worker to adhere to a 28-day course of ARV medicines, the potential toxicity of the regimen, and drug interactions. HCP who are pregnant at the time of their exposure must weigh the risk of fetal exposure to HIV against the potential teratogenic and other risks of the ARV drugs (it should be noted that pregnancy is not a contraindication to PEP, and that a number of ARVs are recommended for use during pregnancy, based on safety and efficacy data) (see chapter *Reducing Perinatal HIV Transmission*).

The efficacy of PEP is related to the specific PEP regimen, the timing of PEP, and the exposed worker’s level of adherence to the PEP regimen. PEP is most likely to be effective if it is started within hours of an exposure, and outcomes may be compromised as the time from exposure increases. Nevertheless, it may be reasonable to offer PEP up to 72 hours after exposure. Adherence to PEP is strongly affected by factors such as the tolerability of the ARVs, the number of pills in the regimen, and the frequency of dosing. As current guidelines emphasize, it is very important to select a PEP regimen that is expected to be tolerated and that is convenient to take; any side effects or adherence difficulties should be managed promptly. The guidelines recommend the use of 3 (or more) PEP drugs for all exposures. Although the optimal duration of PEP is not known; studies support ARV treatment for 28 days.

In the work setting, HIV infection may occur through percutaneous injuries (e.g., needlesticks) or mucocutaneous exposures (e.g., mucous membrane or nonintact skin exposure) to blood or other potentially infectious body fluids. The risk of HIV seroconversion after occupational exposure with an HIV-contaminated hollow-bore needle is best described as 0.3%, on average. Another way of describing this to an exposed HCP is that, without PEP, HIV transmission occurs about

once in 300 instances of needlestick from a known HIV-infected source patient. In a retrospective case-control study of HCP with percutaneous exposure to HIV, the following exposure and source patient factors were associated with an increased risk of HIV transmission:

- Large-gauge (<18-gauge) hollow-bore needle
- Deep injury
- Visible blood on the device
- Procedure with needle in a blood vessel
- Terminal AIDS in the source patient
- High HIV viral load of the source patient

The factor described as “terminal AIDS in the source patient” is considered a surrogate for a source patient with a high HIV viral load (this study was done prior to the routine use of HIV viral load assays); high HIV viral load is known to be a substantial risk factor for HIV transmission. On the other hand, although an undetectable HIV viral load is thought to indicate a low risk of HIV transmission, transmission still is possible, and cases of perinatal and sexual transmission from sources with undetectable serum HIV RNA have been reported.

Compared with percutaneous injury, exposure of infectious body fluids to mucous membranes (e.g., eye or mouth) or to skin with an obvious impairment of integrity (e.g., abrasion or wound) typically involves a lower risk of HIV transmission (the transmission risk for mucous membrane exposure to HIV is approximately 1 in 1,000, and less than 1 in 1,000 for cutaneous exposure). However, mucocutaneous exposures that involve large volumes of blood or other infectious fluid from an HIV-infected patient with a high HIV RNA level or prolonged duration of contact are considered increased-risk exposures.

S: Subjective

An HCP reports possible exposure to HIV through a needlestick injury or mucocutaneous exposure.

Ideally, the HCP should immediately decontaminate the injured or exposed skin with soap and water, or flush the exposed mucous membranes with copious amounts of water or saline. The HCP should report the exposure immediately to appropriate authorities in the health care institution (e.g., the institution’s needlestick hotline).

Take a thorough history of the specific exposure, including the type of exposure, the type and amount of body fluid involved, the point of entry or exposure, the time it occurred, the HIV status of the source patient (if known), and HIV risk factors of the source patient (if HIV status is not known).

A: Assessment

Assess potential exposure to HIV (and to HBV and HCV). Consider the HIV status of the source and the characteristics of the exposure in deciding whether PEP should be offered. The guidelines recommend the use of PEP following percutaneous or mucous membrane exposures to potentially infectious body fluids. They note that PEP should be offered even in the case of an exposure to a source patient with an undetectable HIV viral load. Consult with experts if there is uncertainty about whether a particular exposure poses sufficient risk to warrant PEP.

P: Plan**Laboratory Testing****For the exposed HCP**

- Perform a baseline HIV antibody test.
- Test for other infections transmitted through occupational exposure, particularly hepatitis B (HBV surface antigen, surface antibody, core antibody), and hepatitis C (HCV antibody).
- Obtain complete blood count (CBC), creatinine and estimated glomerular filtration rate (GFR), and hepatic transaminases at baseline, before treatment with ARV medications.
- For women who may be pregnant, perform a pregnancy test.

For the source person

- The institution should perform appropriate testing of the source person for bloodborne pathogens (e.g., HIV, HBV, and HCV) if the person's status is unknown.
- The use of rapid or expedited HIV tests makes it possible to render quick decisions about the need for HIV PEP, and the 4th-generation Ag/Ab tests identify most cases of HIV during the window period of acute HIV infection (see chapter *Expedited HIV Testing*).
- Although a positive expedited test result requires confirmation before the individual is diagnosed as HIV infected, for the purposes of PEP, it should be considered a true positive until proven otherwise, and the exposed worker should be counseled accordingly. If, upon further testing, the source patient is determined to be HIV uninfected, PEP should be discontinued. A negative expedited test result is considered reliable unless the source has signs or symptoms of acute HIV (see chapters *Expedited HIV Testing* and *Early HIV Infection*).

- PEP should not be delayed (beyond 1-2 hours) while source patient HIV testing is under way.

Treatment

A regimen consisting of at least 3 ARV drugs is recommended for all occupational HIV exposures (the U.S. guidelines no longer recommend evaluation of the severity of exposure to determine the number of drugs in a PEP regimen). Recommendations for PEP regimens are based on expert opinion and largely follow the principles of HIV treatment regimens, but the PEP guidelines place particular emphasis on optimizing the tolerability and convenience of the regimen to facilitate adherence for 28 days.

Considerations in choosing the medications for a PEP regimen include:

- Possible ARV adverse effects
- Dosing schedule
- Drug-drug interactions with other medications the HCP may be taking
- The likelihood that the source patient's virus is resistant to 1 or more ARV medications

Provide counseling about the potential risks and benefits of PEP drugs, including possible adverse effects, drug-drug interactions, and the importance of close adherence. Recommended regimens are shown in Table 1; select one that is likely to be effective, tolerable, and convenient. Note that although these regimens are potent in treating HIV infection, their efficacy as prophylaxis has not been demonstrated. Consultation with experts is recommended (see "Expert Consultation," below).

These recommendations are drawn from the 2013 guidelines for occupational PEP; consult the most recently updated version of the guidelines for current information.

Table 1. Antiretroviral Regimens for Occupational Postexposure Prophylaxis of HIV Infection

Preferred Regimen	
• Raltegravir 400 mg BID + tenofovir 300 mg/emtricitabine 200 mg QD (Truvada)	
Alternative Regimens (combine 1 drug or drug pair from left column with 1 NRTI pair from right column)	
• Raltegravir 400 mg BID • Darunavir 800 mg QD + ritonavir 100 mg QD • Etravirine 200 mg BID • Rilpivirine 25 mg QD • Atazanavir 300 mg QD + ritonavir 100 mg QD • Lopinavir/ritonavir 400/100 mg BID	+ • Tenofovir + emtricitabine (Truvada), 1 tablet QD • Tenofovir 300 mg QD + lamivudine 300 mg QD • Zidovudine + lamivudine (Combivir), 1 tablet BID • Zidovudine 300 mg BID + emtricitabine 200 mg QD
OR	
• Elvitegravir/cobicistat/tenofovir/emtricitabine (Stribild) (complete regimen; no additional NRTIs needed)	

Adapted from Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis (2013). Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Refer to the appendix in the updated PEP guidelines for more complete information on the advantages, and disadvantages of the various ARV agents available for PEP, and to the adult and adolescent ARV treatment guidelines (reference below) for more information about ARV adverse effects and drug-drug interactions.

Certain ARVs generally are not recommended for PEP because of elevated risk of toxicities; these include nevirapine (which is contraindicated as PEP), abacavir (testing for HLA-B*5701 must be done), didanosine, enfuvirtide, and tipranavir. Efavirenz may have a higher rate of significant adverse effects than other listed agents. Additionally, efavirenz should not be used with women who are in the first trimester of pregnancy or who may become pregnant while on PEP, because of possible teratogenicity. Some “alternative” ARVs may be considered for use based on consultation with experts.

If the source person is known or suspected to have infection with HIV that is resistant to ARV medications, seek expert consultation in selecting an appropriate PEP regimen.

However, PEP should not be delayed while consultation is being solicited, and it is possible to adjust regimens based on expert advice.

Begin ARV prophylaxis as soon as possible after the exposure occurs, preferably within a few hours and no later than 72 hours postexposure. Treatment should be continued for 28 days unless the source person is determined to be HIV uninfected.

Provide counseling about the efficacy of PEP, including timely initiation of PEP medications, the importance of adherence to the regimen for 28 days, and management of common adverse effects. Counsel exposed workers to avoid possible transmission of HIV, e.g., by using use latex barriers with their sex partners, avoiding breast feeding if possible, avoiding pregnancy, and avoiding blood/tissue donations, until transmission of HIV infection has been ruled out.

Follow-Up

Exposed workers should be reevaluated within 72 hours after exposure to review any available new information about the exposure and the source person as well as test results. For HCP taking PEP, early reevaluation

offers the opportunity for further education and counseling, including assessment and support of PEP adherence and evaluation and management of any side effects. In addition to health education counseling, many exposed workers need emotional support during their follow-up visits.

For persons on PEP, monitoring for adherence and adverse effects should be conducted again at 2 weeks. Blood testing (e.g., CBC, creatinine and electrolytes, liver function tests, others as indicated) should be done to monitor for PEP toxicity, as indicated by the particular ARV regimen.

PEP is discontinued after 4 weeks, and monitoring for ARV toxicity generally should not be repeated unless there is a need to recheck an abnormal result.

Follow-up HIV antibody testing should be done at 6 weeks, 3 months, and 6 months after the exposure. If a 4th-generation HIV Ag/Ab assay is used, the final HIV test can be done at 4 months rather than 6 months. Follow-up for 12 months is recommended for HCP who acquired hepatitis C via exposure to a source who was coinfecting with HIV and HCV.

Symptoms of acute HIV infection such as fever, rash, and lymphadenopathy (see chapter *Early HIV Infection*) may occur in HCP who are infected with HIV through occupational exposure. Exposed HCP should be counseled about the symptoms of acute HIV infection and instructed to return for reevaluation as soon as possible if symptoms develop. If symptoms consistent with acute HIV appear within 4-6 weeks after an occupational exposure, the HCP should be evaluated immediately; an HIV RNA test should be performed if acute HIV infection is suspected. If an HCP is found to be infected with HIV, that individual should be referred immediately to an HIV specialist for further evaluation and care.

Expert Consultation

Consultation with experts in PEP and in ARVs is recommended for assistance with managing all occupational exposures. This is particularly important if the source person is known or suspected to have ARV-resistant virus or if there are unusual or perplexing elements about the case (e.g., if the exposed HCP is pregnant or breast feeding, has significant medical illness, or takes medications that may interact with PEP ARVs). Consultation on the treatment of occupational exposures to HIV and other bloodborne pathogens is available to the clinician managing the exposed person on the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-HIV-4911 (888-448-4911). This service is available 7 days a week, at no charge (additional information is available on the PEPline website at www.nccc.ucsf.edu).

Prophylaxis Against HBV and HCV

Prophylaxis against HBV is recommended for patients with potential exposure to HBV who do not have immunity against HBV. Give hepatitis B immune globulin (HBIG) as a 0.06 mL/kg IM injection and initiate the vaccination series. For patients who received the vaccination series but did not develop protective antibodies (HBV sAb+), give HBIG at the time of the postexposure workup and initiate revaccination; consider repeat of HBIG in 1 month. For patients with immunity to HBV, no treatment is indicated.

For HCV, no prophylactic treatments are recommended. After potential exposure, perform a baseline HCV antibody test. If the source is known to have HCV infection, consider alanine aminotransferase (ALT) and HCV viral load testing at 4-6 weeks. HCV antibody testing should be repeated at 4-6 months. If HCV seroconversion occurs (indicated by ALT elevation, detectable HCV viral load, or confirmed positive HCV

antibody test result), refer the patient to a hepatitis C expert because early treatment of HCV may be indicated.

Addendum: Workplace Obligations

The health care institution has certain obligations to an exposed employee.* The institution should do the following:

- Evaluate the circumstances of the exposure, the type of fluid, and possible entry points.
- Evaluate the source patient.
- Perform baseline HIV antibody testing of the exposed HCP.
- Counsel the exposed HCP about the possible risks and benefits of PEP.
- Offer or recommend PEP as soon as possible after the exposure, preferably within the first several hours.
- Counsel the HCP about avoiding secondary transmission to others (safer sex and other risk-reduction practices, as indicated).
- Support and maintain the confidentiality of the HCP.
- For an HCP who is taking PEP, monitor for medication toxicity and adherence, and check for drug-drug interactions with other medications the HCP may be taking.
- Repeat HIV testing at 6 weeks, 3 months, and 6 months (if a 4th-generation HIV Ag/Ab assay is used, the final HIV test can be performed at 4 months).
- Report the exposure as required by federal and state regulations (including U.S. Occupational Safety and Health Administration requirements).

The PEP guidelines recommend that health care institutions have a formal mechanism for consultation about occupational HIV exposures, appropriate initial lab testing for source patients and exposed HCP, counseling for exposed HCP, availability of initial PEP regimens (e.g., starter packs), and a mechanism for outpatient follow-up. The protocols should

be readily available to emergency department providers and others who manage exposure incidents.

* Legal issues vary from state to state. In many states, institutions and clinics have no obligation toward nonemployees or students who are exposed to HIV in their settings. In such situations, clinical supervisors or school or university officials often are the first contact for notification. However, everyone working in a health care setting should be familiar with the procedures and financial responsibilities for HIV exposure management to avoid delays in HIV PEP treatment.

Patient Education

- Persons who have possible exposures to HIV in the work setting should contact the PEP service of their employer or a qualified medical provider as soon as possible after the exposure, or they should go to an emergency department. Although PEP may be effective if it is started within 72 hours of exposure, the sooner medications are initiated, the better the chance for preventing HIV transmission.
- PEP medications should be taken as directed for the full 28-day course. Adherence to PEP medications is essential for successful treatment.
- PEP recipients should be advised to contact their providers if they experience uncomfortable side effects. Providers may prescribe medications to alleviate the side effects, or they may prescribe different PEP medications.
- Until HIV infection has been ruled out, exposed workers should be advised to use latex or polyurethane barriers to prevent transmission of HIV to their sex partners, to avoid pregnancy, and to avoid breast feeding if possible.
- Exposed HCP should be counseled about the symptoms of primary HIV infection and instructed to contact their care providers immediately if symptoms develop.

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Nonoccupational Postexposure Prophylaxis

Background

Although avoiding exposure to HIV is the only reliable way of preventing HIV infection, postexposure prophylaxis (PEP) can decrease the risk of infection after exposure to HIV. Antiretroviral (ARV) therapy is an important prophylactic intervention for appropriate persons with nonoccupational exposures (e.g., sexual contact; sharing of injection drug needles or other equipment) as well as those with occupational exposures (e.g., needlesticks). The U.S. Department of Health and Human Services (HHS) has developed recommendations for nonoccupational PEP (nPEP) based on data from animal models, perinatal clinical trials, and observational studies. Efficacy of nPEP remains hypothetical, and randomized clinical trials are not possible, but nPEP appears to be safe.

Overall, nPEP is more likely to be effective when the exposure is a single episode and nPEP is initiated in a timely manner. It is not appropriate for cases of multiple sexual exposures or injection drug use (IDU) exposures over time or for exposures that occurred >72 hours before starting nPEP treatment (see Figure 1).

The model for nPEP is derived in part from protocols for occupational PEP (e.g., in terms of risk assessment, pretreatment testing, timing of treatment, treatment regimens, and duration of treatment). (For information on occupational PEP, see chapter *Occupational Postexposure Prophylaxis*.) One significant difference between the protocols is that nPEP protocols should include interventions to reduce the risk of future HIV acquisition. Although exposed individuals usually seek care because they are interested specifically in antiretroviral prophylaxis, the nPEP model takes advantage of a critical opportunity to provide risk-reduction counseling and education.

See chapter *Occupational Postexposure Prophylaxis* for further discussion of evaluating possible benefits and risks of PEP.

S: Subjective

The patient reports potential exposure to HIV through a sexual encounter or the sharing of needles or other equipment for IDU.

Take a thorough history of the specific sexual or drug-use activities, the time the exposure occurred, the HIV status of the source person (if known), and HIV risk factors of the source person (if HIV status is not known). In cases of sexual assault, evidence collection and specific paperwork may be required as well.

O: Objective

Examine for trauma and for signs or symptoms of sexually transmitted diseases (STDs), which may increase the risk of HIV transmission. In injection drug users, examine for abscesses and signs or symptoms of infection. For women who may be pregnant, perform a pregnancy test.

A: Assessment

Assess for potential exposures to HIV and other bloodborne pathogens and for the presence of other STDs. The risk of HIV infection depends on the HIV status of the source and on the characteristics of the exposure (e.g., HIV viral load) and of the exposure (see Figure 1). Note that, although an undetectable HIV viral load is thought to indicate a low risk of HIV transmission, transmission still is possible, and cases of sexual transmission from sources with undetectable serum HIV RNA have been reported.

The estimated risk of HIV exposure will determine whether nPEP should be offered. An algorithm for risk evaluation and treatment decisions is presented in Figure 1.

P: Plan

Laboratory Testing

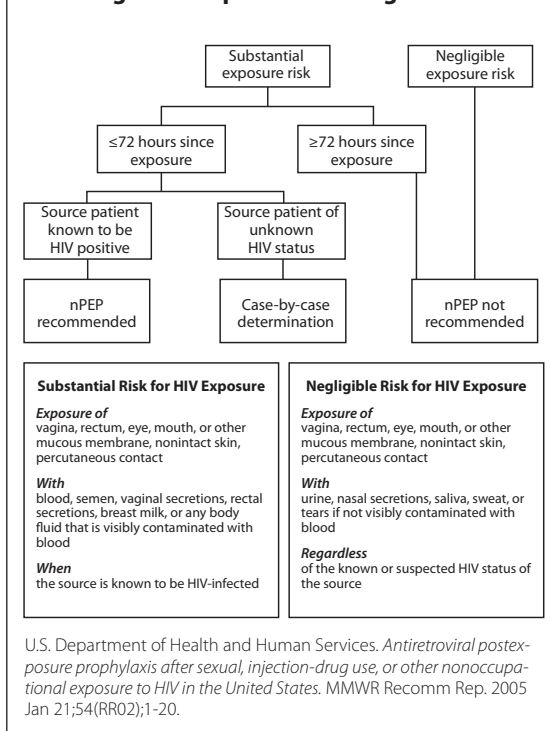
- Perform a baseline HIV antibody test.
- Evaluate and test for other infections transmitted through sexual or IDU exposures, including chlamydia, gonorrhea, syphilis, herpes simplex virus, hepatitis B (HBV surface antigen, surface antibody, and core antibody), and hepatitis C (HCV antibody).
- Obtain complete blood count (CBC), liver function tests (LFTs), and creatinine and estimated glomerular filtration rate (GFR) at baseline before treatment with ARV medications.

Treatment

Follow the algorithm in Figure 1 to determine whether the patient should be offered nPEP medications. If the patient is a candidate for treatment, provide counseling about the potential risks and benefits of nPEP.

Select an nPEP regimen that is likely to be effective but tolerable; consider the potential

Figure 1. Exposure Risk Algorithm



adverse effects and drug interactions of ARV agents (Table 1). Adherence to nPEP is strongly affected by factors such as the tolerability of the ARVs, the number of pills in the regimen, and the frequency of dosing. It is very important to select a regimen that is expected to be tolerated and that is convenient to take; any side effects or adherence difficulties should be managed promptly.

In general, the recommendations for nPEP involve 3-drug combination therapy. In some circumstances, more than 3 ARVs may be appropriate (e.g., if the source virus is resistant to ARVs), and in some cases, 2-drug PEP may be considered (e.g., if the HIV status of the source person is unknown, the exposure is thought to be of relatively low risk, or there is a need to minimize possible toxicity); consultation with experts is recommended.

Note that the HHS nPEP guidelines were last updated in 2005 and do not reflect current practice. **The recommendations presented here have been adapted to reflect current nPEP strategies, current guidelines for occupational PEP, and the availability of newer ARVs** (see Table 1). Note that a number of ARVs that were included in “preferred” or “alternative” regimens in the 2005 guidelines are no longer recommended in current practice, based on factors such as higher likelihood of causing adverse effects, greater pill burden, or inconvenient dosing. A number of alternatives to the recommendations listed below are available; consult with an expert. Note that, although these regimens are effective in treating HIV infection, their efficacy as prophylaxis has not been demonstrated.

If the source person is known or suspected to have infection with HIV that is resistant to ARV medications, seek expert consultation in selecting an appropriate nPEP regimen.

Certain ARVs are not currently recommended for PEP, including nevirapine (which is contraindicated for PEP), abacavir (testing for HLA-B*5701 must be done), didanosine, enfuvirtide, and tipranavir. Although the 2005 nPEP guidelines designate it as a preferred agent, efavirenz may have a higher rate of significant adverse effects than other agents listed in Table 1. Additionally, efavirenz should not be used during the first trimester of pregnancy or for women who may become pregnant while taking PEP, because of possible teratogenicity. Refer to the updated occupational PEP guidelines and to the adult and adolescent ARV treatment guidelines for more complete information on the advantages and disadvantages, adverse effects, and drug-drug interactions of the various ARV agents available for PEP (references below). Consider consultation with experts (see “Expert Consultation,” below).

Table 1. Antiretroviral Regimens for Nonoccupational Postexposure Prophylaxis of HIV Infection*

Preferred Regimens	
• Raltegravir 400 mg BID + tenofovir 300 mg/emtricitabine 200 mg QD (Truvada)	
Alternative Regimens (combine 1 drug or drug pair from left column with 1 NRTI pair from right column)	
• Raltegravir 400 mg BID • Darunavir 800 mg QD + ritonavir 100 mg QD • Etravirine 200 mg BID • Rilpivirine 25 mg QD • Atazanavir 300 mg QD + ritonavir 100 mg QD • Lopinavir/ritonavir 400/100 mg BID + • Tenofovir + emtricitabine (Truvada), 1 tablet QD • Tenofovir 300 mg QD + lamivudine 300 mg QD • Zidovudine + lamivudine (Combivir), 1 tablet BID • Zidovudine 300 mg BID + emtricitabine 200 mg QD	
OR	
• Elvitegravir/cobicistat/tenofovir/emtricitabine (Stribild) (complete regimen; no additional NRTIs needed)	

* Forthcoming HHS guidelines on nPEP may differ from these recommendations; check current recommendations.

Abbreviations: NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside analogue reverse transcriptase inhibitor; PI = protease inhibitor

Adapted from Kuhar DT, Henderson DK, Struble KA, et al; U.S. Public Health Service Working Group. *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis*. Infect Control Hosp Epidemiol. 2013 Sep;34(9):875-92; and U.S. Department of Health and Human Services. *Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States—January 21, 2013*. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Once the decision is made to institute nPEP, do the following:

- Begin ARV prophylaxis as soon as possible after the exposure, but always within 72 hours. Treatment should be continued for 28 days, unless the source person is determined to be HIV negative.
- Provide counseling about the efficacy of nPEP, timely initiation of nPEP medications, adherence to the regimen for 28 days, and the importance of preventing additional HIV exposures during this time.
- Counsel exposed patients to use latex barriers with their sex partners until transmission of HIV infection has been ruled out.
- Counsel patients, as appropriate, about ways to reduce risks of future exposure to HIV.
- In cases of sexual assault, refer the patient to a rape counselor.

Follow-Up

Patients should be evaluated within 1 week for review of all test results and further risk-reduction counseling. For patients taking nPEP, this follow-up should include adherence assessment and evaluation of any adverse effects. Side effects should be managed aggressively in order to maximize the likelihood of adherence to nPEP. A 2-week blood screening (CBC, LFTs, and creatinine) should be performed for patients on the 28-day nPEP regimen to monitor for nPEP toxicity.

Follow-up testing for HIV antibody in patients with a negative baseline HIV antibody test should be done at 6 weeks, 3 months, and 6 months after the exposure. If a 4th-generation HIV Ag/Ab assay is used, the final HIV test can be done at 4 months rather than 6 months.

Patients need health education and risk-reduction counseling and emotional support during their follow-up visits. Nonoccupational PEP programs should focus efforts on

risk-reduction counseling rather than the continued use of medicines for prevention. To this end, many programs have case managers, social workers, and health educators as the key providers of follow-up and counseling after an exposure, with referral to clinicians as needed.

If patients develop acute HIV infection or are discovered to be HIV seropositive at follow-up testing, immediately refer to an HIV specialist for evaluation and care (see chapter *Early HIV Infection*).

Expert Consultation

For consultation on the treatment of exposures to HIV (and HBV and HCV), the clinician managing the exposed person can call the National HIV/AIDS Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 888-HIV-4911 (888-448-4911). This service is available 7 days a week at no charge. Additional information on the Internet is available at www.nccc.ucsf.edu. PEPline support may be especially useful in challenging situations, such as when drug-resistant HIV strains are suspected to be involved in the exposure or when the exposed person is pregnant.

Prophylaxis Against HBV and HCV

Prophylaxis against HBV is recommended for patients with potential exposure to HBV who do not have not have immunity against HBV. Give HBV immune globulin (HBIG) as a 0.06 mL/kg IM injection and initiate the vaccination series. For patients who previously received the vaccine series but did not develop protective antibody (HBV sAb+), give HBIG at the time of the postexposure workup and initiate revaccination; consider repeat of HBIG in 1 month. For patients with immunity to HBV (HBV sAb+), no treatment is indicated.

For HCV, no prophylactic treatments are recommended. After potential exposure, perform a baseline HCV antibody test. If the source is known to have HCV infection, consider alanine aminotransferase (ALT)

and HCV viral load testing at 4–6 weeks. HCV antibody testing should be repeated at 4–6 months. If HCV seroconversion occurs (indicated by ALT elevation, detectable HCV viral load, or confirmed positive HCV antibody test result), refer the patient to a hepatitis C specialist because early treatment of acute HCV may be indicated.

Patient Education

- Persons who have possible exposures to HIV should contact a medical provider or go to an emergency room as soon as possible after the potential exposure has occurred. PEP may be effective if it is started within 72 hours of exposure, but the sooner medications are initiated, the better the chance for preventing HIV transmission.
- PEP medications should be taken as directed for a full 28-day course. Adherence to PEP medications is essential for successful treatment.
- If patients are experiencing uncomfortable adverse effects, they should contact their care provider right away. Providers may prescribe medications to alleviate the adverse effects or select other PEP medications.
- Until HIV infection has been ruled out, exposed persons should be advised to use latex barriers to prevent transmission of HIV to their sex partners.
- Exposed persons should be counseled about the symptoms of primary HIV infection and instructed to contact their care provider immediately if symptoms develop.
- The most effective way to prevent HIV infection is to prevent exposure to HIV by practicing safer sex and safer IDU techniques. Use of condoms and other latex or polyurethane barriers and avoidance of needle sharing are successful preventive measures. If patients have questions about access to condoms or clean needles, they should contact their care provider for assistance.

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Preventing HIV Transmission/ Prevention with Positives

Background

In recent years, the rate of new HIV infections in the United States has remained stable in the range of 50,000 per year. Antiretroviral therapy (ART) not only improves the health of individuals on treatment but also substantially reduces the risk of transmitting HIV infection. It has become a critical component of efforts to prevent new infections (hence the saying, “treatment is prevention”), but it is not fully effective. Additionally, it remains true that only a minority of persons living with HIV infection in the United States is taking ART and a smaller proportion has maximal suppression of HIV viral load. Thus, behavioral and other risk-reduction interventions remain important aspects of HIV prevention. This chapter will focus primarily on interacting with patients around transmission risk behaviors, with the goal of reducing HIV transmission. This aspect of care is often referred to as “prevention with positives” (PWP).

For many years HIV, prevention efforts have been targeted primarily at HIV-uninfected individuals, but HIV-infected persons also must be a crucial focus for HIV prevention. Helping HIV-infected persons reduce their risks of transmitting HIV to others is an important aspect of medical care for HIV-infected patients. Most people with HIV infection want to prevent others from being infected with HIV, but they may practice sexual or injection-drug behaviors that put others at risk of infection.

Health care providers for HIV-infected patients can play a crucial role in prevention efforts, including but not limited to provision and monitoring of ART. Many HIV-infected individuals report that they want to discuss prevention with their health care providers; however, (according to multiple studies), one third to three fourths of HIV medical providers do not ask their patients about sexual behavior or drug use. Each patient visit presents an opportunity to provide effective prevention interventions, even in busy clinical settings.

It is clear that information alone, especially on subjects such as sexual activity and drug use, cannot be expected to change patients’ behavior. However, health care providers can help patients understand the transmission risk of certain types of behavior and help patients establish personal prevention strategies (sometimes based on a harm-reduction approach) for themselves and their partners. Some patients may have difficulty adhering to their safer sex goals. In these cases, referrals to mental health clinicians or other professional resources such as prevention case management may be helpful.

Patient-education needs are variable and must be customized. Providers must assess the individual patient’s current level of knowledge as part of developing a prevention plan. All the information that a patient needs cannot be covered during a single visit. A patient’s prevention strategy should be reinforced and refined at each visit with the clinician. Clinicians also should ask patients questions to determine life changes (e.g., a new relationship, a breakup, or loss of a job) that may affect the patient’s sexual or substance-use practices. If the patient can read well, printed material can be given to reinforce education in key areas, but it cannot replace a direct conversation with the clinician.

HRSA HAB Performance Measures

Percentage of patients with a diagnosis of HIV who received **HIV risk counseling** in the measurement year

(Adult and Adolescent measure)

Note: The U.S. Department of Health and Human Services is expected to publish guidelines on HIV prevention in the near future; those may contain recommendations that differ from the ones presented here.

National Prevention Intervention Efforts

The U.S. Centers for Disease Control and Prevention (CDC) has developed a prevention approach called High-Impact Prevention that focuses on populations at greatest risk of acquiring or transmitting HIV, using proven, scalable, and cost-effective interventions. Proven interventions include:

- HIV testing and linkage to care
- ART
- Prevention programs for people living with HIV and their partners
- Prevention programs for people at high risk of HIV infection
- Access to condoms and sterile syringes
- Screening and treatment for sexually transmitted diseases (STDs)
- Substance abuse treatment

The CDC has identified a number of evidence-based behavioral prevention interventions aimed at persons with HIV infection that meet criteria for efficacy and scientific rigor. These are conducted on the individual, group, or community level, and a number of them may be implemented in the treatment setting. A Compendium of these interventions can be accessed online at the CDC website (see www.cdc.gov/hiv/prevention/research/compendium/rr/index.html). Training and educational materials for effective intervention models can be found on the CDC-supported Diffusion of Effective Behavioral Interventions (DEBI) website (www.effectiveinterventions.org/en/Home.aspx).

Among the many examples of Prevention Intervention Programs with Demonstrated Efficacy in Treatment Settings on the CDC website are the following:

- **Options/Opciones Program:** The program features brief, 5-10 minute patient-centered discussions between patients and providers at each clinic visit using motivational interviewing techniques. Providers evaluate sexual and drug-use behaviors, assess the patient's readiness to change, and elicit methods from the patient on moving toward and maintaining safer behaviors. The provider and the patient develop an individually tailored plan, which the provider writes out on a prescription pad and gives to the patient.
- **Partnership for Health:** This intervention involves brief, 3-5 minute, one-on-one counseling sessions between the provider and the patient on self-protection, partner-protection, and disclosure. The approach features loss-framed messages that emphasize the risks or negative consequences of risky behavior. The provider then helps the patient develop a plan for risk reduction.
- **Positive Choice – Interactive Video Doctor:** This program involves an approximately 24-minute session during which HIV-infected patients complete the Positive Choice risk assessment on a laptop computer while waiting for scheduled visits with their providers. Based on the risk-assessment results, a video clip appears with the actor-portrayed Video Doctor who delivers interactive risk-reduction messages that are tailored to the patient's gender, risk profile, and readiness to change. The messages are delivered with motivational interviewing principles, using a patient-centered, empathetic and nonjudgmental approach. After the video session, the computer prints out an individualized educational sheet for the patient and an assessment sheet for the patient and the provider to use for follow-up.

The U.S. Preventive Services Task Force (USPSTF) has recommended high-intensity behavioral counseling to prevent STDs (including HIV) in persons at risk of these infections; these approaches also are being used in persons with HIV infection to reduce their risk of transmitting HIV. Effective high-intensity behavioral counseling typically comprises multiple sessions with either groups or individuals. Examples of these are included amongst the models presented on the CDC and DEBI websites.

Strategies for Brief, Effective Interventions by Providers

A number of strategies have been shown to be more effective than providing information alone. Effective and brief provider-initiated interventions often include the following elements:

- **Establish rapport** and provide services in an understanding, nonjudgmental manner. Patient educators, nurses, peer counselors, social workers, and mental health providers may be effective in discussing prevention strategies with patients.
- **Conduct a quick, detailed behavioral risk assessment:**
 - See the key areas of risk assessment and intervention listed in Table 1, below.
 - Assess where the patient's risk behavior lies along the risk continuum (described in chapter *Smoking Cessation*).
 - Correct misinformation and answer questions.
 - Assess the patient's readiness for behavior change (see "Stages of Change model," below).
 - Screen for and treat STDs: a positive STD test result can be a biologic marker of behavioral risk, and STDs may facilitate HIV transmission (see chapter *Initial and Interim Laboratory and Other Tests*).
 - Supply medications, condoms, and lubricant as needed.
- **Assess the patient's readiness for change** and approach any high-risk behavior in a step-wise manner, recognizing when the patient is ready for next steps. Such interventions may be carried out for 5-10 minutes per visit over a series of visits. The "Stages of Change" model and appropriate strategies include the following:
 - **Precontemplation:** The patient is not ready to change; reassess at subsequent visits.
 - **Contemplation:** The patient is considering a change in the future; discuss and help the patient to identify concrete next steps, such as a date for initiating change.
 - **Preparation:** The patient is ready to change soon; discuss a concrete action plan and connect the patient with appropriate resources as needed.
 - **Action:** The patient is actively engaged in changing behavior; continue to discuss and address challenges; offer encouragement.
 - **Maintenance:** The patient has made behavioral changes; continue to discuss and address challenges, offer encouragement and congratulations.
 - **(Relapse):** The patient has relapsed to previous risky behaviors; recognize the triggers and difficulties the patient had with maintenance and offer support and encouragement to try again when the patient is ready.
- **Customize messages**, as each individual patient's needs are variable.
- **Understand** that patients often have competing priorities and pressures involving mental health needs, relationships, finances, housing, employment, and other issues that may result in risky sexual and drug-use behaviors.

Prevention with Positives: Key Areas of Assessment and Intervention

These topics should be explored over time. Some sample questions and areas for intervention are presented in Table 1. More detailed discussions of topics follow this table.

Table 1. Components of a Detailed Risk Assessment, with Key Areas for Intervention

Topic	Sample Questions, Assessment, and Plan
General Risk Assessment	Subjective/objective questions to ask: 1. What do you know about HIV transmission? 2. What, if anything, are you doing that could result in transmitting HIV to another person? Assessment and plan: • Use this as an opportunity to help educate the patient on HIV transmission and to correct misinformation. • Place the patient's behaviors on a risk spectrum and try to prioritize the behaviors that are riskiest or the behaviors that the patient is most willing to address.
Sexual Practices	Subjective/objective questions to ask: 1. Tell me about any sexual activity since your last clinic visit. 2. What do you know about the HIV status of each sex partner? 3. Tell me about condom use during any sexual activity. 4. What has made it more difficult for you to use condoms during this sexual encounter or with this partner? 5. Do your sex practices differ with HIV-infected versus HIV-uninfected partners ("sexual positioning")? See below for more on partner notification. Other information: • Number of sex partners in the past 6 months • Gender of each partner • Type of relationship with each partner (main, casual, anonymous) • Type of sexual activity engaged with each partner • Safer and less-safe sexual practices with each partner • Substance use, including alcohol, associated with sex • Circumstances of risky sex behaviors (e.g., bars/clubs, anonymous partners, intoxication) Assessment and plan: • Assess the patient's level of risk of sexual transmission. • Assess the patient's willingness and ability to use condoms during each sexual encounter, particularly with partners who are HIV uninfected or of unknown HIV serostatus. • Assess the patient's ability to use condoms (male and/or female) and correct any misinformation. See information on how to use condoms below. • Supply the patient with condoms and lubricant. • If the patient is unwilling to use condoms, counsel that risk of transmission can be reduced by screening for and treating STDs, using abundant amounts of lubrication, avoiding concurrent drug use, avoiding the use of spermicides and douching, and by choosing less risky sexual activities. Additionally, serosorting, in which the HIV-infected person has sex only with other HIV-infected individuals, can prevent transmission to uninfected persons (note: this is <i>not</i> an effective strategy for persons who are HIV uninfected or are unsure of their serostatus).

Partner Notification	Subjective/objective questions to ask: 1. What are your thoughts and experiences talking with your partner(s) about your HIV infection? This may be one of the hardest things you have to do. 2. (If the patient has not disclosed to main partner[s]): How might you approach this? 3. Are you afraid for your safety if you tell your partner(s)? Assessment and plan: ways to offer help for disclosure • Local health departments may have partner services programs that help locate and notify partners in a confidential manner. • Providers and support staff can help disclose to partners with the patient present. • Providers and support staff can help disclose to partners without the patient present.
Antiretroviral Therapy (ART)	• ART has been shown to reduce the rate of HIV transmission in serodiscordant heterosexual couples by 96%. In other studies, lower levels of HIV in the blood (in particular, complete suppression of the HIV RNA through ART) have been associated with lower levels of HIV virus in genital secretions and with reductions in the rate of sexual transmission of HIV. • Current HHS guidelines recommend ART for all HIV-infected persons, both for their own health and to reduce risk of HIV transmission. • Close adherence to ART and continuous HIV suppression are likely to be key factors in making this an effective prevention tool; assess and reinforce adherence at every visit. • For a number of reasons, ART alone is not completely effective in preventing transmission; it should be viewed as one important tool in a broader approach to prevention. Be watchful for attitude shifts away from safer sexual and needle-sharing behaviors among patients who believe that ART protects them from transmitting HIV.
STD Screening and Treatment	• The presence of an STD suggests behaviors that can increase HIV transmission, and it is detrimental to the patient's health. • Additionally, some STDs may increase the risk of HIV transmission. • Screen all patients at baseline and regularly afterward, depending on their risk factors according to CDC and USPSTF guidelines. For example, screen men who have sex with men (MSM) every 3-6 months if multiple sex partners. • Routinely ask patients if they have symptoms of an STD and educate about the importance of seeking care if symptoms are present. • Depending on risk, it is recommended to screen for the following STDs (see chapters <i>Initial History</i> and <i>Initial and Interim Laboratory and Other Tests</i> for screening questions and lab tests): • Syphilis: Serologic test (e.g., RPR, VDRL) • Gonorrhea: For pharyngeal infections, use nucleic acid amplification test (NAAT) or culture of oral swab*; for rectal infections, use NAAT or culture of rectal swab*; for urethral or cervical or vaginal infections, use first-catch urine or urethral (male) or cervical (female) specimen for NAAT, or culture of urethral (male) or cervical (female) specimen • Chlamydia: For rectal infections, use NAAT or culture of rectal swab*; for urethral or cervical infections, use first-catch urine or urethral (men) or cervical or vaginal (women) specimen for NAAT; testing for pharyngeal chlamydial infection is not recommended although the test result often accompanies the GC pharyngeal NAAT result • Trichomonas: Wet mount (insensitive), culture, or NAAT on vaginal secretion • Herpes simplex virus (HSV): Type-specific HSV-2 antibody testing Although hepatitis B and hepatitis C are not known to increase the risk of HIV infection, they may be transmitted sexually, and persons with risk factors (particularly MSM with risky sexual practices) should be screened regularly (see chapter <i>Initial and Interim Laboratory and Other Tests</i>). * NAAT is not yet approved for this indication by the U.S. Food and Drug Administration (FDA), though there is evidence that NAAT can accurately diagnose pharyngeal and rectal gonorrhea and chlamydia infections. Many local public health departments and other laboratories have received Clinical Laboratory Improvement Amendments (CLIA) waivers to perform these tests.

Drug and Alcohol Risk Assessment	Subjective/objective questions to ask: 1. Tell me about any drug or alcohol use since your last clinic visit. 2. How do you think your drug or alcohol use affects your sexual behaviors? 3. What are your thoughts about quitting or cutting down on drug and alcohol use, and about separating it from sex? See below for follow-up on needle-sharing practices. Assessment and plan: • Assess the patient's level and circumstances of risk to target your intervention. • Emphasize that nasal straws or sniffers (e.g., for cocaine) should not be shared. • Assess the patient's readiness to quit or cut down on drug and alcohol use, and to separate these activities from sex. • Deliver messages tailored to the patient's readiness; for example, educate on the risks of harming oneself or others, facilitate a plan for harm reduction, or refer to rehabilitation/detoxification programs and centers.
Needle-Use Practices	Subjective/objective question to ask: 1. Tell me about any needle sharing since your last clinic visit. Assessment and plan: • After assessing the patient's risks and readiness, and if the patient is not ready for treatment (e.g., referral to detoxification programs or to buprenorphine and methadone programs for heroin users), the following messages for harm reduction can be offered: • Use only sterile needles and syringes, e.g., from pharmacies or syringe service (needle exchange) programs. (Provide information about local syringe service programs. Some are listed on the North American Syringe Exchange Network website at www.nasen.org.) • Never reuse or share needles, syringes, or drug preparation equipment because it leads not only to transmission of HIV, hepatitis B, and hepatitis C, but also to bacterial infections and abscesses. • Use new or disinfected cookers and new cotton filters to prepare drugs. • Clean the skin with a new alcohol swab before injecting. • If equipment must be reused, it should be cleaned properly with bleach or water. • Safely dispose of syringes in a sharps container (which can be a clean detergent or other container), then take them to a needle exchange program or pharmacy for disposal.
Mental Health Assessment	Mental illnesses such as bipolar disorder, depression, and post-traumatic stress disorder can increase the chances of risky sexual and drug-use behaviors. Ask about mental health illnesses directly and pay attention to any symptoms that may indicate a psychiatric illness (e.g., manic episodes, depressive episodes, hallucinations). Subjective/objective questions to ask: 1. Tell me about any previous diagnoses or hospitalizations for mental health illnesses. 2. Have you taken any medications for mental health illnesses? 3. Perform a depression screen: see chapter <i>Major Depression and Other Depressive Disorders</i>. Assessment and plan: See section <i>Neuropsychiatric Disorders</i> for more information.

Pregnancy Screening	Subjective/objective questions to ask: For women of childbearing potential: 1. Are you currently pregnant or wanting to become pregnant at some point in the future? 2. Have you missed any periods recently? Are you having any symptoms of pregnancy? 3. What are your thoughts and plans about birth control? For men with female sex partners: 1. What are your thoughts on having a baby with your partner? What are your thoughts about fathering? 2. What are your thoughts on using birth control with your partner? Assessment and plan: See chapter <i>Health Care of HIV-Infected Women Through the Life Cycle</i>.
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Sexual Transmission and Prevention of HIV

Begin the education process by learning what the patient and his or her immediate family members (if the family is aware of the patient's HIV status) believe about HIV transmission. Also be sure the patient understands how the virus is not transmitted (e.g., via sharing plates and eating utensils or using the same bathrooms) to allay any unnecessary fear.

Advise the patient not to share toothbrushes, razors, douche equipment, or sex toys to avoid transmitting HIV via blood or sexual secretions. This also will help prevent the transmission of other bloodborne or sexually transmitted diseases, including hepatitis C, from coinfecting patients. The patient should not donate blood, plasma, tissue, organs, or semen because these can transmit HIV to the recipient.

There is no reason why a person with HIV cannot have an active, fulfilling, and intimate sex life. However, the patient must be counseled properly about the risk of transmission. This discussion between the provider and patient should be client centered. This means that the provider should let the patient guide the discussion, starting from the patient's current point of knowledge and practice, always addressing any presenting concerns the patient may have prior to proceeding with a discussion about sexual

transmission and risk. The provider should ask open-ended questions, in a nonjudgmental manner, to elicit information about the patient's relationships, sexual behaviors, and current means of reducing transmission risk.

It is important to recognize that not every patient seeks the complete elimination of risk (e.g., via abstinence) but rather a reduction in risk, chosen after the options are discussed with the provider. The clinician may help the patient select and practice behaviors that are likely to be less risky. There are many methods for reducing risk, including the following:

- Disclosing HIV status
- Maintaining maximal suppression of HIV through ART
- Reducing the number of sex partners
- Using condoms, particularly for anal or vaginal intercourse (insertive or receptive)
- Avoiding drug use in conjunction with sex
- Using adequate lubrication to avoid trauma to genital or rectal mucosa

If the patient requires more extensive counseling to support behavioral changes, the provider should refer the patient to support groups or prevention case management to meet those needs. Certainly, if the patient is dealing with a dual or triple diagnosis (including substance abuse or mental illness), a referral to address those needs is indicated.

Partner Notification and Partner Services

A good way to begin a discussion about HIV prevention and transmission is with an inquiry about any previous experiences disclosing to partners. The provider then can ask whether the patient currently has a need to disclose to one or more partners and whether he or she is ready and motivated to share information about HIV status. The provider should prompt patients to consider several questions about disclosure, including how they might approach the discussion, how their partners might react, what information they might offer their partners, whether partners are likely to keep their status confidential, and whether they have any concerns about personal safety (e.g., owing to fear of a violent reaction). If patients fear violence or retaliation or are not ready to share their status but want their partners to know, the provider may offer assistance with partner services, for example through the local health department, through which partners can be notified and linked to services in a confidential manner. As an alternative, patients may want the provider to talk with their partners, and that option can be offered as well. See the CDC website (www.cdc.gov/nchhstp/partners/Partner-Services.html) for information on partner services.

Antiretroviral Therapy

ART that results in maximal HIV suppression is an important means of HIV prevention. In serodiscordant heterosexual couples, one randomized controlled trial showed that ART reduced the risk of sexual transmission of HIV by 96%. Similar study data for MSM, injection drug users, and other HIV risk groups do not exist, but multiple other lines of evidence suggest that effective ART sharply reduces risk of HIV transmission. Thus, ART should be offered to all HIV-infected persons, both to benefit their own health and to reduce risk of HIV transmission to others, as recommended

in HHS guidelines. Support patients' adherence to ARVs in order to optimize the effectiveness of ART as both treatment and prevention.

Note that ART does not eliminate HIV transmission risk. In some individuals, there can be substantial discrepancies between HIV RNA levels in the serum and the sexual fluids. There have been case reports of HIV transmission from HIV-infected individuals who had maximal virologic suppression on ART. Thus, other behavioral and biologic risk-reduction approaches (e.g., screening for and offering interventions or treatment for risky sexual behaviors, substance use, depression, STDs, and other factors listed in Table 1) are important aspects of prevention in patients taking ART, as in patients not taking ART.

Helping Patients Reduce the Risk of Sexual Transmission Standard Condom Use

Make sure that the patient understands how HIV is transmitted and which types of sexual acts are more and less risky than others. For vaginal or anal sex, correct use of latex or polyurethane condoms reduces the risk of HIV transmission considerably. Patients should be encouraged to use condoms as much as possible. For HIV-infected individuals, condom use is effective in reducing the risk of contracting another illness (such as hepatitis C or another STD) and the (apparently low) risk of becoming reinfected with another strain of HIV. It should be noted that condoms are less effective in reducing the transmission of organisms such as human papillomavirus (HPV) and HSV, which may result from viral shedding from skin. In the event of allergy to latex or other difficulty with latex condoms, polyurethane male or female condoms may be substituted. "Natural skin" or "lambskin" condoms are not recommended for HIV prevention.

Of course, condoms must be used correctly to be highly effective in preventing HIV transmission. Be sure that the patient knows exactly how to use a condom. Table 2, in the Appendix, provides instructions for condom use.

Advise patients to avoid using nonoxynol-9 (N-9) spermicides. Data suggest that N-9 may increase risk of HIV transmission during vaginal intercourse and can damage the rectal lining. N-9 never should be used for anal intercourse.

For patients who complain about lack of sensitivity with condom use, the following techniques may help:

- Apply a drop of lubricant inside the condom (not more, because it increases the risk that the condom will come off).
- Use polyurethane condoms instead of latex because they conduct heat and may feel more natural.
- Use insertive (female) condoms, which are not as restrictive to the penis.
- Use specially designed condoms that do not restrict the top of the penis (e.g., Inspiral, Xtra Pleasure).

For patients who are unable or unwilling to use condoms, the following suggestions may help reduce HIV transmission risk:

- Use plenty of lubricant to reduce friction and microtrauma, which create portals of entry for the virus.
- Avoid spermicides that damage the vaginal or anorectal linings.
- Avoid douching products.
- Avoid recreational drugs, especially methamphetamine, that impair the ability to maintain “safer” sexual behaviors.
- Avoid the use of drugs such as nitrates (poppers) that enhance blood flow to the genitals.

Insertive (Female) Condom Use

The insertive “female” condom may be used for vaginal or anal intercourse. It is a thin polyurethane pouch with a flexible ring at the opening, and another unattached flexible ring that sits inside the pouch to keep it in position in the vagina (for use in the anus, the inner ring must be removed and discarded). The female condom may be an option for women whose male partners will not use male condoms or for couples who do not like standard condoms. Female condoms are more expensive than male condoms, but may be procured at a lower cost at some health departments or Planned Parenthood clinics. They generally are less well known to patients and may be unacceptable to some women whose culture or religion prohibits or discourages touching one’s own genitals. Note that the female condom cannot be used at the same time as a male condom.

Be sure the patient knows how to use the insertive condom before she or he needs it; after teaching, encourage practice when alone at home and unhurried. Women who have used the diaphragm, cervical cap, or contraceptive sponge may find it easy to use the female condom. Illustrated directions are included in each box of insertive condoms. Instructions on the use of insertive condoms are provided in Table 3, in the Appendix.

Oral Sex

Although there is evidence that some people have become infected through receptive oral sex, the risk of HIV transmission via oral sex, in general, is much lower than the risk of transmission by vaginal or anal sex. Thus, most public health and prevention specialists focus their attention on riskier sexual and drug-use behaviors. However, because HIV transmission can occur with oral sex, clinicians should address this issue with patients and help them make informed decisions about risk reduction. Sores or lesions

in or around the mouth or on the genitals may increase the risk of HIV transmission, as may a concurrent STD. Patients (and their partners) should avoid oral-genital contact if they have these conditions. Similarly, patients and partners can further reduce risk by not brushing or flossing teeth before oral sex. Individuals who wish to further reduce the risk of HIV transmission during oral sex may use barriers such as condoms, dental dams, and flexible plastic nonporous kitchen wrap.

Individuals who smoke crack cocaine often develop open burns, cracked lips, or damaged mucous membranes inside the mouth and thus may be at elevated risk of HIV transmission via oral sex. HIV-infected crack users should be counseled about the risk of transmitting HIV to uninfected partners through those portals of entry during oral sex and should receive risk-reduction counseling. In addition, they (or their partners) may benefit from techniques such as insulating the end of the crack pipe to reduce burns while smoking (e.g., with a rubber band or spark plug cap) and avoiding the brittle or sharp-edged copper scrubbing pads used as screens in the crack pipe.

Influence of Substance Use on Sexual Behavior

Alcohol and drug use can contribute significantly to the risk of sexual transmission of HIV, because of behavioral disinhibition. While intoxicated, substance users may, for example, forgo condom use, practice riskier sexual behaviors, have multiple partners, or use erectile dysfunction agents to sustain sexual activity. Addressing substance use issues is an important aspect of PWP. Patients should be assessed for HIV transmission risks associated with alcohol and injection or noninjection drug use, including crystal methamphetamine, in the context of their sexual behaviors (for injection drug use, see below). As always, it is important to approach the patient in a nonjudgmental manner. If

alcohol or other drugs are posing barriers to practicing safer behaviors, the provider should counsel the patient to reduce or avoid substance use before engaging in sex, or refer the patient to prevention case management for more specialized risk reduction. Often, the provider can help the patient identify methods for reducing HIV transmission risk, including means that do not require abstaining from alcohol and drug use.

Injection Drug Use and Prevention of HIV

Clinicians should discuss substance use, including steroid use, and reinforce the patient's understanding of the adverse effects that these drugs can have on the body and the immune system. Assess whether referral for treatment is appropriate, and be knowledgeable about referral resources and mechanisms. If the patient is using injection drugs (including steroids and other hormones), emphasize the fact that HIV is readily transmitted by sharing needles and other injection equipment and that reusing or sharing needles and syringes can cause additional infections (e.g., endocarditis, hepatitis C). Assess the patient's readiness to change his or her drug injection practices, and refer to drug treatment programs as appropriate. Refer to an addiction counselor for motivational interviewing or other interventions, if available. After completion of substance abuse treatment, relapse prevention programs and ongoing support will be needed. If the patient continues to use needles, discuss safer needle-use practices (Table 1) and consider referral to a syringe service (needle exchange) program, if one is available, so that syringes and needles are not reused. A partial listing of needle exchange sites may be found on the North American Syringe Exchange Network website at www.nasen.org, although many states either do not have facilities or are prohibited from listing them. Local harm-reduction activists may be

aware of specific programs for obtaining clean needles and syringes. Patient-education flyers on safer injection practices, safer stimulant use, overdose prevention, and other topics are available on the Midwest AIDS Education and Training Center website (www.uic.edu/depts/matec/resource.html).

Noninjection Drug Use and Prevention of HIV Transmission

Exposure to HIV through contaminated blood may occur with the use of noninjection drugs; for example, by sharing cocaine straws or sniffers through which cocaine is inhaled. These straws easily can penetrate fragile nasal mucosa and become contaminated with blood from one user before being used by another individual, who may then experience mucous membrane exposure or even a cut or break in the mucous membrane from the bloody object. Straws or sniffers should not be shared.

Tattoo, Piercing, and Acupuncture Equipment

Patients should be aware of the risk of contamination of tattoo equipment, inks, and piercing equipment, and they should avoid situations wherein they might either transmit HIV or pick up other bloodborne pathogens. Acupuncturists generally use sterile needles, but clients should verify that before using their services.

Perinatal HIV Transmission

HIV-infected women can have healthy pregnancies, with good health outcomes for both mother and baby. For this to occur, women must know their HIV status as early as possible, preferably before becoming pregnant, and must receive effective ART. Although intervention to reduce the risk of perinatal infection is most effective if begun early in pregnancy, or preferably before pregnancy, it may be beneficial at any point

in the pregnancy, even as late as during labor. For further information, see chapter *Reducing Perinatal HIV Transmission*.

Preexposure Prophylaxis (PrEP)

Preexposure prophylaxis (PrEP) refers to the use of oral or topical ARVs before HIV exposure with the goal of preventing HIV infection. Studies have evaluated PrEP strategies using either oral tenofovir + emtricitabine (Truvada), oral tenofovir, or vaginal tenofovir to prevent sexual acquisition of HIV in MSM and high-risk heterosexually active women and men. Most have shown efficacy (ranging from about 40% to 75%) in reducing infection risk, but two others have not demonstrated protective benefit. A study of PrEP using tenofovir in injection-drug users also showed a reduction in HIV infections in the tenofovir group (a 49% reduction in incidence). In all studies, the effectiveness of PrEP has been strongly related to the study participants' adherence to the PrEP medication. It should be noted that, in these PrEP studies, the ARV prophylaxis was given in conjunction with other risk-reduction interventions, including counseling, condom provision, and STD testing and treatment.

The CDC has issued interim guidelines on the use of oral tenofovir-emtricitabine as PrEP in MSM, heterosexually active adults, and injection-drug users (see "References," below); these guidelines offer recommendations for PrEP screening and use, as well as ongoing monitoring for adherence, safety, and HIV infection. They emphasize that PrEP should be delivered in the context of a comprehensive package of health and prevention services. In 2012, the FDA approved the fixed-dose combination tenofovir/emtricitabine (Truvada) to reduce the risk of sexually acquired HIV-1 in adults at high risk; it has not yet approved an indication for PrEP in injection-drug users.

U.S. Public Health Service (PHS) guidelines for PrEP use are currently in development.

Postexposure Prophylaxis for Nonoccupational HIV Exposure

Postexposure prophylaxis (PEP) may be considered for certain sexual exposures, sexual assaults, and other nonoccupational exposures to HIV. As with occupational PEP, a risk assessment must be completed and PEP medications, if indicated, must be started as soon after exposure as possible. The risks and toxicities of ARV drugs must be weighed against potential benefits, and the client's informed consent must be obtained. For further information, see chapter *Nonoccupational Postexposure Prophylaxis*.

Appendix

Table 2. Instructions for Use of Standard Condoms

- Use a new latex or polyurethane condom with each act of sex (oral, anal, or vaginal). Make sure that the condom is undamaged, and that its expiration date has not passed.
- Carefully handle the condom to avoid damage (e.g., from fingernails, teeth).
- Being sure that the condom roll faces out, unroll the condom onto the erect penis before any genital contact with partner.
- Ensure that the tip of the condom is pinched when applying it to the top of the penis, to eliminate air in the tip that could cause breakage during ejaculation.
- Use only water-based lubricants with latex condoms. Oil-based lubricants (such as mineral oil, cooking oil, massage oil, body lotion, and petroleum jelly) can weaken latex or cause it to break, although they are fine with the use of polyurethane condoms. Adequate lubrication during intercourse helps reduce the risk of condom breakage.

Table 3. Instructions for Use of Insertive (Female) Condoms

Vaginal Intercourse
• Open the pouch by tearing at notched edge of packet, and take out the female condom. Be sure that the lubricant is evenly distributed on the inside by rubbing the outsides together. • Find a comfortable position, such as standing with one foot on a chair, sitting with knees apart, or squatting. Be sure the inner ring is inside, at the closed end of the pouch. • Hold the pouch with the open end hanging down. While holding the outside of the pouch, squeeze the inner ring with your thumb and middle finger. Still squeezing, spread the labia with your other hand and insert the closed end of the pouch into the vagina. • Now, put your fingers into the pouch itself, which should be inside the vagina, and push the inner ring and the pouch the rest of the way up into the vagina with your index finger. Check to see that the front side of the inner ring is just past the pubic bone. The back part of the inner ring should be up behind the cervix. The outer ring and about an inch of the pouch will be hanging outside the vagina. • Until you and your partner become comfortable using the female condom, use your hand to guide the penis into the vagina, keeping it inside the pouch. If, during intercourse, the outer ring is pushed inside the vagina, stop, remove the female condom, and start over with a new one. Extra lubricant on the penis or the inside of the female condom may help keep this from happening. • After intercourse, take out the condom by squeezing and twisting the outer ring to keep the semen inside the pouch. Throw away in a trash can; do not flush. Do not reuse. • More information is available on the Planned Parenthood website (www.plannedparenthood.org).
Anal Intercourse
• Remove the inner ring and discard it. Put the female condom on the penis of the insertive partner and insert the condom with the penis, being careful not to push the outer ring into the rectum. The outer ring remains outside the anus, for ease of removal after ejaculation.

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Immunizations for HIV-Infected Adults and Adolescents

Background

Immunocompromised individuals are at higher risk of acquiring many types of infections compared with immunocompetent people. Although HIV-infected persons could benefit greatly from immunization against preventable infections, little specific research on the effectiveness of immunizations in this population has been completed. In general, vaccines have better efficacy in HIV-infected patients when immune function is relatively well preserved, notably when the CD4 count is >200 cells/ μ L. Persons with advanced immunodeficiency may have an impaired humoral response, and may not respond to vaccines, or they may require supplemental doses to develop serologic evidence of protection. If possible, vaccines should be administered before the CD4 count decreases to <200 cells/ μ L; if given when the CD4 count is <200 cells/ μ L, consideration should be given to repeating the vaccination when the CD4 count increases to >200 - 300 cells/ μ L (unless there is evidence of immunity).

Live vaccines generally should not be administered to individuals with HIV infection, particularly those with advanced immunodeficiency, unless the anticipated benefits of vaccination clearly outweigh the risks.

Administration of vaccines can be associated with a transient rise in plasma HIV RNA.

Recommendations about vaccination for patients with HIV infection are presented in Table 1.

HRSA HAB Performance Measures

Percentage of patients, aged 6 months and older seen for a visit between October 1 and March 31, who received an **influenza immunization** OR who reported previous receipt of an influenza immunization

(All-Age measure)

Percentage of patients with a diagnosis of HIV who completed the **vaccination series for hepatitis B**

(Adult and Adolescent measure)

Percentage of patients with a diagnosis of HIV who ever received **pneumococcal vaccine**

(Adult and Adolescent measure)

Table 1. Vaccine Recommendations

Vaccine Type	Recommendation
Pneumococcal Pneumococcal (polysaccharide) (PPV23) Pneumococcal 13-valent conjugate (PPV13)	• Recommended for all. • If CD4 count is <200 cells/μL, may be less effective; consider revaccination when CD4 count increases in response to ART. • Two types of pneumococcal vaccine; both should be given, as follows. • 1 dose as soon as possible after HIV diagnosis (or PCV13 may be given first, see below); revaccinate 5 years after initial vaccination. • For those who received 1-2 doses of PPV23 before age 65, repeat at age ≥ 65 if ≥ 5 years since their previous dose. • PPV23 should not be given <8 weeks after PPV13 (see below). • 1 dose recommended for all HIV-infected adults; timing varies according to whether PPV23 has been given: • No previous pneumococcal vaccination: • 1 dose PCV13 followed by PPV23 ≥ 8 weeks after PCV13. (If CD4 <200 cells/μL, PPV23 can be offered ≥ 8 weeks after PCV13 or can await increase of CD4 to >200 cells/μL.) • Previous PPV23 vaccination: • 1 dose of PCV13, given ≥ 1 year after last receipt of PPV23.
Hepatitis A Virus (HAV)	• Recommended, for persons with chronic liver disease, injection drug users, men who have sex with men, international travelers, and hemophiliacs. Consider for all, unless there is serologic evidence of previous disease. • Serologic response (HAV IgG Ab) should be checked 1 month after completion of series, and nonresponders should be revaccinated. • 2 doses (Havrix: 0, 6-12 months; Vaqta: 0, 6-18 months).
Hepatitis B Virus (HBV)	• Recommended for all, unless there is evidence of immunity (HBV surface Ab+) or active HBV infection (HBV surface Ag+, or HBV core Ab+ and evidence of HBV activity). • Many experts recommend giving a high dose of HBV vaccine (40 mcg), as is standard for hemodialysis patients; this may improve immunologic response in HIV-infected patients. • Most HIV-infected patients with isolated HBV core Ab+ (without HBV viremia) are not immune and should receive a complete series of HBV vaccine. • Anti-HBV surface Ab titers should be checked 1 month after completion of vaccine series. Patients whose titer level is ≤ 10 IU/mL should be revaccinated. • Standard dosing schedule is 3 doses (0, 1, and 6 months). If 40 mcg is given, the recommended schedule is 3 doses of Recombivax HB at 0, 1, and 6 months or 4 doses of Engerix-B at 0, 1, 2, and 6 months.
Influenza (inactivated vaccine)	• Recommended (yearly). • Vaccination is most effective among persons with CD4 counts of >100 cells/μL and HIV RNA of <30,000 copies/mL. • In patients with advanced disease and low CD4 cell counts, inactivated vaccine may not produce protective antibodies. A second dose of vaccine does not improve response in these patients. • Live, attenuated cold-adapted vaccine (LAIV, FluMist) is not recommended for use in patients with HIV infection as the efficacy of the vaccine in this population has not been evaluated. • Close contacts of severely immunocompromised persons (including household members and health care personnel) should not receive live, attenuated influenza vaccine.

Vaccine Type	Recommendation
Tetanus, Diphtheria (Td); Tetanus, Diphtheria, Pertussis (Tdap)	- Recommended (booster is recommended every 10 years in adults; or, if potential exposure [wound], after 5 years). - To protect against pertussis, substitute single dose of Tdap for Td booster in all patients aged 19-65 who have not received Tdap previously.
Measles, Mumps, Rubella (MMR)	- Live vaccine is contraindicated for use in patients with severe immunosuppression (CD4 count of <200 cells/μL). - Recommended for all nonimmune persons with CD4 counts of $\geq$200 cells/μL.
Varicella-Zoster (VZV) Varicella vaccine (primary immunization) Zoster vaccine	- Two doses (0, 3 months). - Live vaccine; contraindicated for use in patients with severe immunosuppression (CD4 count of <200 cells/μL). - Consider for HIV-infected, VZV-seronegative persons with CD4 counts of $\geq$200 cells/μL. - If vaccination results in infection with attenuated virus, treat with acyclovir. - Transmission of vaccine virus from vaccine recipients to susceptible individuals is possible; vaccine recipients should avoid close contact with high-risk susceptible individuals for 6 weeks after vaccination. - One dose. - Live vaccine; contraindicated in persons with AIDS or other clinical manifestations of HIV infection. - Consider for select patients aged >50 with CD4 counts of >200 cells/μL and with evidence of varicella immunity (if no evidence of varicella immunity, give primary varicella vaccination). Limited data show safety and immunogenicity in this group. - Transmission of vaccine virus to susceptible contacts is possible.
Human Papillomavirus (HPV)	- Two vaccines: - Gardasil includes HPV strains 16 and 18 (oncogenic) and 6 and 11 (wart causing); approved for use in women and men. - Cervarix: includes HPV strains 16 and 18; approved for use in women. - Gardasil or Cervarix recommended for females aged 9-26. - Gardasil vaccine recommended for males aged 9-26. - Not contraindicated for use in HIV-infected individuals; limited data on efficacy; may be less effective if CD4 count is <200 cells/μL.
Meningococcal	- Two doses (0, $\geq$8 weeks). - Recommended if risk factor is present (e.g., college freshmen living in dormitory, military recruits, asplenia, complement component deficiency, travel to or residence in area with outbreaks,* occupational exposure).

Abbreviations: Ab = antibody; Ag = antigen; ART = antiretroviral therapy

* In 2012, the New York City Department of Health and Mental Hygiene reported ongoing outbreak of meningococcal meningitis in men who have sex with men (MSM) and recommended vaccination for those with recent or future exposure risk. Many health departments in other areas have recommended vaccination of MSM, including HIV-infected MSM, who recently had or expect to have close contact with a man who is known to be, or could potentially be, from New York City.

Immunizations for HIV-Infected Patients Traveling to Developing Countries

Routine vaccinations should be reviewed and updated before travel. All patients traveling to other countries should be evaluated for both routine and destination-specific immunizations and prophylaxes. Inactivated (killed) and recombinant vaccines (e.g., diphtheria-tetanus, rabies, hepatitis A, hepatitis B, Japanese encephalitis) should be used for HIV-infected persons just as they would be used for HIV-uninfected persons anticipating travel. For further information, see the U.S. Centers for Disease Control and Prevention (CDC) webpage (wwwnc.cdc.gov/travel). Recommendations specific to HIV-infected travelers are located in “The Immunocompromised Traveler” under the section called “Advising Travelers with Special Needs.” Select the “Traveler’s Health” option for regional travel documents and information on outbreaks.

Decision making about immunization for the HIV-infected traveler should take into consideration the traveler’s current CD4 cell count, history of AIDS-defining illness, and clinical manifestations of symptomatic HIV. In the CDC recommendations, asymptomatic HIV-infected persons with CD4 counts of 200-500 cells/ μ L are considered to have limited immune deficits, whereas patients with CD4 counts of >500 cells/ μ L are considered to have no immunologic compromise. For patients taking antiretroviral therapy, current CD4 counts rather than nadir counts should be used in deciding about immunizations. The CDC recommends that newly diagnosed, treatment-naïve patients with CD4 counts of <200 cells/ μ L delay travel until after immunologic reconstitution with antiretrovirals to minimize risk of infection and immune reconstitution illness during travel.

The following should be noted about specific vaccinations:

- Inactivated (killed), enhanced-potency polio and typhoid vaccines should be given instead of the live, attenuated forms. In adults aged >18 , vaccinate 8 weeks before travel to allow time for the initial 2 doses of polio vaccine.
- Measles or measles, mumps, and rubella (MMR; omit if patient has evidence of immunity) should not be given to severely immunocompromised patients. Instead, immune globulin should be given to measles-susceptible, severely immunocompromised persons traveling to measles-endemic countries.
- Yellow fever vaccine is a live-virus vaccine with uncertain safety and efficacy for HIV-infected persons, and it should be avoided if possible. Travelers with asymptomatic HIV infection and relatively high CD4 counts who cannot avoid potential exposure to yellow fever should be offered the choice of vaccination. If travel to a zone with yellow fever is necessary and vaccination is not administered, patients should be advised about the risk of yellow fever, instructed about avoiding the bites of vector mosquitoes, and provided with a vaccination waiver letter (though travelers should be warned that not all countries accept waiver letters).
- The influenza season in the Southern Hemisphere is April through September, but in the tropics, influenza is a year-round infection. Immunocompromised patients should be protected on the basis of influenza risk at the destination. HIV-infected patients should not be given live intranasal influenza vaccine.

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Preventing Exposure to Opportunistic and Other Infections

Background

Persons with HIV infection are more susceptible than others to certain infections. HIV-infected persons may come into contact with opportunistic pathogens in the course of various aspects of their daily activities. Pets, children, personal and sexual contacts, and food and water, as well as involvement in occupational tasks, recreation, hobbies, and other activities all potentially can expose an HIV-infected person to opportunistic pathogens, some of which are ubiquitous and cannot be avoided. Among the ubiquitous pathogens are *Candida*, *Mycobacterium avium*, *Pneumocystis jiroveci*, and human herpesvirus 6 and 7. Exposure to other opportunistic pathogens may be minimized if patients are aware of the risks.

The following tables group opportunistic pathogens by type of exposure. Mechanisms of transmission and recommendations for avoidance are outlined. Note that a number of infections can be transmitted by several of these modes.

For information about vaccinations, see chapter *Immunizations for HIV-Infected Adults and Adolescents*; for opportunistic infection (OI) prophylaxis, see chapter *Opportunistic Infection Prophylaxis*.

Topics:

- | | |
|----------------------------------|---------------------------------|
| • Water related | • Injection drug use associated |
| • Food associated | • Other bloodborne related |
| • Environmental | • Pet and animal related |
| • Respiratory and bodily contact | • Contact with children |
| • Associated with sexual contact | • Travel related |

Water Related	
Pathogens	• Hepatitis A virus (HAV) • <i>Cryptosporidium</i> • <i>Shigella</i> • <i>Campylobacter</i> • <i>Amoeba</i> • <i>Giardia</i> • <i>Isospora</i> • Microsporidia
Transmission	• Infection occurs through drinking contaminated water or eating produce or other food that has been washed in contaminated water. • Water ingested accidentally during recreation also can make people sick.
Recommended avoidance measures	• To decrease exposure from water in developing countries, take the following precautions: • Do not drink tap water or use it to brush teeth. • Avoid ice that is not made from bottled water. • Avoid raw fruits or vegetables, as they may have been washed in tap water. • Bring tap water to a rolling boil for at least 1 minute before consuming. If this is not possible, treatment with iodine or chlorine, especially in conjunction with filtering, reduces risk of infection. • Additional recommendations, include the following: • Avoid drinking untreated water. • When choosing a home water filter, especially for filtering untreated water, be aware that not all filters remove the pathogens listed above. • Do not drink water from lakes or rivers. • Avoid swimming in water that may be contaminated with stool. • Avoid swallowing water during recreational activities (lakes, rivers, saltwater beaches, pools, hot tubs, and ornamental fountains may be contaminated with <i>Cryptosporidium</i>). • In the event of a cryptosporidiosis outbreak in the municipal water supply, boil tap water for at least 1 minute to eliminate risk of infection. • <i>Cryptosporidium</i> may be present in municipal water outside outbreak settings, though the magnitude of this risk is unknown. Some HIV-infected patients may choose to take precautions to decrease risk. • Be aware that bottled water may be contaminated with <i>Cryptosporidium</i>. • See the discussion of travel-related topics, below.

Food Associated	
Pathogens	• <i>Toxoplasma</i> • <i>Salmonella</i>, <i>Shigella</i>, <i>Campylobacter</i> (enteric infections) • <i>Listeria</i> • <i>Cryptosporidium</i> • Other enteric pathogens
Transmission	• Exposure may occur through eating or handling contaminated food.
Recommended avoidance measures	• Always wash hands before preparing and consuming food. • Wash hands, cutting boards, counters, and utensils thoroughly after contact with uncooked foods. • Do not allow raw meat or eggs to come into contact with other foods. • Wash produce thoroughly. • Cook meat and poultry to an internal temperature of 165-170°F. It is safest to confirm temperature with a thermometer. Meat that is no longer pink inside likely has reached a temperature of 165°F. • Avoid raw or unpasteurized milk, including goat milk, and foods that contain unpasteurized milk or milk products. • Avoid foods that might contain raw egg (e.g., Hollandaise sauce, Caesar salad dressing, some mayonnaises, uncooked cake and cookie batter, eggnog, homemade ice cream). Pasteurized eggs can be used safely in recipes that call for raw egg. • Avoid eating raw or lightly steamed shellfish. • Avoid eating raw seed sprouts, as these may be contaminated with enteric pathogens. • Avoid foods from street vendors, especially in developing countries. • Be aware that unpasteurized juices may be contaminated with <i>Cryptosporidium</i>. • Rates of infection with <i>Listeria</i> are low, but HIV-infected people who are severely immunocompromised are at increased risk. • HIV-infected persons who wish to decrease their risk of listeriosis should take the following precautions: • Avoid soft cheeses including feta, brie, camembert, blue-veined, and Mexican-style cheeses such as queso fresco unless they are clearly labeled as pasteurized. Hard cheeses, processed cheeses, cream cheese, cottage cheese, and yogurt generally are safe. • Before eating leftover foods or ready-to-eat foods, such as hot dogs, cook them until they are steaming hot. • Avoid foods from deli counters, such as prepared meats, salads, and cheeses, or heat these foods until steaming hot before eating them. • Avoid refrigerated pâté, or heat until steaming hot. Canned or shelf-stable pâté generally is safe. • Avoid refrigerated smoked seafood, unless it is part of a cooked dish. Canned or shelf-stable smoked seafood generally is safe. • Also see information on travel-related infections, below.

Environmental	
Pathogens	• <i>Toxoplasma gondii</i> • <i>Cryptosporidium</i> • <i>Coccidioides</i> • <i>Histoplasma capsulatum</i> • <i>Cryptococcus neoformans</i> • <i>Aspergillus</i>
Transmission	• <i>Cryptosporidium</i> and <i>Toxoplasma</i> may be present in soil and sands, and infection can occur through handling soil during gardening or playing in or cleaning sandboxes. • Infection with <i>Coccidioides</i> and <i>Histoplasma</i> occurs with inhalation of fungal spores that become airborne owing to disturbance of contaminated soil.

Environmental	
Recommended avoidance measures	• Wash hands thoroughly after contact with soil or sand. • Endemic fungi cannot be completely avoided in certain geographic areas; however, avoiding high-risk activities can decrease risk of infection. • In endemic coccidioidomycosis areas, avoid exposure to soil disturbance such as that which occurs during dust storms and at excavation and construction sites. • Risk of <i>Aspergillus</i> infection also may be decreased by avoidance of dusty environments. • Patients with CD4 counts of <150 cells/μL should avoid activities that put them at increased risk of exposure to <i>Histoplasma</i> in endemic areas, such as: • Cleaning, remodeling, or demolishing old buildings • Disturbing soil beneath bird roosting sites • Cave exploration • Other contact with bird or bat droppings • Limiting exposure to bird droppings may decrease risk of infection with <i>C. neoformans</i>.

Respiratory and Bodily Contact	
Pathogens	• <i>Mycobacterium tuberculosis</i> • Enteric pathogens • Influenza • Varicella-zoster virus (VZV)
Transmission	• Tuberculosis (TB) is transmitted when a person with pulmonary or laryngeal TB coughs, sneezes, shouts, or sings, generating infected droplets that are inhaled by a susceptible person. • HIV-infected persons working or residing in certain environments, such as hospitals, nursing homes, homeless shelters, and correctional institutions, may become exposed to TB. • Influenza virus is spread by exposure to infected respiratory droplets or contaminated surfaces. • VZV is transmitted through contact with aerosolized respiratory droplets or by contact with skin lesions. • Many respiratory and enteric pathogens may be spread by contact with contaminated fomites.
Recommended avoidance measures	• HIV-infected persons should be aware of the increased risk of TB infection associated with certain environments. The following measures decrease risk of infection: • In settings with a high risk of TB transmission, patients with known or suspected TB should be physically separated from others. • All HIV-infected persons should be tested for latent TB infection. • All HIV-infected patients with latent TB infection (LTBI) should receive a complete course of LTBI treatment. • HIV-infected persons with a history of significant TB exposure should be treated presumptively for LTBI regardless of the results of LTBI testing, once active infection has been ruled out. • Bacillus Calmette-Guérin (BCG) vaccination is not recommended in the United States, and it is contraindicated for HIV-infected persons. • People susceptible to VZV should avoid persons with active chickenpox or herpes zoster (shingles). • VZV-susceptible, HIV-negative household contacts should be vaccinated against VZV, so that they will not transmit VZV to their HIV-infected contact. • Frequent handwashing can reduce risk of diarrhea in HIV-infected persons.

Associated with Sexual Contact	
Pathogens	• HIV • Hepatitis B virus (HBV) • Hepatitis C virus (HCV) • Hepatitis A virus (HAV) • Human papillomavirus (HPV) • Cytomegalovirus (CMV) • Herpes simplex virus (HSV) • Syphilis • <i>Chlamydia</i> • <i>Gonorrhea</i> • <i>Trichomonas</i> • Lymphogranuloma venereum (LGV) serovars of <i>Chlamydia trachomatis</i> • <i>Cryptosporidium</i> • <i>Shigella</i> • <i>Campylobacter</i> • <i>Amoeba</i> • <i>Giardia</i> • <i>Isospora</i> • Microsporidia
Transmission	• Depending on the pathogen, infection may be transmitted by exchange of body fluids, by skin-skin contact, or by oral-fecal contact. • Sexually transmitted diseases (STDs) can occur at genitals, rectum, or mouth, depending on sexual practices. • A number of enteric pathogens can be transmitted during sex (by oral-fecal contact).
Recommended avoidance measures	• Male latex condoms, when used consistently and correctly: • Are highly effective in preventing sexual transmission of HIV and many other STDs, including syphilis, chlamydia, gonorrhea, and trichomoniasis. • Decrease risk of acquiring HSV-2, HPV, CMV, HBV, and HCV. • Do not prevent enteric pathogen exposure (which is via fecal-oral contact). • HIV-infected persons should be screened for STDs at least annually. Those with multiple partners or high-risk partners or sexual practices should be screened more frequently. • To avoid infection with HSV, HIV-infected persons should avoid sexual contact when a partner has an overt herpetic lesion (genital or oral-labial), though HSV transmission also can occur during asymptomatic shedding. Consistent use of male condoms also has been shown to reduce HSV transmission risk in heterosexual couples. • The use of suppressive antiviral therapy by persons with genital herpes reduces HSV-2 transmission to susceptible partners, though the effectiveness of this approach in HIV-infected patients has not been evaluated. • Patients who are CMV seronegative should be advised that CMV can be sexually transmitted. • To decrease risk of exposure to enteric pathogens during sex, patients can: • Use barriers such as dental dams during oral-anal contact. • Change condoms after anal sex. • Wear latex gloves during digital-anal contact. • Wash hands after sex.

Injection Drug Use Associated	
Pathogens	• HIV • HCV • HBV • CMV • <i>Staphylococcus aureus</i>, including MRSA • <i>Pseudomonas aeruginosa</i> • <i>Streptococcus</i> • <i>Clostridium</i> • Enteric bacteria and oral anaerobes • <i>Leishmania</i> • Fungi
Transmission	• Injection drug users are at risk of a host of infections, including viral hepatitis, skin and soft-tissue infections, infective endocarditis, and pulmonary infections. • Injection drug use also may put users at risk of acquiring TB and STDs. • Infection may occur from contaminated drug-injection equipment (needles, syringes, water, and other preparation equipment). • Infection also may occur from the user's own skin or mouth bacteria, which can enter the bloodstream. • The drug itself, or an adulterating substance, may be contaminated.
Recommended avoidance measures	• Injection drug users should be advised not to share needles or drug preparation equipment, and should be educated about needle exchange programs. • If receptive, injection drug users should be referred to substance abuse treatment programs. • Injection drug users should be educated about methods of reducing risk, including the following: • If equipment is being reused, clean with bleach and water. • Avoid dangerous injection sites such as groin and neck. • Do not crush capsules or tablets in the mouth prior to injecting, as this may introduce harmful oral bacteria into the bloodstream. • Do not lick injection needles or syringes. • Use boiled water for preparing drugs for injection; if not available, use tap water. • Boil the drug before injecting. • Use a new or disinfected "cooker," and a new filter to prepare drugs for injection. • Always clean injection sites with alcohol before injecting. • Be aware that black tar heroin may be contaminated with <i>Clostridium</i> spores, which are not killed by heating the drug prior to use.

Other Bloodborne Related	
Pathogens	• HIV • HCV • HBV • CMV
Transmission	• Tattooing and body piercing. • Reuse of medical equipment and transfusion of infected blood (primarily outside the United States). • Occupational exposures (e.g., needlesticks) of health care workers.
Recommended avoidance measures	• Persons considering tattooing or piercing should be educated about the potential risk of bloodborne pathogen transmission if proper infection control procedures are not followed. • When receiving a transfusion, HIV-infected patients who are seronegative for CMV should be administered only CMV antibody-negative or leukocyte-reduced cellular blood products in nonemergency situations. • Universal precautions always should be followed by health care workers.

Pet and Animal Related	
Pathogens	• <i>Toxoplasma</i> • <i>Cryptosporidium</i> • <i>Salmonella</i> • <i>Campylobacter</i> • Shiga toxin-producing <i>Escherichia coli</i> • <i>Bartonella</i> • <i>Leptospira</i> • <i>Brucella</i> • <i>Capnocytophaga</i> • <i>Cryptococcus</i> • <i>Mycobacterium avium</i> and <i>marinum</i> • <i>H. capsulatum</i>
Transmission	• For the most part, people with HIV infection can and should keep their pets. • HIV-infected persons should be made aware of the potential risks posed by animals and of the avoidance measures for decreasing risks of infection. • Exposure may occur though a lick, a bite, or a scratch, or through contact with a pet's stool. Some infections may be spread though contact with an animal's coat or skin. • Fleas may spread some infections to pet owners. • Patients also may be exposed while performing occupational tasks that bring them into contact with animals (e.g., in pet stores, veterinary clinics, farms, and slaughterhouses).
Recommended avoidance measures	• Always wash hands after handling animals, and after cleaning cages or aquariums. • When acquiring a new pet, avoid animals <6 months of age (cats younger than 1 year) and those with diarrhea. • Stray animals may carry many infections and should be avoided. • Avoid contact with animal stool. • Avoid animals with diarrhea. • Pets with diarrhea should be examined by a veterinarian and should have stool checked for <i>Cryptosporidium</i>, <i>Salmonella</i>, <i>Campylobacter</i>, and Shiga toxin-producing <i>E. coli</i>. • Wash any bites or scratches with soap and water, and seek medical attention. • Animals should not be allowed to lick people in the mouth, or on any open cuts or wounds. • Cats may increase risk of <i>Toxoplasma</i> and <i>Bartonella</i> infection. • To minimize risk of <i>Toxoplasma</i> exposure: • Litter boxes should be cleaned daily, preferably by someone who is not HIV infected or pregnant. • If an HIV-infected person is cleaning a litter box, gloves should be used, and hands should be washed afterward. • Keep cats indoors and do not allow them to hunt. • Do not feed cats raw or undercooked meat. • In areas where histoplasmosis is endemic, avoid contact with bird droppings, including soil under bird roosting sites. • Always use gloves when cleaning aquariums to avoid contact with <i>Mycobacterium marinum</i>. • Avoid contact with reptiles (such as lizards, snakes, and turtles), as well as chicks and ducklings, as these may carry <i>Salmonella</i>. • Avoid exotic pets such as monkeys, ferrets, and other wild animals.

Contact with Children	
Pathogens	• CMV • <i>Cryptosporidium</i> • <i>Giardia</i> • HAV • Influenza • VZV • Enteric pathogens
Transmission	• HIV-infected persons who work as childcare providers, or who have children in daycare, may be exposed to opportunistic pathogens. • The poor personal hygiene habits of children facilitate spread of infection. • Risks specific to the individual, given his/her immune status and medical history, should be discussed with a health care provider. • CMV infection may occur through contact with many body fluids, including stool, urine, and saliva. • Diapering may bring a person into contact with <i>Cryptosporidium</i> and other enteric pathogens. • In addition to opportunistic pathogens, childcare providers are exposed to other illnesses, carried by children, to which they may be more susceptible.
Recommended avoidance measures	• Wash hands thoroughly after contact with stool or urine. • Wash hands after diapering and disinfect changing station often. • Wash hands after contact with saliva or objects covered with saliva, such as cups or pacifiers. • Ensure that the immunization status of HIV-infected persons is up to date, as appropriate for their immune status. • HIV-infected persons who are susceptible to VZV should avoid exposure to people with chickenpox or shingles. • VZV-susceptible household contacts of HIV-infected persons should be vaccinated against VZV if they are HIV negative, so that they will not transmit VZV to their HIV-infected contact.

Travel Related	
Pathogens	• Enteric pathogens • <i>Plasmodium</i> species (malaria) • Yellow fever virus • Dengue virus • Other geographically specific infections
Transmission	• Travelers to developing countries are at risk of foodborne and waterborne infections. • Malaria is transmitted by the bite of an infected female <i>Anopheles</i> mosquito. • HIV-infected patients are at higher risk of severe malaria. • Yellow fever and dengue fever are spread by mosquito bites.

Travel Related	
Recommended avoidance measures	• Plan the travel itinerary, vaccinations, and prophylaxis in consultation with a health care provider experienced in travel medicine. • Discuss area-specific risks and avoidance measures with the health care provider. • The U.S. Centers for Disease Control and Prevention (CDC) Traveler's Health website has detailed information on most issues pertaining to infections in travelers (wwwnc.cdc.gov/travel). • Review and update routine vaccination history prior to travel. • Generally, live vaccines for HIV-infected persons should be avoided, with some exceptions: • Measles vaccination is recommended for all nonimmune persons with CD4 counts of ≥ 200 cells/μL. Measles immune globulin should be considered for those with CD4 counts of < 200 cells/μL who are traveling in measles-endemic areas. • Varicella vaccination can be considered for VZV-seronegative persons with CD4 counts of ≥ 200 cells/μL. • Yellow fever vaccination may be considered, see below. • Inactivated (killed) enhanced-potency polio and typhoid vaccines should be given instead of the live, attenuated forms. • Killed and recombinant vaccines including influenza, diphtheria-tetanus, rabies, HAV, HBV, Japanese encephalitis, and meningococcal vaccines should be administered as they would be for HIV-uninfected persons preparing for travel. • The oral cholera vaccine (not available in the United States) is not recommended for most travelers by the CDC. Traveler's diarrhea: • See sections on foodborne and waterborne infections (above) for risk-reduction strategies. • Antimicrobial prophylaxis is not routinely recommended for HIV-infected persons traveling in developing countries. • Prophylaxis may be appropriate in select situations (for example, high risk of infection and short length of travel). • For those to whom prophylaxis is given, fluoroquinolones (such as ciprofloxacin 500 mg PO QD) may be considered for nonpregnant patients. • HIV-infected patients traveling in developing countries should bring antibiotics to be used empirically in the event of developing diarrhea. • Appropriate regimens include: • Ciprofloxacin 500 mg PO BID for 3-7 days • Azithromycin 500 mg PO QD as an alternative, and for pregnant women • Antiperistaltic agents such as loperamide or diphenoxylate can be useful in the treatment of traveler's diarrhea. • Do not use antiperistaltic agents if high fever or blood in the stool is present. Stop use if symptoms persist > 48 hours. • Seek medical care if diarrhea is severe, bloody, accompanied by fever and chills, leads to dehydration, or does not respond to empiric therapy.

Travel Related	
Recommended avoidance measures	Malaria: • HIV-infected patients should be advised to avoid travel in malarious areas. • If travel to a malarious area cannot be avoided, effective chemoprophylaxis should be given. Consult the CDC Traveler's Health website (wwwnc.cdc.gov/travel) for specific information. • Be aware that some malaria prophylaxis medications may have drug-drug interactions with antiretrovirals. • Personal protection measures should be followed, including avoidance of peak biting times and use of insect repellants, protective clothing, and permethrin-soaked bed netting. Yellow fever: • HIV-infected patients should be discouraged from visiting areas where yellow fever infection is a risk. • Vaccination may be considered in some HIV-infected persons with high CD4 counts who cannot avoid potential exposure, after discussion of risks and benefits. • Vaccine response may be poor, and serologic testing can be considered. • If vaccination is not administered, patients should be advised about the risk of yellow fever, instructed about avoiding the bites of vector mosquitoes, and provided with a vaccination waiver letter. • Personal protection measures should be followed, including avoidance of peak biting times and use of insect repellants, protective clothing, and permethrin-soaked bed netting. Other geographically specific opportunistic infections include visceral leishmaniasis, <i>Penicillium marneffe</i> infection, coccidiomycosis, histoplasmosis, and TB.

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Opportunistic Infection Prophylaxis

Background

Prophylaxis against an opportunistic infection (OI) is treatment given to HIV-infected individuals to prevent either a first episode of an OI (primary prophylaxis) or the recurrence of an OI (secondary prophylaxis). Prophylaxis is recommended to prevent three important OIs: *Pneumocystis jiroveci* pneumonia (PCP), *Mycobacterium avium* complex (MAC), and toxoplasmosis. Prophylaxis also is recommended to prevent tuberculosis (TB) in patients with latent *Mycobacterium tuberculosis* infection (see chapter *Latent Tuberculosis Infection*). In endemic regions, prophylaxis against *Histoplasma capsulatum* and *Coccidioides* species is advised. And in some situations, prophylaxis against other OIs may be reasonable; see the OI prevention recommendations of the U.S. Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association (reference below) for additional information.

HRSA HAB Performance Measures

Percentage of patients, aged 6 weeks or older with a diagnosis of HIV/AIDS, who were prescribed *Pneumocystis jiroveci* pneumonia prophylaxis
(Core measure)

Pneumocystis jiroveci Pneumonia

Background

PCP remains the most common life-threatening infection among U.S. residents with advanced HIV disease.

Primary Prophylaxis: Indications

- Prophylaxis should be administered to all HIV-infected patients with a CD4 count of <200 cells/ μ L, a history of an AIDS-defining illness, or a history of oral thrush. PCP prophylaxis also is indicated for patients with CD4 counts of >200 cells/ μ L in the presence of a CD4 percentage <14%.
- For patients whose CD4 counts are declining toward 200 cells/ μ L, the CD4 count should be monitored closely. PCP prophylaxis should be considered for patients with a CD4 count of 200-250 cells/ μ L if laboratory monitoring will not be possible within 3 months.

Prophylaxis Options: Recommended Regimens

- Trimethoprim-sulfamethoxazole (TMP-SMX) (also known as cotrimoxazole, Bactrim, and Septra) 1 double-strength (DS) tablet PO QD (Note: This regimen also is effective in preventing toxoplasmosis.)
- TMP-SMX 1 single-strength tablet PO QD (this lower-dose regimen may be better tolerated) (Note: This also is likely to be effective in preventing toxoplasmosis.)
- **Warning:** Many patients have adverse reactions to sulfa medications. Severe reactions may include persistent neutropenia, rash (including severe erythroderma), and Stevens-Johnson syndrome (bullae and desquamation of the skin). For patients with milder reactions, chemoprophylaxis with TMP-SMX should be continued if clinically possible. Some patients with a history of serious adverse reaction may undergo desensitization, but this must be done cautiously and it requires diligence from the patient and careful management by the provider (see chapter *Sulfa Desensitization*).

Prophylaxis Options: Alternative Regimens

Other options for prophylaxis include the following:

- TMP-SMX DS, 1 tablet TIW (e.g., Monday, Wednesday, and Friday) (Note: This regimen also is likely to be effective in preventing toxoplasmosis.)
- Dapsone 100 mg PO QD or 50 mg PO BID (Note: These regimens do not prevent toxoplasmosis.)
- Dapsone 50 mg PO QD + pyrimethamine 50 mg PO once weekly + leucovorin 25 mg PO once weekly (Note: This regimen also is effective in reducing the risk of toxoplasmosis.)
 - **Warning:** Glucose-6-phosphate dehydrogenase (G6PD) deficiency can increase the risk of hemolytic anemia or methemoglobinemia in patients receiving dapsone. Screen for G6PD deficiency before starting dapsone. (G6PD deficiency is found in approximately 10% of African-American males, and in 1-2% of males of Mediterranean, Indian, and Asian descent.)
- Dapsone 200 mg PO once weekly + pyrimethamine 75 mg PO once weekly + leucovorin 25 mg PO once weekly
- Aerosolized pentamidine 300 mg once per month, via Respigard II nebulizer (Note: This regimen does not prevent toxoplasmosis.)
 - **Warning:** Aerosolized pentamidine may increase the risk of extrapulmonary pneumocystosis, pneumothorax, and bronchospasm. It increases the risk of TB transmission to others if the patient has active pulmonary tubercular disease, unless ventilation (negative-pressurized facility with outside venting) is adequate. Do not use for patients in whom TB is suspected. The availability of treatment facilities offering aerosolized pentamidine may be limited.

- Atovaquone 1,500 mg QD (Note: This also is effective in reducing the risk of toxoplasmosis.) Atovaquone is more expensive than dapsone. It should be taken with high-fat meals for optimal absorption.
- Atovaquone 1,500 mg + pyrimethamine 25 mg + folinic acid 10 mg, all taken PO QD (Note: This regimen also is effective in reducing the risk of toxoplasmosis.)

Secondary Prophylaxis Indications

Prophylaxis should be given to all patients with a history of PCP.

Discontinuing Prophylaxis

Primary or secondary prophylaxis can be discontinued if the CD4 count has increased to ≥ 200 cells/ μ L for at least 3 months in response to effective antiretroviral therapy (ART), with the following cautions:

- If the patient had PCP in the past and the episode of PCP occurred at a CD4 count of >200 cells/ μ L, it may be prudent to continue PCP prophylaxis for life, regardless of how high the CD4 count rises as a consequence of ART.
- PCP prophylaxis should be reinitiated if the CD4 count decreases to <200 cells/ μ L or the patient meets other criteria as indicated above.

Prophylaxis During Pregnancy

TMP-SMX is the recommended agent for use during pregnancy; dapsone may be used as an alternative. Some experts recommend high-dose folate supplementation (e.g., 4 mg daily) for pregnant women receiving TMP-SMX, because TMP-SMX may worsen folate deficiency; however, this may increase risk of TMP-SMX failure; if high-dose folate supplementation is given, it should be limited to the first trimester. Prophylaxis that includes pyrimethamine generally should be deferred until after pregnancy. During the first trimester, aerosolized

pentamidine (which is not systemically absorbed) can be used if the potential teratogenicity of oral agents is a concern.

***Mycobacterium avium* Complex**

Background

MAC is common among patients with advanced HIV disease and it generally occurs in people with CD4 counts of <50 cells/ μ L.

Primary Prophylaxis: Indications

Prophylaxis should be administered to all HIV-infected patients with CD4 counts of <50 cells/ μ L. Before starting prophylaxis, rule out active MAC infection by clinical assessment and, if warranted, by acid-fast bacilli (AFB) blood cultures (see chapter *Mycobacterium avium Complex Disease*). Also rule out active TB prior to starting any rifabutin-containing regimen for MAC prophylaxis. Review the current drug regimen for medications that may interact with MAC prophylaxis.

Prophylaxis Options: Recommended Regimens

- Azithromycin 1,200 mg PO weekly
- Clarithromycin 500 mg PO BID (Note: Clarithromycin is not recommended for use during pregnancy, and it can have significant interactions with efavirenz, atazanavir, and other drugs; see chapter *Drug-Drug Interactions with HIV-Related Medications*.)
- Azithromycin 600 mg PO BIW

Prophylaxis Options: Alternative Regimens

Rifabutin 300 mg QD (Note: Rifabutin has significant interactions with many drugs; certain nonnucleoside reverse transcriptase inhibitors and protease inhibitors should be avoided or dosage adjustment of rifabutin

may be required. See chapter *Drug-Drug Interactions with HIV-Related Medications*.)

Secondary Prophylaxis

Patients should receive lifelong chronic maintenance therapy, unless immune reconstitution occurs in response to ART. See chapter *Mycobacterium avium Complex Disease*.

Discontinuing Prophylaxis

Primary prophylaxis for MAC can be discontinued in persons who have responded to effective ART with sustained increases in CD4 counts to >100 cells/ μ L for at least 3 months. Careful observation and monitoring are required, and prophylaxis should be restarted if the patient's CD4 count decreases to <50 cells/ μ L.

Secondary prophylaxis can be discontinued in patients who received at least 12 months of treatment for MAC, are asymptomatic, and have sustained (for at least 6 months) CD4 counts of >100 cells/ μ L on ART. Secondary prophylaxis should be reintroduced if the CD4 count decreases to <100 cells/ μ L.

Prophylaxis During Pregnancy

Azithromycin is the prophylactic drug of choice during pregnancy, although evidence for its safety in the first trimester is limited. Clarithromycin is teratogenic in animals.

Toxoplasmosis

Background

Toxoplasmic encephalitis (TE) usually is caused by reactivation of latent *Toxoplasma gondii* infection in patients with advanced immunosuppression (especially those with CD4 counts of <100 cells/ μ L). The CDC/NIH recommendations state that all HIV-infected patients should be tested for *Toxoplasma* immunoglobulin G (IgG) antibody soon after the diagnosis of HIV infection. *Toxoplasma* IgG-negative patients should be counseled

to avoid sources of infection (see chapter *Preventing Exposure to Opportunistic and Other Infections*), and should be retested for *Toxoplasma* IgG if CD4 counts fall to <100 cells/ μ L to determine whether they have seroconverted and are therefore at risk of TE. (See chapter *Toxoplasmosis* for more information on active disease and secondary prophylaxis.)

Primary Prophylaxis: Indications

Prophylaxis should be administered to all HIV-infected patients with CD4 counts of <100 cells/ μ L who are seropositive for *Toxoplasma*. IgG-negative patients should avoid exposure to *Toxoplasma*; see “Patient Education,” below, and chapter *Preventing Exposure to Opportunistic and Other Infections*.

Prophylaxis Options: Recommended Regimens

- TMP-SMX DS, 1 tablet QD (Note: This option also is effective in preventing PCP.)

Prophylaxis Options: Alternative Regimens

(Note: The following options also are effective in preventing PCP.)

- TMP-SMX DS, 1 tablet PO TIW
- TMP-SMX single strength, 1 tablet PO QD
- Dapsone 50 mg PO QD + pyrimethamine 50 mg PO weekly + folinic acid 25 mg PO weekly
- Dapsone 200 mg PO weekly + pyrimethamine 75 mg PO weekly + folinic acid 25 mg PO weekly
 - **Warning:** G6PD deficiency can increase the risk of hemolytic anemia or methemoglobinemia in patients receiving dapsone. Screen for G6PD deficiency before starting dapsone. (G6PD deficiency is found in approximately 10% of African-

American males, and in 1-2% of males of Mediterranean, Indian, and Asian descent.)

- Atovaquone 1,500 mg PO QD, with or without pyrimethamine 25 mg PO QD + folinic acid 10 mg PO QD (This alternative is quite expensive.)
- Neither aerosolized pentamidine nor dapsone alone provides protection against TE.

Secondary Prophylaxis

Patients should receive lifelong chronic maintenance therapy, unless immune reconstitution occurs in response to ART (see chapter *Toxoplasmosis*).

Discontinuing Prophylaxis

Primary prophylaxis for TE can be discontinued in patients who have responded to effective ART with sustained CD4 counts of >200 cells/ μ L for at least 3 months. CD4 counts should be monitored carefully, and prophylaxis should be restarted in patients whose CD4 counts decrease to <100-200 cells/ μ L.

Secondary prophylaxis may be discontinued if TE signs and symptoms have resolved with treatment and if patients have sustained (for at least 6 months) CD4 counts of >200 cells/ μ L on ART. Secondary prophylaxis should be reintroduced if CD4 counts drop to <200 cells/ μ L.

Prophylaxis During Pregnancy

TMP-SMX may be used as primary prophylaxis during pregnancy. Risks of TMP-SMX in the first trimester must be balanced against the risks of reactivated toxoplasmosis. Some experts recommend high-dose folate supplementation (e.g., 4 mg QD) for pregnant women receiving TMP-SMX, because TMP-SMX may worsen folate deficiency; however, this may increase risk of TMP-SMX failure; if high-dose folate supplementation is given,

it should be limited to the first trimester. Pyrimethamine has been associated with birth defects in animal studies, but limited data in human studies have not shown an increased risk; guidelines support its use after the first trimester. Secondary prophylaxis generally should be provided using the same guidelines as for nonpregnant women.

Histoplasmosis

Background

Infection with *Histoplasma capsulatum* is common in several geographic areas, including the Ohio and Mississippi River Valleys as well as parts of Central and South America, Asia, and Africa. Symptomatic disease can occur via primary infection or reactivation of previously silent infection in the setting of waning cellular immunity. CD4 counts of ≤ 150 cells/ μL , along with positive *Histoplasma* serology and environmental exposure, are associated with increased risk of symptomatic disease. Histoplasmosis can cause a range of clinical manifestations including respiratory, gastrointestinal, central nervous system (CNS), and cutaneous disease.

Primary Prophylaxis: Indications

Prophylaxis can be considered for HIV-infected patients with CD4 counts of ≤ 150 cells/ μL who are at high risk because of occupational exposure and for those who live in an area where histoplasmosis is highly endemic. HIV-infected patients with CD4 counts of ≤ 150 cells/ μL should be educated to avoid exposure.

Prophylaxis Options: Recommended Regimens

- Itraconazole 200 mg PO QD (Note: Itraconazole has significant interactions with many drugs, including nonnucleoside reverse transcriptase inhibitors, protease inhibitors, and maraviroc. Dosage adjustments may be required, and some combinations may be contraindicated; consult with a pharmacist or other specialist.)

Secondary Prophylaxis

Patients with a history of severe disseminated disease or CNS infection and those who have relapsed despite receiving appropriate therapy should receive long-term suppressive therapy.

Discontinuing Prophylaxis

Primary prophylaxis can be discontinued once CD4 counts are ≥ 150 cells/ μL for at least 6 months. CD4 counts should be monitored carefully, and prophylaxis should be restarted for patients whose CD4 counts decrease to < 150 cells/ μL .

Secondary prophylaxis may be discontinued if patients have received at least 1 year of itraconazole, have negative blood cultures, have had CD4 counts of ≥ 150 cells/ μL for at least 6 months on ART, and have serum *Histoplasma* antigen < 2 units. Suppressive therapy should be restarted for patients whose CD4 counts decrease to < 150 cells/ μL .

Prophylaxis During Pregnancy

Azoles should be avoided during pregnancy, especially during the first trimester, because of teratogenicity concerns.

Coccidiomycosis

Background

The *Coccidioides* species fungus is endemic to many arid regions. In the United States, it is found primarily in the Sonoran Desert in Arizona and the San Joaquin “Central” Valley in California, but also in areas of New Mexico, western Texas, Nevada, and Utah. It also is endemic to many arid regions in Central and South America. Immune response to *Coccidioides* species declines as CD4 counts decrease, and risk of developing symptomatic disease in endemic areas is increased when the CD4 count is <250 cells/ μ L. In HIV-infected patients, six syndromes have been described: focal pneumonia, diffuse pneumonia, cutaneous involvement, meningitis, liver or lymph node involvement, and positive serology without localized infection.

Primary Prophylaxis: Indications

- Primary prophylaxis is not beneficial and is not recommended. Patients in endemic areas cannot avoid *Coccidioides* but should be educated to avoid extensive exposure (e.g., through disturbed soil and dust storms). Annual monitoring for seroconversion of HIV-infected patients in endemic areas is reasonable; in patients with CD4 counts of <250 cells/ μ L who develop a new positive IgM or IgG, antifungal therapy is recommended to preempt active disease (fluconazole 400 mg PO QD).

Secondary Prophylaxis

Patients who have completed initial treatment for coccidiomycosis should receive lifelong suppressive therapy.

Discontinuing Prophylaxis

Patients with a history of meningeal disease should be treated with suppressive therapy for life, as they are at high risk of relapse. Patients with a history of diffuse pulmonary disease or nonmeningeal disseminated infection also are at high risk of relapse; consult with experts. Patients with focal coccidioidal pneumonia who have had good clinical response to antifungals can discontinue secondary prophylaxis once they have received 12 months of therapy, and have CD4 counts of >250 cells/ μ L on ART. These patients should undergo close radiologic and serologic monitoring for recurrence.

Prophylaxis During Pregnancy

Women who acquire coccidiomycosis in the second or third trimester of pregnancy are at increased risk of dissemination. Azoles should be avoided during the first trimester of pregnancy because of teratogenicity concerns.

Patient Education

- Discuss adverse effects of the selected medication(s) and how the patient should respond in the event of rashes, diarrhea, and other complications.
- Explain the purpose of each medication, and be sure that patients understand the dosage and frequency of administration.
- Reinforce the need to continue taking the medication indefinitely (potentially for life) to reduce the risk of the OI.
- OIs can occur despite prophylaxis. Instruct patients to contact their health care provider if they become ill.
- Counsel patients who are *Toxoplasma* IgG negative to avoid exposure to *Toxoplasma*. Specifically, they should avoid eating raw or undercooked meat, especially pork, lamb, game, and venison. Patients should wash hands after handling raw meat and after gardening or contact with soil. Encourage patients not to adopt or handle stray cats, and, if they own cats, to wash hands thoroughly after cleaning litter boxes. (See chapter *Preventing Exposure to Opportunistic and Other Infections*.)
- For women of childbearing potential who are taking clarithromycin, emphasize the need for effective contraception to avoid potential teratogenic effects of clarithromycin.
- Educate patients in *Histoplasma*- and *Coccidioides*-endemic areas regarding measures to decrease exposure. (See chapter *Preventing Exposure to Opportunistic and Other Infections*.)

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Latent Tuberculosis Infection

Background

Latent (or inactive) tuberculosis (TB) infection occurs when an individual has dormant *Mycobacterium tuberculosis* organisms and no active disease. It can be diagnosed by a tuberculin skin test (TST) or by a blood test called an interferon-gamma release assay (IGRA); both are described below. HIV-infected persons with latent TB infection (LTBI) have a much higher risk of developing active TB (estimated at 3-16% per year) than the general population (estimated at <10% in a lifetime). Whereas treatment of HIV infection with antiretroviral therapy (ART) reduces the risk of active TB, this risk remains higher than that for HIV-uninfected persons. The risk of an HIV-infected individual with LTBI developing active TB can be reduced 60% with treatment of LTBI. Hence, identifying and treating HIV-infected persons with LTBI is a high priority. Treatment of LTBI not only reduces the risk of disease to the individual but also reduces the risk of further TB transmission within the community. Standard treatment with isoniazid (INH) is effective and safe.

Issues of concern regarding treatment of LTBI among HIV-infected persons include the following:

- Excluding active pulmonary or extrapulmonary TB disease before treatment with INH alone
- Assessing the risk of latent infection with drug-resistant TB
- Avoiding or managing drug interactions if rifamycin-containing regimens are used (rifampin, rifabutin, rifapentine)

S: Subjective

Ask about symptoms of active TB, including fever, cough, and weight loss; see chapter *Mycobacterium tuberculosis*. Patients with symptoms that could represent active TB must be evaluated for active TB and ruled out by appropriate diagnostic methods before initiating treatment (see “Assessment,” below). HIV-infected persons are eligible for LTBI treatment if they have positive LTBI screening results, no symptoms of active TB, and have not been treated previously for active or latent TB (re-treatment of LTBI should be considered if a patient is a close contact to an active TB case).

Persons who have had bacillus Calmette-Guérin (BCG) vaccine can be evaluated by an IGRA (preferably) or by a TST with correct interpretation. Immigrants from many countries

will have had childhood BCG vaccination.

Health care providers should ask about a history of potential exposure to TB. Close contact with an active TB case is an indication for LTBI treatment, after active TB has been excluded, regardless of the screening results on TST or IGRA.

O: Objective

Diagnostic Evaluation

Current U.S. Centers for Disease Control and Prevention (CDC) and U.S. Department of Health and Human Services (HHS) guidelines strongly recommend LTBI testing for all newly diagnosed HIV-infected persons. Repeat testing is recommended for patients whose CD4 lymphocyte count increases

HRSA HAB Performance Measures

Percentage of patients aged 3 months and older with a diagnosis of HIV/AIDS, for whom there was **documentation that a tuberculosis screening test was performed** and results interpreted (for tuberculin skin tests) at least once since the diagnosis of HIV infection

(All-Age measure)

from low numbers to counts of >200 cells/ μ L, and annual testing is suggested for patients whose initial test result is negative and who are considered at high risk of repeated or ongoing exposure to TB (risk factors include incarceration, residence in a congregate setting, active drug use, and residence in or travel to a TB-endemic setting).

CDC and HHS guidelines recommend use of either the TST or one of the three currently available IGRAs (QuantiFERON-TB Gold, QuantiFERON-TB Gold In-Tube [QFT-GIT], or TSPOT-TB). The TST evaluates delayed hypersensitivity to antigens from a number of *Mycobacterium* species (including non-tuberculosis species). The IGRAs are in vitro tests of lymphocyte recognition and response to antigens more specific to *M. tuberculosis*, but they still may cross-react with *M. kansasii*, *M. marinum*, or *M. szulgai*. Because the IGRAs use antigens more specific to *M. tuberculosis*, they generally are thought to have greater specificity and a lower false-positive rate. A positive TST or IGRA result suggests previous contact with *M. tuberculosis*, and it implies latent or active TB infection. Neither TST nor IGRA screening can distinguish between LTBI and active TB infection.

Use of an IGRA is preferred for persons with previous BCG exposure and for patient groups at risk of not returning for TST readings. The TST is preferred for children under 5 years of age. The cost of an IGRA is higher than the cost of a TST, and individual clinics should compare the total costs of both testing approaches, including the costs involved in TST protocols of recalling patients who miss visits, repeating TSTs, and treating persons with previous BCG exposure who may have false-positive TST results. Both IGRAs and TST testing have increased rates of anergic test results in HIV-infected patients with advanced immunosuppression (particularly those with CD4 counts of <100 cells/ μ L).

Tuberculin skin test

The TST is administered as an intradermal injection of 0.1 mL (5 tuberculin units) of purified protein derivative (PPD), which raises a wheal in the skin. This is sometimes referred to as the Mantoux test. Multiple-puncture tests such as tine tests and the use of other strengths of PPD are considered unreliable. Anergy testing with *Candida* and mumps antigens is not routinely recommended because a randomized controlled study of HIV-infected patients in the United States did not show an advantage to treating anergic, tuberculin-negative persons.

PPD tests are not designed for reading by the patient; a trained health care worker must measure the area of induration (not erythema) 48-72 hours after the test is administered. Induration of 5 mm or more is considered a positive result for HIV-infected persons, other immunosuppressed persons, anyone with recent TB exposure, and anyone with fibrosis on chest X-ray that is consistent with previous TB. For HIV-uninfected health care workers, 10 mm of induration is a positive result; in various other populations, either 10 mm or 15 mm of induration may be considered positive. Care providers at many large HIV clinics find it challenging to ensure that their patients return for the PPD reading. One randomized study found that offering incentives (e.g., a fast-food coupon) plus counseling was more effective than counseling alone in obtaining return visits for PPD readings.

Interferon-gamma release assay

IGRA tests performed on peripheral blood samples are available in the United States from two manufacturers. Although the tests are expensive, results are obtained without the patient having to make a return visit to the clinic, and false-positive readings following BCG vaccination do not occur. In addition, IGRAs do not appear to be boosted by prior TST testing and two-step testing is not required. Three test results

are possible with IGRA testing: positive, negative, and indeterminate. Unlike the TST, interpretation of IGRA test results does not vary by the risk category of the person tested. An indeterminate test indicates either a high background IFN-gamma level or failure of the mitogen to respond, and should be interpreted as “no test result” (not as “partially positive”). Repeating the IGRA once may yield interpretable test results. However, if the subsequent IGRA result is indeterminate, no further testing is recommended until there is a change in the patient’s immune status, such as reconstitution with ART.

Limited data suggest that the QFT-GIT is the most specific test (lowest rate of false-positive results) and the T-SPOT is the most sensitive test (with the lowest rate of false-negative results). However, few studies have compared the IGRA assays, and there is no reliable “gold standard” for sensitivity or specificity for latent TB infection. Although these tests do not detect previous BCG exposure, they will yield positive results in all three TB-causing species of the *M. tuberculosis* complex – *M. tuberculosis*, *M. bovis*, and *M. africanum* – and may yield positive results in persons with exposure to certain mycobacteria other than *M. tuberculosis* (*M. kansasii*, *M. marinum*, and *M. szulgai*).

There are accumulating data to support the use of IGRA testing in HIV infection. Data suggest that IGRAs are more specific than the TST and correlate more closely with risk factors for TB infection. As with TST, false-negative and indeterminate test results are more likely with advanced immunosuppression. One case series suggests that a significant number of QTF tests may be falsely positive on initial testing but negative on retesting, particularly in patients who were not born in TB-endemic settings. Accordingly, for patients with a positive IGRA result but no risk factors for TB other than HIV infection, it may be reasonable to repeat the IGRA and confirm positivity before treatment.

A: Assessment

After screening for symptoms (see “Subjective”), a chest X-ray should be obtained for all HIV-infected persons with positive TST or IGRA test results. Asymptomatic patients with negative chest X-ray results should be offered treatment for LTBI. (As above, it may be reasonable to repeat the IGRA for HIV-infected patients in non-TB-endemic settings who have no other risk factors for TB prior to LTBI treatment.) Persons with symptoms consistent with pulmonary or extrapulmonary TB, and those with abnormal chest radiography, require further assessment before LTBI treatment. This assessment may include sending two to three separate sputum specimens for acid-fast bacilli (AFB) stain, nucleic acid amplification testing if available, and culture, or obtaining other specimens depending on the suspected site of extrapulmonary TB. If suspicion of TB is low, patients with negative sputum smears (or other biopsy or tissue samples) can begin LTBI treatment. If suspicion of active disease is high, treatment for active disease should be started while the culture results are pending (see chapter *Mycobacterium tuberculosis*). HIV-infected persons with significant exposure (close contact) to someone with infectious TB should receive a full course of TB prophylaxis regardless of TST or IGRA results. Health departments can assist clinicians in assessing the degree of exposure for an HIV-infected patient and in determining whether there is a need for a full course of treatment.

An HIV-infected person with fibrosis on a chest X-ray that is consistent with previous TB and with no history of TB treatment (or a history of inadequate treatment) should be evaluated for active TB regardless of TST or IGRA results. If found not to have active TB, the patient should be treated for LTBI. If the patient is strongly suspected to have active TB, standard treatment for active TB should be given while culture analysis is under way. If

cultures are negative, patients may be switched to LTBI treatment. Highly suspect but culture-negative patients may be given a 4-month total course of treatment for active TB. (See chapter *Mycobacterium tuberculosis*.)

P: Plan

As with any treatment of TB, adherence to the regimen is required for success. Treatment regimens for LTBI in the United States and other low-prevalence TB countries are presented in Table 1. Treatment should be offered to all HIV-infected persons with evidence of LTBI or close contact with an active TB case, regardless of age.

In some highly TB-endemic settings outside the United States, LTBI treatment given to TST-negative patients or patients of unknown TB status has led to reduction of active TB, although TST- or IGRA-positive patients appear to benefit most from LTBI treatment.

INH is preferred for treatment of LTBI because of extensive data supporting its efficacy and

because it has no significant interactions with ARV medications. Treatment with INH for 9 months is recommended. Rifampin-based LTBI treatment is an alternative and is given for 4 months. However, rifampin has substantial drug interactions with a number of ARVs (see “Potential ARV Interactions,” below). Rifabutin is an alternative for patients on PI-based regimens, although there are limited data for use in LTBI. Rifapentine, in combination with INH, has been approved as part of a 12-week treatment course for LTBI; however, it is not recommended for ART-treated patients outside clinical trials because of possible interactions with ARV medications. Rifampin + pyrazinamide is not recommended for LTBI treatment owing to unacceptable rates of hepatotoxicity.

For treatment of LTBI in persons exposed to drug-resistant TB, there are limited data on efficacy of various regimens in preventing progression to disease; consult with experts.

ART is indicated for all persons with LTBI.

Table 1. Treatment Regimens for Latent Tuberculosis

Drug	Dosage (taken orally)	Frequency	Duration (minimum number of doses for completion)
Preferred therapies			
INH*	Adults: 300 mg Children: 5 mg/kg	Daily	9 months or 270 doses within 12 months
INH*	Adults: 900 mg Children: 10-20 mg/kg	Twice weekly (DOT)**	9 months or 76 supervised doses within 12 months
Alternative therapies			
Rifampin [#]	Adults: 600 mg Children: 10-20 mg/kg	Daily	4 months or 120 doses in 6 months; if used in children, 6 months is recommended
Rifabutin [#]	Dose according to ARV medications	Daily	4 months or 120 doses in 6 months
Exposure to Multidrug-Resistant TB			
Treatment options depend on sensitivity of the organism.	Seek expert advice from public health authorities and those experienced in treatment of multidrug-resistant TB. Treatment may be postponed until sensitivity test results are available or may be based on resistance pattern of index case, if known.		

* 25 mg of pyridoxine (vitamin B6) should be given with each INH dose to reduce the risk of INH-induced peripheral neuropathy.

** DOT = directly observed treatment

[#] Rifampin and rifabutin have significant interactions with a number of ARV and other medications. See text and “Potential ARV Interactions,” below, about contraindicated combinations and dosage adjustments.

Length of LTBI Treatment

LTBI treatment is recommended for 9 months with INH (4 months with rifampin/rifabutin) in low-prevalence TB settings such as the United States. Accumulating data suggest that 36 months or indefinite LTBI treatment may be of benefit in some highly TB-endemic settings where TB reinfection may be common.

Monitoring on therapy

INH may cause liver toxicity and it should be used cautiously in patients with active alcohol consumption, liver disease, or chronic hepatitis B or C infection. INH is contraindicated for use in patients with acute hepatitis or decompensated liver disease. Baseline liver function tests are recommended for all HIV-infected persons prior to starting LTBI treatment. Monthly assessment to screen for signs and symptoms of hepatotoxicity (e.g., abdominal pain, jaundice, nausea, vomiting, and fatigue) and neuropathy is recommended. Patients with abnormal hepatic enzymes at baseline or liver disease such as viral hepatitis should receive regular checks of transaminases. If patients develop abnormalities in liver transaminases while taking INH (ALT or AST >3 times the upper limit of normal [ULN] with symptoms, or >5 times above the ULN in the absence of symptoms), the INH should be withheld. Obtain expert consultation before treating patients with abnormal liver function or advanced liver disease. All patients should receive pyridoxine (vitamin B6) 25 mg QD during INH treatment to reduce the risk of peripheral neuropathy.

Rifampin and rifabutin may cause liver and bone marrow toxicity. Before use, obtain baseline liver and renal function tests and a complete blood count. Given the potential for interaction with ARV and other drugs, a careful review of current medications should be done to assess for possible drug interactions. Follow-up is the same as for INH use.

Potential ARV Interactions

Rifampin and rifabutin have important interactions with certain antiretroviral drugs, and dosage adjustments or treatment modifications may be required. Rifampin reduces the blood levels of nonnucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), integrase inhibitors, and the CCR5 antagonist maraviroc; it also may decrease elvitegravir/cobicistat levels. Rifampin can be used by persons taking efavirenz or the integrase inhibitors raltegravir or dolutegravir, though dosage adjustments may be required. Coadministration of rifampin and maraviroc is not recommended, but may be possible with appropriate dosage adjustment of maraviroc; consult with an expert. Rifampin should not be used with nevirapine, etravirine, or rilpivirine, or with PIs or elvitegravir/cobicistat. (In some cases, the adverse pharmacokinetic effect of rifampin on PIs may be overcome with large doses of ritonavir, but consultation with a specialist should be obtained before this approach is undertaken; rifampin should not be used in combination with ritonavir-boosted saquinavir because of high rates of hepatic toxicity.)

No data are available on the use of rifabutin for treatment of LTBI. Nevertheless, rifabutin may be considered in place of rifampin for patients taking antiretroviral combinations that include certain NNRTIs (other than efavirenz) or PIs (other than ritonavir alone), and the integrase inhibitor raltegravir. In these cases, the dosages of both rifabutin and the antiretroviral agent usually require adjustment.

See Table 3 in chapter *Mycobacterium tuberculosis* for details on dosage adjustments.

Other Drug Interactions

Rifampin decreases the blood concentrations of estrogens, anticonvulsants, hypoglycemic agents, and many other drugs. Review all medications a patient is taking before initiating rifampin and make adjustments as necessary. (See Table 12, “Clinically Significant Drug-Drug Interactions Involving the Rifamycins,” at www.cdc.gov/mmwr/preview/mmwrhtml/rr5211a1.htm#tab12.)

Pregnancy

HIV-infected pregnant women with positive LTBI test results and no evidence of active TB should be evaluated for prophylaxis. The potential risks of INH should be evaluated in light of the potential risks of active TB. Consult with an expert. All pregnant women should receive ART for prevention of perinatal HIV transmission; ART also serves to reduce risk of LTBI progression.

Patient Education

- Patients should know that TB bacteria in their bodies cannot be passed to others while the TB is latent. However, because they have HIV infection, the TB bacteria is more likely to make them sick at some point in the future.
- Treatment for LTBI will help kill the TB bacteria and reduce patients' chances of becoming sick with active TB.
- Patients must take all of their medicine, every day, to prevent the TB from spreading and making them sick.
- Advise patients to contact their health care provider immediately if they have adverse effects to the medication, such as rash or itching. Occasionally, INH can cause tingling or numbness in the hands or feet. The pyridoxine (vitamin B6) they are taking should help prevent that, but they should let their provider know if it occurs.

- Advise patients to avoid the consumption of alcohol while taking INH. The medicines for TB are processed by the liver and, when combined with alcohol, they easily can overload the liver. Acetaminophen (Tylenol) also is processed by the liver, so patients should keep their intake to a minimum. (Patients with hepatitis C, liver disease, or chronic alcohol consumption should be cautioned to strictly limit their use of acetaminophen.)
- Tell patients that blood tests may be done regularly to make sure the liver is working well, so it is important to keep follow-up appointments. They should take all their medications, vitamins, and supplements with them to the clinic so that their health care provider can review them and make sure there are no drug interactions.
- If patients experience nausea, vomiting, poor appetite, or abdominal pain; if they notice their urine darkening or becoming “cola” colored; or if they notice their eyes or skin yellowing, they should contact the clinic immediately. These problems may indicate that the liver is being overwhelmed, and it is important to find out before permanent damage is done.
- Rifampin and rifabutin will cause sweat, tears, urine, and plastic contact lenses to turn orange; this is not harmful.
- Rifampin and rifabutin can make birth control pills ineffective. Patients should use a backup method of contraception until treatment is complete. Condoms can help prevent HIV transmission and reduce the likelihood of pregnancy.

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Smoking Cessation

Jeffery Kwong, MS, MPH, ANP

Background

According to the U.S. Centers for Disease Control and Prevention, smoking prevalence among the general adult population in the United States is approximately 20%. Among HIV-infected persons, the prevalence of cigarette smoking appears to be two to three times greater than in the general population, with estimates ranging from 50% to 70%.

The health effects of cigarette smoking are extensive and have been well documented. There are approximately 400,000 smoking-related deaths annually in the United States. HIV-infected smokers appear to be at higher risk of a variety of tobacco-related conditions than HIV-uninfected smokers. These include lung cancer, head and neck cancers, cervical and anal cancers, oral candidiasis, and oral hairy leukoplakia. HIV-infected smokers who smoke are more likely to develop the conditions listed above, as well as bacterial pneumonia, *Pneumocystis jiroveci* pneumonia, other pulmonary conditions, and cardiovascular disease. Additionally, HIV-infected smokers have been shown to have a decreased immunologic and virologic response to antiretroviral therapy.

Thus, for HIV-infected persons, even more so than for HIV-uninfected persons, clinicians should consider smoking cessation a health care priority. Although many care providers may feel that they can do little to affect the smoking behaviors of patients, evidence suggests that brief interventions by physicians are quite effective. Studies indicate that smoking cessation interventions as brief as 3 minutes in duration, when delivered by a provider, have a positive impact on abstinence rates of current smokers. Furthermore, studies have found that more than half of current HIV-infected smokers have expressed interest in, or have thought about, smoking cessation.

Cigarettes are highly addictive; the U.S. Surgeon General has equated the addictive potential of cigarettes to that of heroin and cocaine. This is in part because nicotine stimulates the release of several neurotransmitters in the brain, including dopamine. Over time, chronic exposure to nicotine causes physiologic changes in the brain that contribute to the addictive potential of cigarettes.

Cigarette smoking involves dependence on more than a single chemical compound, however. It is a multidimensional behavior that has both physiologic and psychological components. Therefore, smoking cessation efforts often require a combined approach to be successful.

HRSA HAB Performance Measures

Percentage of patients aged 18 years and older who were **screened for tobacco use** one or more times within 24 months AND who **received cessation counseling intervention** if identified as a tobacco user

(Adult and Adolescent measure)

Behavioral Model for Smoking Cessation

Several behavioral models present a psychological framework for understanding individuals who are attempting to change behaviors. The transtheoretical model of health

behavior change is one of the more frequently cited frameworks for understanding the stages of behavior change of smokers. According to this model, there are five phases of behavior change: precontemplation, contemplation, preparation, action, and maintenance. Using this framework, clinicians can devise

interventions that are most appropriate for the patient's current stage on the continuum.

- **Precontemplation:** The individual does not expect to make any change in behavior within the next 6 months. At this stage, the individual is resistant to hearing or learning about health behavior change.
- **Contemplation:** The individual plans to make a behavior change within the next 6 months. This stage is characterized by ambivalence about smoking.
- **Preparation:** The individual anticipates making a behavior change within the next month. Individuals in this phase have made plans for taking action and intend to make a change.
- **Action:** The individual has made a significant change; in the case of smoking cessation, this means that the individual

has quit completely.

- **Maintenance:** The individual attempts to prevent relapse.

Patients may move back and forth among these stages at various points during the process of smoking cessation.

Cessation interventions in the clinic

As suggested above, brief smoking cessation interventions delivered by clinicians can significantly increase abstinence rates of current smokers. The U.S. Surgeon General has developed guidelines for clinicians to use during clinic visits to help patients who are interested in smoking cessation. These include use of the Five A's model, which provides a brief and structured framework for addressing smoking cessation in clinical settings (see Table 1).

Table 1. The Five A's Model for Treating Tobacco Use and Dependence

Component	Action	Example
ASK every patient about tobacco use	Identify and document tobacco use at every visit .	Incorporate questions about tobacco use when obtaining vital signs or when reviewing a patient's history. • "Do you currently use tobacco?" • "Do you currently smoke cigarettes?"
ADVISE to quit	Using a clear, strong, and personalized message , urge every tobacco user to quit.	• "It is important for you to quit smoking now." • "Quitting is the most important thing you can do to protect your health." • "I can help you quit." Also link smoking with something specific to the patient, such as secondhand exposure to children or partners, his/her own lung, cardiovascular, or cancer risk, or the expense of cigarettes.
ASSESS readiness to make a quit attempt	Determine whether the tobacco user is willing and ready to make a quit attempt within 30 days.	• "Are you willing to give quitting cigarettes a try?"
ASSIST in the quit attempt	For the patient willing to quit, assist in developing a quit plan . Provide practical counseling, support, and supplementary materials.	• Have patient set a quit date and enlist the support of his/her family and friends. • Offer pharmacotherapy, as appropriate, including nicotine replacement. • Provide counseling that includes problem solving and skills building.

Component	Action	Example
ARRANGE for follow-up	Arrange for follow-up contacts beginning within the first week after the quit date.	• Contact patient via telephone or in person soon after the quit date. This can be done by the primary clinician or other trained staff members. • During the follow-up encounter, assess and identify any problems, review medication use and side effects, provide reminders about additional resources. • Congratulate patients on their successes. • Help those with relapses assess problems with and barriers to quitting, and offer additional or different assistance. • For patients who report a relapse, help them identify the circumstances that led the relapse and assist them with recommitting to smoking abstinence.

Adapted from Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service; May 2008. Available at www.ncbi.nlm.nih.gov/books/NBK63952. Accessed December 1, 2013.

For patients who are not ready to quit, techniques such motivational interviewing (MI) can be used in conjunction with the stages-of-change model to explore the smokers' beliefs, feelings, and barriers to successful cessation efforts. Components of MI include: a) expressing empathy; b) developing discrepancy; c) rolling with resistance; and d) supporting self-efficacy. Effective use of MI involves specialized training. Partnering with clinic staff or outside agencies that are familiar with MI techniques can help improve behavior change outcomes, such as smoking cessation. (For further information, see "References," below.)

Pharmacologic interventions

In addition to counseling, the use of pharmacologic interventions such as nicotine replacement therapy and other adjuvant therapies should be considered. These therapies were developed for the general population, but current clinical guidelines suggest that they should be efficacious for HIV-infected smokers.

Clinicians should be aware of potential medication adverse effects (see Table 2).

S: Subjective

- Ask all patients about their smoking status at every visit. This can be easily incorporated as part the initial intake when vital signs are obtained.
- Document smoking history, including the number of cigarettes smoked per day.
- If the patient is not ready to quit, use MI techniques to identify beliefs and barriers and to create ambivalence about smoking.
- For the smoker interested in quitting:
 - Help identify triggers to smoking, and develop a quit plan.
 - Assess for potential complications of or considerations related to pharmacologic smoking cessation treatments such as history of seizure disorders, sleep disturbances, mood disorders, and pregnancy.
- For patients who recently quit, congratulate them on their accomplishments and reinforce the benefits of continued cessation.
- For patients who recently relapsed, help them identify what led to the relapse and how to avoid relapses in the future. Assist them in getting back on track with a cessation program.

O: Objective

During the physical examination, assess for evidence of smoking-related illnesses and the comorbid conditions that may be affected by smoking. At a minimum, measure blood pressure and oxygen saturation and examine for oral lesions, abnormal breath sounds, and decreased peripheral perfusion.

A/P: Assessment and Plan

Determine the smoker's readiness to change (see behavioral model for smoking cessation, above). For those smokers in the preparation or action stage, assist with implementing a quit plan. For those who are in the relapse stage, reinforce self-efficacy and encourage them to recommit to cessation. For those in the maintenance stage, congratulate them and reinforce the benefits of smoking cessation.

For patients willing to quit, offer resources and information that will help them to be successful in their quit attempt. Evidence suggests that the combination of counseling and medication is more effective than either intervention alone. Therefore, every effort should be made to combine counseling sessions with pharmacotherapy for patients who are motivated and ready to quit smoking.

Components of effective counseling include problem solving, skills training, and social support. Problem solving and skills training should focus on how to deal with triggers or urges that may lead to relapse. Examples

include recognition of situations or events that may prompt a person to smoke (e.g., drinking alcohol, being around other cigarette smokers, situational stress) and means of reducing or coping with these situations. Social support interventions include providing reassurance that the patient has the ability to succeed with smoking cessation, communicating caring and concern, and encouraging the patient to talk about the quit process.

Offer medications, if there are no contraindications to pharmacologic interventions (see Table 2). All currently available over-the-counter and prescription medications have been shown to be effective. However, studies have shown that combination therapy may be more efficacious than monotherapy. The current tobacco cessation guidelines recommend the following combinations, all of which include nicotine preparations: long-term nicotine patch (>14 weeks) with ad lib use of nicotine gum or spray, nicotine patch with nicotine inhaler, and nicotine patch with sustained-release (SR) bupropion.

Both bupropion SR and varenicline may cause sleep disturbance, and varenicline may cause exacerbation of neuropsychiatric symptoms. For HIV-infected patients who take efavirenz as part of their antiretroviral therapy, concomitant use of either bupropion SR or varenicline may increase the possibility of these side effects. Additional research in this area is needed.

Table 2. Pharmacologic Options for Smoking Cessation

Drug Recommended	Dosing	Common Side Effects	Comments
Nicotine Formulations*			
Nicotine Patch (available OTC) <i>Dosage varies by brand:</i> Nicoderm or Habitrol: • 21 mg/24 hours • 14 mg/24 hours • 7 mg/24 hours Nicotrol: • 15 mg/24 hours • 10 mg/24 hours • 5 mg/24 hours	Dosing recommendations vary based on the number of cigarettes smoked. Individualize treatment. Sample treatment recommendation for smokers who smoke ≥ 10 cigarettes per day: • High-dose patch for 4-6 weeks, then • Medium-dose patch for 2 weeks, then • Low-dose patch for 2 weeks For smokers who smoke < 10 cigarettes per day: • Medium-dose patch for 6-8 weeks, then • Low-dose patch for 2 weeks	Local skin reaction, insomnia or vivid dreams	• Apply upon awakening. • Place patch on a relatively hairless location, rotating sites to avoid irritation. • If experiencing sleep disturbance, remove patch prior to bedtime or use the 16-hour patch.
Nicotine Lozenge (available OTC) • 2 mg and 4 mg	• For patients who smoke their first cigarette > 30 minutes after waking, start with 2 mg dose. For patients who smoke their first cigarette within the first 30 minutes after waking, start with 4 mg. • Most patients should use 1 lozenge Q1-2H during the first 6 weeks. • Allow lozenges to dissolve, do not chew or swallow. Most individuals use 9 lozenges per day; maximum is 20 per day. • Lozenges should be used for up to 12 weeks, decreasing dosing from 1 lozenge Q1-2H for the first 6 weeks, to 1 lozenge Q2-4H during weeks 7-9, and 1 lozenge Q4-8H during weeks 9-12.	Nausea, hiccups, heartburn, headache, cough	• Do not eat or drink anything except water for 15 minutes before using a lozenge.

Drug	Recommended Dosing	Common Side Effects	Comments
Nicotine Formulations*			
Nicotine Inhaler (prescription only) 4 mg per inhalation 10 mg cartridge	Recommended dosage: 6-16 cartridges per day. Duration of therapy: up to 6 months, taper dosage in last 3 months.	Local irritation in the mouth and throat, cough, rhinitis; may cause bronchospasm (<1%)	Use caution in persons with severe reactive airway disease.
Nicotine Nasal Spray (prescription only) 0.5 mg per spray	- Patient should use 1-2 sprays each nostril per hour (total 1-2 mg per hour), increasing as needed for symptom relief. - Minimum recommended treatment is 16 sprays (8 mg) per day, with a maximum limit of 80 sprays per day (10 sprays per hour). - Recommended duration of therapy: 3-6 months. - Do not sniff, swallow, or inhale through the nose while administering doses. Tilt head slightly back when dosing.	Nasal irritation, transient changes in sense of smell and taste; may cause bronchospasm (<1%)	- Use caution in persons with severe reactive airway disease. - Nicotine nasal spray has highest dependence potential of the nicotine replacement therapies.
Non-Nicotine Medications, First Line			
Bupropion SR 150 mg	Begin 1-2 weeks before quit date. - Start at 150 mg daily for 3 days, then increase to 150 mg BID for 7-12 weeks. - May consider longer-term therapy.	Insomnia, dry mouth	- May lower seizure threshold in certain patients. - Levels increased in patients on P450 3A4 inhibitors. - Use with caution in patients with history of seizures or eating disorders, and those who have used a monoamine oxidase (MAO) inhibitor in the past 14 days.

Drug	Recommended Dosing	Common Side Effects	Comments
Varenicline 0.5 mg and 1 mg	Begin 1 week before quit date. - Start with 0.5 mg daily for 3 days, increase to 0.5 mg BID for 4 days, then 1 mg BID for duration of therapy. - Typical duration: 12 weeks. - Varenicline is approved for maintenance therapy for up to 6 months.	Nausea; flatulence; headache; sleep disturbance; abnormal, vivid, or strange dreams; depression; agitation; suicidal ideation; and suicide FDA Black Box warning regarding neuropsychiatric adverse effects	- Use with caution in patients with history of psychiatric illness. Monitor closely for mood and behavior changes. - Dosage reduction recommended for patients who have creatinine clearance (CrCl) of <30 mL/min or are on dialysis. - To reduce nausea, should be taken with food. To reduce insomnia, second pill can be taken at dinner rather than at bedtime. - Dosage may be reduced for patients with adverse effects.
Non-Nicotine Medications, Second Line			
Clonidine 0.1 mg tablet 0.1 mg transdermal patch	0.1 mg tablet PO BID OR 0.1 mg transdermal patch per day. Can increase by 0.1 mg/day per week if needed. - Duration of treatment: 3-10 weeks. - Do not discontinue therapy abruptly.	Dry mouth, drowsiness, dizziness, sedation, and constipation Rebound hypertension if discontinued abruptly	- Monitor blood pressure when using this medication. If discontinuing, taper medication to avoid rebound hypertension. - If using patch, place on relatively hairless location between the neck and waist. - Avoid in elderly patients
Nortriptyline	- Begin 10-28 days before quit date. - Start at 25 mg QD and increase to target dosage of 75-100 mg QD if tolerated. - Treatment duration: approximately 12 weeks; some may consider extending treatment up to 6 months.	Sedation, dry mouth, blurred vision, urinary retention, lightheadedness, tremor, cardiac conduction abnormalities	- Use with caution in patients with cardiac conduction abnormalities disease. - Do not coadminister with MAO inhibitors. - Overdose may produce life-threatening cardiovascular toxicity, as well as seizures and coma. - Avoid in elderly patients

* Use with caution for patients with cardiovascular disease (particularly those within 2 weeks of myocardial infarction), those with serious arrhythmias, and those with unstable angina pectoris (however, note that, for many patients, continued smoking may be more dangerous than nicotine replacement).

The adverse effects of cigarette smoking during pregnancy are well established, and smoking generally is more harmful than the use of nicotine replacements. Smoking cessation aids may help motivated patients quit during pregnancy.

All patients who are actively quitting should have close follow-up, and they should be offered support. Research has shown that ongoing support during the quit phase results in higher abstinence rates.

Follow-up can include telephone calls or in-person evaluation.

For patients who recently quit or relapsed, continue to provide support and encouragement. Assist individuals who relapsed with the opportunity to continue with cessation plans.

Refer patients to smoking cessation groups, classes, and other resources.

Patient Education

- For patients who have decided on pharmacologic interventions and for whom there are no contraindications, provide education regarding medication side effects, anticipated withdrawal symptoms, and strategies for managing withdrawal.
- Review and reinforce strategies in the event of relapse.
- For those who are not ready to quit, inform them of the consequences of continued smoking and remind them about the available resources.

Suggested Resources:

- National Telephone Counseling and Quit Line (800-QUIT-NOW) (800-784-8669)
- American Cancer Society (www.cancer.org)
- American Lung Association (maintains profiles of state tobacco control activities) (www.lungusa.org)
- National Cancer Institute (www.cancer.gov)
- Office on Smoking and Health at the Centers for Disease Control and Prevention (www.cdc.gov/tobacco)

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Nutrition

Background

Maintaining good nutritional status is important to support overall health and immune system function for people with HIV/AIDS. Many HIV-related conditions affect and are affected by the body's nutritional status. These include conditions related to HIV itself (e.g., opportunistic infections and other illnesses), comorbid conditions, and adverse effects of therapies.

Inadequate nutrition in people with HIV infection may result from many factors, including conditions such as nausea, vomiting, and anorexia (see chapter *Nausea and Vomiting*) that may prevent adequate intake of nutrients and medications; diarrheal infections (see chapter *Diarrhea*) that prevent absorption of nutrients and medications; poor oral health conditions that interfere with chewing or tasting food (see chapter *Oral Health*); systemic illnesses (including HIV itself) that create a catabolic state; and psychological conditions (such as depression) that impair patients' ability to nourish themselves. In addition, financial constraints may limit patients' access to nutritious food.

Evaluation and enhancement of patients' nutritional status may help correct or compensate for deficiencies (e.g., in the case of weight loss or nutrient deficits), may be a key treatment modality for certain conditions (e.g., dyslipidemia, hyperglycemia), and may help to maintain good health and immune function. This chapter focuses on the evaluation of patients with nutritional deficiencies, particularly weight loss, and on simple strategies for maintaining good nutrition in individuals with barriers to maintaining adequate weight.

It should be noted that obesity and overweight conditions are increasingly common in HIV-infected individuals; many of the principles described here also may be applied to the evaluation of overweight patients. Recommendations for weight reduction for HIV-infected patients are the same as for the general population and will not be discussed in detail; for overweight patients with lipohypertrophy, diabetes, dyslipidemia, or coronary artery disease, see the respective chapters on these conditions.

Ideally, HIV-infected individuals will receive the services of HIV-experienced nutrition specialists, who may contribute to the patient care team in the following ways:

- Conducting routine screening to identify and treat nutritional problems
- Preparing a tailored nutritional plan to optimize patients' nutritional status, immune status, and overall well-being
- Screening and developing interventions for growth problems in children
- Developing strategies to prevent loss of weight and lean body mass
- Adapting dietary recommendations to help reduce the risk of comorbid conditions such as diabetes and heart disease, or treating these complications
- Educating patients about how to modify their dietary habits to maximize the effectiveness of medical and pharmacologic treatments
- Tailoring nutritional recommendations to fit patients' lifestyles and financial resources
- Counseling patients to promote nutrition self-care using available resources

- Providing nutritional support to patients may help to do the following:
 - Address common problems associated with HIV disease and its treatment (e.g., weight loss, wasting, fatigue, loss of appetite, adverse changes in taste, dental problems, gastrointestinal complaints)
 - Treat chronic comorbid conditions (e.g., cardiovascular disease, hypertension, diabetes, cirrhosis)
 - Improve quality of life
 - Enhance immune responses, slow disease progression, and prolong life

S: Subjective

History

Identify nutrition risk factors at the start of care through interview, questionnaire, or both. Update the history at least annually.

The history should elicit signs and symptoms related to nutrition issues, indications regarding dietary habits, and symptoms that suggest nutritional deficiencies.

Nutrition-Related Questions		
Factor	Areas to Explore	
Signs, Symptoms, and Comorbid Conditions	• Poor or sporadic appetite • Early satiety • Weight gain or loss • Trouble chewing or swallowing • Dental problems including poor dental hygiene • Gastrointestinal complaints, including nausea, diarrhea, constipation, heartburn, gas	• Changes in body contours with fat gain in abdomen, back of neck, and breasts (lipodystrophy) or fat loss in extremities and face (lipoatrophy) • Depression, stress • Fatigue • Chronic pain • Other diseases affecting diet and nutrition • Medications, including over-the-counter and herbal products
Medication-Related Factors	• Medication side effects • Difficulty coordinating meals with medicines	• Use of nutritional supplements
Social and Behavioral Factors	• Frequent eating out • Smoking • Alcohol or substance abuse • Erratic meal patterns • Unbalanced diet (e.g., high intake of low-nutrient foods; deficiency in key nutrients)	• Resources to ensure secure, continued food access • Availability of food storage and preparation facilities • Housing (stable, homeless, marginally housed, or in transition) • Nutrition literacy

To develop a specific dietary history, ask about the following:

Dietary History	
Usual Dietary Intake	Factors That May Affect or Limit Intake
• Frequency of intake of foods providing key nutrients (e.g., dairy products, fortified or whole grains, fruits and vegetables, eggs, beans, fluids, meat) as well as those that perhaps should be limited (fast-food items, highly processed or salted products) • Usual meal patterns (number of times per day, snacks) and whether meals are prepared and eaten at home or eaten at restaurants or fast-food establishments • Specific information about nutritional supplements (e.g., vitamins, minerals, herbs, protein), including contents, amounts, formulation (pills, powders, drinks), cost, and overlap among products	• Amount of money available for food, or participation in food assistance programs (e.g., food stamps, food pantries) • Appetite, general well-being (e.g., fatigue, pain, depression) • Food allergies, intolerances • Problems with dentition, swallowing, heartburn, diarrhea, constipation • Coordination of foods and supplements with medications (HIV or other)

Elicit symptoms that may be related to nutritional deficiencies.

Symptoms with Possible Relationship to Nutritional Deficiencies	
• General symptoms (e.g., fatigue, decreased cognitive function, headache) • Behavioral changes (e.g., irritability, apathy, decreased responsiveness, anxiety, attention deficit) • Body habitus changes (e.g., loss or gain of fat)	• Gastrointestinal symptoms (e.g., diarrhea, constipation, bloating) • Changes in skin, nails, hair (e.g., dryness, breaking, thinning) • Muscle loss • Neurologic symptoms (e.g., weakness, sensory changes, gait abnormalities)

O: Objective

Physical Examination

Perform a careful physical examination, if possible with anthropometric and body composition testing as described below (Table 1). Compare current findings with past assessments and review at least every 6 months.

The physical examination should include the following:

- Vital signs, with orthostatic vital signs if dehydration is suspected
- Weight (compare with previous values) and body mass index (BMI)
- General appearance and gross nutritional status (e.g., obesity, cachexia, wasting)
- Body habitus: loss of subcutaneous fat in face, buttocks, arms and legs and/or

increased fat in abdomen, breasts, neck, and upper back (“buffalo hump”)

- Muscle mass
- Mouth: breakdown in oral mucosa, cheilosis, angular stomatitis, glossitis, papillar atrophy
- Abdomen: hepatomegaly (may be caused by fatty infiltration)
- Skin: dryness, peeling, breakdown, pallor, hypopigmentation or hyperpigmentation
- Nails: pale nail beds, fissures or ridges
- Neurologic system, including strength, sensation, coordination, gait, deep tendon reflexes

Anthropometric and body composition tests are usually performed by registered dietitians. They can provide important information about patients’ nutritional status.

Table 1. Anthropometric Measurements for Adults and Children

	Height	Weight	Assessment for Changes over Time
Adults	Measure at baseline (self-report is not accurate).	- Measure at least quarterly and consider intervention when small changes are observed. Do not wait until major amounts of weight have been lost or gained. - Record sequentially at the front of the patient's chart and monitor for trends.	Use healthy, premorbid weight to assess change, not the first clinic weight or the ideal weight. (Use the patient's weight at a time when the patient is healthy, feels well, and can easily maintain that weight.)*
Children	Measure at least quarterly using length board (0-2 years) or wall-mounted stadiometer (≥2 years).	- Measure at least quarterly and consider intervention when small changes are observed. Do not wait until the patient has dropped significantly on the growth chart. - Calculate age and plot the measurements on growth charts specific for age, sex, and country.#	Assessment of optimal growth is based on the observed pattern over time. General goals include a weight relatively "matched" for length or height (about the same percentile) and relative stability of percentile tracking over time.* #

* BMI (body mass index) is useful as an evaluative index. See chapter *Initial Physical Examination*, and the U.S. Centers for Disease Control and Prevention (CDC) online calculator at www.cdc.gov/healthyweight/assessing/bmi. Accessed December 1, 2013.

Growth charts for children in the United States are available online from the CDC at www.cdc.gov/growthcharts. A variety of growth charts are available for children from specific ethnic groups (e.g., Chinese, Vietnamese, Thai), children with selected conditions affecting growth (e.g., Down syndrome), or those who are born prematurely. Percentiles for both height and weight should be recorded sequentially.

Body Composition Testing

Body composition commonly is tested by bioelectrical impedance analysis (BIA) (Table 2) or skinfold thickness and circumference (Table 3).

Table 2. Bioelectrical Impedance Analysis

BIA testing is the standard of care for adults but has not been well validated for children:

- BIA is useful for assessing disease progression or health maintenance, documenting response to treatment, and justifying the cost of nutritional supplements and AIDS-wasting medications.
- The test is simple, noninvasive, and quick (<5 minutes). However, staff training and specialized software are required to interpret the results.
- Perform BIA at baseline, if possible. Update every 6-12 months or more frequently if the patient is ill, has a decline in immune status, or has a weight change of 5-10%.
- The BIA test reports the following:
 - Body cell mass (BCM):** the target component, reflecting cells in muscles, organs, and the circulation; losses may indicate AIDS wasting. BCM is recorded in pounds. Monitor for trends.
 - Fat:** an index of energy stores; recorded in pounds and percentage.
 - Phase angle:** a measure of cellular integrity, an independent indicator of morbidity and mortality in HIV-infected patients.

Table 3. Skinfold Thickness and Circumference Measures

Skinfold thickness and circumference measures can be used for adults and children in resource-limited settings, and for situations in which bioelectrical impedance analysis is not available. Circumference measures also can be used to monitor changes over time associated with lipodystrophy in adults. • Skinfold thickness is measured with calipers. • Circumference measures are taken at specific anatomical landmarks with nonstretchable tape. • Techniques and protocols for taking anthropometric measurements can be found at the CDC website (www.cdc.gov/nchs/data/nhanes/nhanes_03_04/BM.pdf).

Laboratory Testing

Perform basic laboratory (blood) tests, including the following:

- Hemoglobin and/or hematocrit
- Total protein, albumin
- Fasting blood glucose
- Fasting lipids (triglycerides, total cholesterol, low-density lipoprotein cholesterol [LDL], high-density lipoprotein cholesterol [HDL])
- CD4 cell count and HIV viral load, if no recent values are available
- Specific vitamin and nutrient tests as indicated by symptoms (e.g., iron studies in case of anemia, vitamin B12 in case of peripheral neuropathy)
- Others tests, such as testosterone and thyroid hormone levels as appropriate, to rule out other causes of symptoms

A: Assessment

Assess subjective information and objective findings to evaluate nutritional status.

Identify Nutrition Concerns

Several factors may influence nutrition, including the following:

- Barriers to good nutrition (e.g., lack of knowledge or motivation for self-care, poor appetite, lack of money for food, lack of facilities for food storage and preparation)
- Lifestyle factors (e.g., smoking, substance abuse, frequent eating out, erratic eating patterns, hectic schedule, high stress)

- Physical problems affecting food and nutrient intake (e.g., poor appetite, nausea, fatigue, pain, weakness, mouth or throat pain, acid reflux, missing or decayed teeth, poorly fitting dentures, poor eyesight, constipation)
- Nutrient losses (e.g., owing to diarrhea, vomiting)
- Potential confounding factors (e.g., use of multiple overlapping or questionable supplements, eating disorders)

Evaluate Dietary Intake

Assess the following diet-related issues:

- Expected excesses or deficiencies from dietary history or interview
- Rating of food security, including access to cooking and refrigeration
- Food intolerances, aversions, or allergies likely to affect adequacy of intake
- Special needs related to other conditions (e.g., documented cardiovascular disease, diabetes, hypertension)

Evaluate Weight, Body Composition, and Weight Distribution

Assess physical findings of malnutrition and confirm with nutrition history, laboratory tests, and anthropometric evidence. Normal and abnormal findings of anthropometric tests and recommendations for monitoring changes over time are presented in Table 4.

Table 4. Evaluating the Findings of Anthropometric Tests	
Monitoring Trends and Recommendations	
Adults - Chart trends over time relative to previous measurements and the following population norms: BMI (healthy range: 19-25) BIA: BCM (percentage of weight): women 30-35%; men 40-45% Fat (percentage of weight): women 20-30%; men 15-25% Phase angle: women >5; men >6 Skinfold thicknesses and circumferences: Chart changes in absolute measures and percentiles Changes in body contours: Evaluate lipodystrophy (excess accumulation of fat in abdomen, breasts, dorsocervical area) and lipoatrophy (loss of subcutaneous fat in face, extremities, buttocks)	Children Plot measurements on growth charts and track percentiles over time (the consistency of percentiles rather than the absolute percentile is important) Skinfold thicknesses and circumferences: Chart changes in absolute measures and percentiles

Abbreviations: BCM = body cell mass; BIA = bioelectrical impedance analysis; BMI = body mass index

Evaluate Laboratory Findings

- Evidence of malnutrition (e.g., low iron or protein stores)
- Evidence of disease or risk of disease for which dietary treatment is indicated (e.g., high fasting glucose, hypertension, hyperlipidemia)

Develop a Problem List

The following suggests a useful format for a nutrition-related problem list.

Nutrition-Related Problem List

Problem Number	Description of Problem (circle/describe)
	Nutrition barriers: insufficient knowledge, poor appetite, food insecurity, no food preparation or storage facilities, homelessness
	Lifestyle: substance abuse, smoking, erratic eating, frequent fast-food intake, high stress
	Weight or body composition: undesirable weight gain or loss (adult), changes in growth trajectory (children), loss of lean body mass (wasting), gain of excess fat (obesity), lipoatrophy or lipodystrophy
	Physical problems: fatigue, pain, early satiety, poor dentition, clinical signs of malnutrition
	Laboratory findings: low hematocrit or hemoglobin, low protein or albumin, low or high fasting glucose, high total cholesterol, high LDL, high triglycerides, low HDL, low testosterone
	Gastrointestinal: diarrhea, vomiting, reflux, constipation
	Poor diet: poor food choices, bingeing, skipping meals, high sugar intake, high alcohol consumption, high intake of refined foods, low fruit and vegetable intake, insufficient protein, insufficient calcium, food allergies or intolerances that limit intake
	Comorbid conditions: diabetes, hypertension, cardiovascular disease, cancer, gastroesophageal reflux disease (GERD)
	Medications: drug-drug or drug-nutrient interactions or difficulty coordinating medicines with meals
	Supplements: insufficient or excessive intakes, cost of supplements unaffordable, supplements with potential or unknown risks

P: Plan

Develop a nutritional plan and provide practical nutrition education for common problems (see “Resources,” below).

Evaluate and treat concurrent medical problems (e.g., diarrhea, nausea, infections, malignancies, depression, pain). For severe or persistent nutritional problems, or for

specific needs, refer to a nutrition specialist for evaluation and treatment.

Common nutrition-related problems are presented in Table 5, along with simple management suggestions that may help resolve them and help patients maintain adequate nutrition.

Table 5. Practical Interventions for Common Nutrition-Related Problems

Problem	Suggestions
Weight Loss (decrease in both body cell mass and fat)	• Early identification and ongoing monitoring are key. • Identify and treat underlying risk factors. • Try to add calories without adding “bulk”: • Fat (9 calories/gram): butter, margarine, avocado, cream, mayonnaise, salad dressing • Carbohydrate (4 calories/gram): jam, jelly, sugar, icing, gum drops • Protein (4 calories/gram): protein powders, cheese, nut butters, trail mix, powdered breakfast drinks, nonfat dry milk • Eat more frequently. • Maximize good days. • Use canned supplements (e.g., Ensure, Boost). • For wasting or substantial weight loss, consider referral for therapies such as appetite stimulants or human growth hormone.
Diarrhea	• Increase soluble fiber; decrease insoluble fiber. • Replenish beneficial bacteria (e.g., with lactobacilli or other probiotic preparations). • Avoid intestinal irritants and stimulants. • Decrease dietary fat. • Decrease or eliminate lactose. • Increase fluids and provide electrolytes (sodium, potassium). • Treat with pancreatic enzymes.
Early Fullness	• Take small, frequent meals. • Concentrate on solid foods, with liquids between meals. • Eat lower-fat, lower-fiber foods. • Wear loose-fitting clothing. • Sit up while eating. • Eat, walk, and eat again.
Nausea	• Take small, frequent meals. • Try dry snack foods. • Avoid fried foods, very sweet foods, spicy foods, and foods with strong odors. • Try cool, clear beverages, popsicles. • Try ginger-containing foods and drinks. • Keep liquids to a minimum at meals.

Problem	Suggestions
Changes in Taste	• Eat a variety of foods, not only favorite foods. • Try protein sources other than red meat. • Marinate foods, use sauces. • Use more and stronger seasonings. • Try tart foods. • Use sugar or salt to tone down the flavor of foods. • Try a mouth rinse of 1 teaspoon of baking soda in 1 cup of warm water before eating.
Loss of Appetite	• Rely on favorite foods. • Ask family members and friends to prepare meals. • Eat small, frequent meals. • Keep snacks handy for nibbling. • Eat before bedtime. • Eat in a pleasant place, with other people. • Make the most of good days. • Try light exercise to stimulate appetite. • Add extra calories without adding bulk. • Consider appetite stimulants (e.g., megestrol, dronabinol).
Difficulty Chewing or Swallowing or Sore Mouth and Throat	• Choose soft, nutritious foods. • Blend or puree foods (e.g., soup or stew, smoothies). • Add cream sauces, butter, or gravy for lubrication. • Sip liquids with foods. • Use a straw or drink foods from a cup. • Choose bland, low-acid foods. • If hot foods cause pain, serve foods cold or at room temperature. • Avoid alcohol and tobacco. • Soothing lozenges or sprays may help.
Food Insecurity	• Refer to social services for assistance with accessing resources such as food stamps, community meals, or a food pantry program. • Refer to a dietitian for assistance with low-cost food ideas. • Use materials provided by CheapCooking.com (www.cheapcooking.com/index.htm).
Unbalanced Diet and Other Conditions Requiring Dietary Modification	• Refer to a dietitian for counseling and education.

Nutrition Specialists

Whenever possible, nutritional services should be provided by a registered dietitian (RD) who is a qualified HIV care provider. In the United States, holding this status requires a nutrition degree from an accredited college, graduation from an approved internship or master's degree program, and maintenance with 75 continuing-education units every 5 years, including specific and ongoing HIV training. An RD with HIV/AIDS expertise in the United States can be located by going to www.eatright.org, clicking on "Find a Registered Dietitian," entering the patient's zip code or city, and selecting "HIV/AIDS" under areas of specialty. Membership in the Infectious Diseases Nutrition Dietetic Practice Group (idndpg.org) also may indicate HIV experience.

Resources

The following online resources provide information, guidelines, and tools for providers and patients in managing issues related to nutrition and HIV:

- **2000 CDC Growth Charts: United States**
Center for Disease Control and Prevention, National Health and Nutrition Examination Survey. Available at www.cdc.gov/growthcharts.
- **Center for Disease Control and Prevention National Center for Health Statistics**
Available at www.cdc.gov/nchs/products/series.htm.
- **CheapCooking.com**
Website with recipes using low-cost ingredients and tips for frugal meal planning. Available at www.cheapcooking.com.

- **Infectious Diseases Nutrition Dietetic Practice Group**

Affiliate of the American Dietetic Association. Website includes screening tool (Nutrition Screen and Referral Criteria for Adults with HIV/AIDS). Formerly HIV/AIDS Dietetic Nutrition Practice Group. Available at idndpg.org.

- **ChooseMyPlate.gov**

A U.S. Department of Agriculture website with dietary guidelines, tips, resources, and consumer-oriented information. Available at www.choosemyplate.gov.

- **Health Care and HIV: Nutritional Guide for Providers and Clients**

Manual from HRSA. Available at aidsetc.org/aidsetc?page=etres-display&resource=etres-193

- **Nutrition.gov**

Available at www.nutrition.gov

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- Association of Nutrition Services Agencies. *ANSA Nutrition Guidelines and Fact Sheets*. Washington, DC: ANSA; 2006.
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Antiretroviral Therapy

Susa Coffey, MD

Background

Potent combination antiretroviral therapy (ART), typically consisting of three or more antiretroviral (ARV) drugs, has greatly improved the health and survival rates of HIV-infected patients in areas of the world with access to ARVs. More than 20 individual ARVs in six classes are available in the United States, in addition to several fixed-dose combination preparations. These can be combined to construct a number of effective regimens for initial and subsequent therapy. Although ART has its limitations (see below), it saves lives and improves immune system function, reduces the risk of many HIV-related and “non-AIDS” complications, and reduces the risk of HIV transmission. Increasingly, several lines of evidence point to the benefit of ART even for patients with high CD4 counts.

Mortality and morbidity benefits of ART are particularly obvious in patients with relatively advanced immune suppression or with symptoms related to HIV infection. For asymptomatic patients with higher CD4 counts (particularly >500 cells/μL), the question of when to initiate ART remains an area of research and debate. It is clear there is a spectrum of risk for adverse outcomes that increases as the CD4 count declines. In persons with CD4 counts of <200 cells/μL, effective ART dramatically decreases morbidity and mortality. For persons with CD4 counts of 200-350 cells/μL, data from randomized controlled studies as well as cohort studies also demonstrate a reduction in both AIDS and non-AIDS events among those who start ART. For patients with higher pretreatment CD4 levels, randomized and cohort studies also have found decreased rates of complications and death in those who initiated ART with CD4 counts of >350 cells/μL rather than <350 cells/μL, and some (though not all) observational evidence suggests a mortality benefit of ART among persons with CD4 counts of >500 cells/μL. For patients with CD4 counts of >500 cells/μL, the limited data that are currently available (from cohort studies) are inconsistent on the question of whether initiation of ART results in better outcomes. A randomized clinical trial of earlier (>500 cells/μL) versus deferred (<350 cells/μL) treatment is under way, and the results of that study along with those from the cohort studies may help define an optimal threshold at which to initiate ART.

Meanwhile, in recent years, a growing body of evidence has demonstrated ongoing and adverse effects of untreated HIV on many organ systems and aspects of functioning, even in persons with high or relatively high CD4 counts (>350-500 cells/μL). These include the following:

- Cardiovascular disease
- Kidney disease, specifically HIV-associated nephropathy (HIVAN)
- Liver disease, particularly among patients with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV)
- Neurocognitive deficits, including dementia
- Cancers, both AIDS-malignancies and non-AIDS malignancies

HRSA HAB Performance Measures

Percentage of clients, regardless of age, with a diagnosis of HIV who were **prescribed antiretroviral therapy** for the treatment of HIV infection during the measurement year

(Core measure)

Percentage of patients, regardless of age, with a diagnosis of HIV with an **HIV viral load of <200 copies/mL** at last HIV viral load test during the measurement year

(Core measure)

Many of these effects appear to be mediated through persistent immune system activation and ongoing inflammation in various organ systems. ART with virologic suppression appears to reduce immune activation and protect against many of these morbidities, but it may not restore immune system function to normal and may not fully reverse disease processes. The beneficial effects of ART may be attenuated for patients who start ART with lower CD4 cell counts. Additionally, the risk of certain ARV-related adverse events may be greater for those who start ART at lower CD4 levels.

Although ART can confer substantial health benefits, it has significant limitations. ART does not cure HIV infection and it requires that multiple medications be taken for life (i.e., potentially many decades). It may cause a variety of adverse effects (some severe), is expensive, requires close adherence to be effective and to prevent the emergence of resistance, and it sometimes fails (because of the patient's imperfect adherence or other factors). The failure of an ARV regimen when accompanied by drug resistance may mean that subsequent regimens are less likely to succeed, despite the availability of second-line ARV combinations.

In past years, many of the available ARVs presented challenges in the realms of adverse effects, pill quantity, dosing frequency, and durability. Given these limitations of ART, much attention was devoted to estimating the point at which the potential benefits of ART outweighed the potential risks of ART. Today, the newer ARV regimens, specifically those currently recommended by the U.S. Department of Health and Human Services (HHS) for initial therapy, are for most patients, simple, tolerable, and effective. As a result of both the availability of ARV regimens that are less toxic and easier to administer, and the increasing appreciation of the adverse impacts of untreated HIV, the balance between the potential benefit and the potential risk of ART has shifted strongly toward treatment for all willing individuals regardless of CD4 count, unless there are compelling reasons not to treat (see “When to Initiate Therapy: HHS ARV Guidelines,” below; also see the *HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* for a full discussion of these issues).

Recent data also demonstrate that ART very substantially reduces the risk of transmission of HIV between serodiscordant heterosexual partners. The prevention effect of ART in men who have sex with men (MSM) and other risk groups has not yet been established in randomized controlled trials, but other lines of evidence suggest that ART strongly protects against HIV transmission in all risk groups. Thus, an additional benefit of earlier treatment with ART is a reduction in the risk of HIV transmission.

Of course, in deciding when to start ART for the individual patient, practitioners must weigh the expected benefits of ART for that person (e.g., improvements in health, reduction in HIV transmission) against the possible risks of ART (e.g., toxicity, drug resistance, adverse drug interactions). Patients must be willing to start and to continue on treatment, with an understanding that high levels of adherence are needed for treatment success.

Although implementing and monitoring ART is complex, a number of guidelines from expert panels are available to help clinicians select effective regimens for particular patients. HHS keeps a repository of frequently updated recommendations on the use of ARV medications for adults and adolescents, pregnant women, and children. All clinicians who treat HIV-infected patients should be familiar with the most current versions of these treatment guidelines. They are available on the Internet at the AIDSinfo website (www.aidsinfo.nih.gov/guidelines). The HHS *Guidelines* are referenced frequently in this chapter.

HHS Guidelines: When to Start Therapy

The following recommendations have been adapted from the HHS *Guidelines*.

HHS guidelines recommend ART for all HIV-infected individuals, both for their own health and to prevent transmission:

“ART is recommended for all HIV-infected individuals to reduce the risk of disease progression. The strength and evidence for this recommendation vary by pretreatment CD4 cell count:”

• CD4 count <350 cells/μL:	Strongly recommended
• CD4 count 350-500 cells/μL	Strongly recommended
• CD4 count >500 cells/μL	Moderately recommended

“ART also is recommended for HIV-infected individuals for the prevention of transmission of HIV. The strength and evidence for this recommendation vary by transmission risks:”

• Perinatal transmission:	Strongly recommended
• Heterosexual transmission:	Strongly recommended
• Other transmission risk groups:	Strongly recommended

Note that these recommendations assume that resources are available for universal ART provision. In settings with limited resources, persons with lower CD4 counts or coexisting conditions (as below) may be prioritized.

ART also is strongly recommended for persons with certain conditions, regardless of CD4 count. These conditions include the following:

- Pregnancy (see chapters *Reducing Perinatal HIV Transmission* and *Care of HIV-Infected Pregnant Women*)

- History of AIDS-defining illness (including HIV-associated dementia)
- HIVAN (see chapter *Renal Disease*)
- HBV coinfection (see chapter *Hepatitis B Infection*)
- Acute HIV infection (see chapter *Early HIV Infection*)

In some situations, ART may be needed relatively urgently. These include the following:

- Pregnancy
- Acute/recent HIV infection
- AIDS-defining conditions
- Acute opportunistic infections
- HIVAN
- HBV coinfection
- HCV coinfection
- Lower CD4 counts (e.g., <200 cells/μL)
- Rapidly declining CD4 counts (e.g., >100 cells/μL/year)
- Higher viral loads (e.g., >100,000 copies/mL)

S: Subjective

Obtain the patient’s history and review of systems, including the following (see chapter *Initial History*):

- CD4 cell count history, including nadir
- HIV RNA (viral load) history, including pretreatment values if the patient is currently taking ARVs
- History of HIV-related conditions
- Previous and current ARV regimens, including start and stop dates, regimen efficacy, toxicity, resistance
- Current medications, including herbal preparations, supplements, and over-the-counter medications
- Medication allergies, intolerances, or prominent adverse effects

- Comorbid conditions (e.g., HBV, HCV, depression)
- Current and previous substance use, including alcohol and recreational drugs
- Self-assessment of adherence to previous regimens
- Desire to start or continue an ARV regimen
- Commitment to adherence (see chapter *Adherence*)
- Occupation and daily schedule
- Willingness and indicators of ability to adhere to various types of regimens (e.g., QD, BID, with or without food) given current life situation
- For women of childbearing potential: last menstrual period, current method of birth control (if any), current pregnancy status, thoughts on whether or when to have children

O: Objective

Perform the following objective tests:

- Complete physical examination (see chapter *Initial Physical Examination*).
- Current CD4 count and HIV viral load: preferably two or more separate results approximately 1 month apart.
- Drug resistance test, as appropriate; to look for transmitted ARV resistance mutations, a genotype should be performed for all patients before initiating ART; this should be done as early in the course of infection as possible, because mutations may revert to wild-type. Review the results of previous resistance testing or obtain a baseline resistance test, if this was not done earlier; if a test was done in the past, consider retesting before ART is begun (see chapter *Resistance Testing*). Patients on ART whose viral loads are not suppressed also should undergo resistance testing.
- Complete blood count (CBC) and

platelet count, liver function tests (LFTs), renal function tests, fasting lipid panel, fasting glucose, rapid plasma reagin (RPR), tuberculin skin test, hepatitis serologies, *Toxoplasma* IgG, urinalysis, (see chapter *Initial and Interim Laboratory and Other Tests*).

A: Assessment

Make the following basic decisions:

- This is or is not an appropriate time to start ART (e.g., do potential benefits of starting at this time outweigh the risks at this time?). See the HHS *Guidelines* noted above, which thoroughly address the issue, and note that many experts are increasingly concerned about the potential harm of untreated HIV infection, even in individuals with high CD4 cell counts. See chapters *Risk of HIV Progression/Indications for ART* and *CD4 Monitoring and Viral Load Testing*.
- The patient is or is not willing to start ARVs at this time (the choice to accept or decline therapy ultimately lies with the patient). If not, work with the patient on readiness issues, with more urgency if the CD4 count is low or the patient has symptoms, comorbidities, or coexisting conditions that suggest treatment is needed.
- The patient is or is not likely to adhere to an ARV regimen (an adherence counselor, with or without a mental health clinician, may be able to assist with this assessment and should be called upon if available). No patient should be automatically excluded from consideration for ART; the likelihood of adherence must be discussed and determined individually (see chapter *Adherence*).

P: Plan

After educating the patient about the purpose and logistics of the proposed regimen and assessing the patient's potential for adherence, ART can be initiated, changed, or postponed accordingly.

The primary goals of therapy are to reduce HIV-related morbidity and mortality and to prevent HIV transmission; this includes improving the quality of life, maximally and durably suppressing HIV virus, and improving immune function and reducing HIV-associated inflammation.

Considerations Before Initiating ART

No “average patient” exists. Some patients will do better during treatment and some will do worse than clinical studies would predict. Health care providers must work with each patient to develop a treatment strategy that is both clinically sound and appropriate for that individual’s needs, priorities, and circumstances of daily life. Despite the fact that the regimens currently recommended by the HHS *Guidelines* are more compact and have fewer adverse effects than earlier regimens, not all patients will be able to take or tolerate all drugs, and the patient’s understanding, readiness to commit to the regimen, and history of adherence to previous regimens must be considered when choosing ARV combinations. Major considerations are as follows:

- Degree of immunodeficiency and risk of disease progression as reflected by the CD4 count and HIV RNA level. ART is more urgent for patients with lower or rapidly declining CD4 counts and also is less likely to be successful in those with low CD4 counts or very high HIV RNA levels (see “HHS Guidelines, When to Start Therapy.” above, and chapters *Risk of HIV Progression/Indications for ART* and *CD4 Monitoring and Viral Load Testing*)
- Comorbidities
- Potential benefits and risks of ARV drugs
- Resistance, if any, to ARV medications (obtain resistance testing prior to ARV initiation for ARV-naïve patients)

Of course, the patient’s willingness to begin ART is critical, as mentioned above. Patients have the right to decline or postpone ART. This

decision should not affect any other aspect of care, and ART should be offered again at each visit to patients for whom treatment is indicated. If mental health issues, addiction, or the patient’s social situation are barriers to adherence, initiate appropriate referrals and reassess adherence barriers at regular intervals.

Preparing the Patient for ART

Before starting ART, it is important to have a detailed discussion with patients about their readiness to commit to a medication regimen, the expected benefits and possible adverse effects, and required monitoring and follow-up visits. Patients must understand that the first treatment regimen offers the best opportunity for effective viral suppression and immune reconstitution, which are primary goals of ART.

Supporting Adherence

Numerous strategies have been tested for their effectiveness in supporting patients’ adherence to the ART regimen. Successful approaches include extensive patient education, telephone contact with office staff members who can answer questions about adverse effects or other difficulties, family meetings, and peer support. Trust and accessibility appear to be important predictors of adherence, and some practitioners see the patient for two or three appointments before starting ART.

Compact regimens consisting of fewer pills and once-daily dosing often encourage adherence. Advise patients about potential adverse effects and at the same time let them know that many adverse effects may be treated or that substitutions often can be made for problematic ARVs. The choice to accept or decline ART ultimately lies with the patient (see chapter *Adherence*).

Anticipating Difficulties

Choosing an initial regimen that fits the patient’s lifestyle and that is likely to be tolerable and easy to take will improve the likelihood of long-term success with that regimen. If patients develop toxicities to one

or more components of an initial regimen, substitutions typically can be made without limiting the success of the regimen. Close monitoring and “check-in” appointments allow these adjustments to be made under clinical supervision. Close monitoring also can help to identify medication toxicities that may limit treatment and to detect early signs of inadequate medication adherence; early intervention to treat adverse effects and to support adherence may increase the likelihood of treatment success.

Considerations in Regimen Selection

Regimens should be selected with consideration of both patient factors and medication factors. The patient’s schedule, adherence history, and self-defined goals of ART should be considered in selecting a regimen to which the patient will adhere closely. The patient’s comorbid conditions and potentially interacting medications should be evaluated for possible contraindications or synergism with ARVs. The ARV history and all resistance profiles should be reviewed carefully so that a regimen that will be likely to achieve durable viral suppression can be chosen. Other factors should be evaluated with regard to specific ARV medications. For example, the HLA-B*5701 status and viral tropism should be determined if abacavir or maraviroc, respectively, are being considered: the HIV RNA level and creatinine clearance (CrCl) should be reviewed if rilpivirine or elvitegravir/cobicistat is being considered, and creatinine and CrCl should be evaluated if tenofovir is being considered. The patient’s HBV status will influence selection of NRTIs (tenofovir + emtricitabine or lamivudine should be included in the ART regimen, for co-treatment of HIV and HBV, unless contraindicated). In women who are pregnant or likely to become pregnant, FDA pregnancy categories and teratogenicity potential for specific ARVs should be taken into account. Drug interactions among ARVs or between ARVs and other medications should be evaluated, as dosage adjustments may be required or certain combinations may be

contraindicated (see relevant tables in the HHS *Guidelines*).

The advantages and disadvantages of various drug classes and individual drugs recommended for use in initial therapy are reviewed in Table 6 of the HHS *Guidelines*.

Use of Multiple Classes of Drugs

For initial therapy in patients with wild-type HIV virus, the HHS *Guidelines* recommend the use of two nucleoside reverse transcriptase inhibitors (NRTIs) in combination with a nonnucleoside reverse transcriptase inhibitor (NNRTI), a ritonavir-boosted protease inhibitor (PI), or an integrase inhibitor (INSTI). Alternative types of combinations generally do not reduce virus levels as effectively as these recommended types. The question of whether to use an NNRTI, a PI, or an INSTI in initial therapy is a matter of debate. Some clinicians advocate using an NNRTI or INSTI initially to preserve use of the PI class for later and to avoid PI-related toxicities. Others are more concerned about the potential toxicities of NNRTIs or the low genetic barrier to resistance presented by NNRTIs and some INSTIs, and instead recommend starting with a PI-containing regimen. Each of the initial regimens proposed by the HHS *Guidelines* is highly effective if taken as directed, and each has specific advantages and disadvantages (see Table 6 of the HHS *Guidelines*). In the end, the regimen should be selected with the individual patient in mind because the only effective combination for that patient is the one that he or she is willing and able to take on a consistent basis. See the information on drug resistance and toxicities below as well as the full text of the HHS *Guidelines* for more complete discussions.

Salvage therapy for patients with ARV-resistant HIV often comprises agents from three or more ARV classes; consult with an expert.

Boosted Protease Inhibitors

Ritonavir is used at low doses in combination with most other PIs to enhance or “boost” the serum level and prolong the half-life of the PI. This strategy generally decreases the dosing

frequency and the number of pills required, and it improves the activity of some PIs. Several currently used PIs require boosting with ritonavir, and some require ritonavir boosting when used with certain other medications, in order to overcome drug-drug interactions (e.g., atazanavir must be boosted with ritonavir if tenofovir also is a component of the ARV regimen); see “Drug Interactions,” below, and appropriate tables in the HHS *Guidelines*.

Preferred Starting Regimens

More than 20 ARVs in six drug classes have been approved for use in the United States by the U.S. Food and Drug Administration (FDA) (see relevant tables in the HHS *Guidelines*). In recent years, an increasing number of fixed-dose combinations (FDCs) have become available to simplify dosing and reduce pill burden.

These include four NRTI combinations:

- Abacavir + lamivudine (Epzicom)
- Abacavir + lamivudine + zidovudine (Trizivir)
- Tenofovir + emtricitabine (Truvada)
- Zidovudine + lamivudine (Combivir)

One PI coformulation:

- Lopinavir + ritonavir (Kaletra)

And three one-pill-per-day formulations of two NRTIs + one NNRTI or one INSTI:

- Efavirenz + tenofovir + emtricitabine (Atripla)
- Rilpivirine + tenofovir + emtricitabine (Complera)
- Elvitegravir + cobicistat + tenofovir + emtricitabine (Stribild)

Other FDCs are in development and may become available in coming years.

The HHS *Guidelines* suggest “preferred” and “alternative” components for initial therapy (Table 1). Clinicians should note that these recommendations change over time as new data regarding efficacy or toxicity become

available and should refer to the most up-to-date HHS guidelines. Among regimens with adequate potency (taking into account possible ARV resistance), regimen selection should be guided by factors such as anticipated tolerability, pill burden, drug interactions, and the patient’s comorbid conditions.

Table 1. Recommended Regimens for Initial Antiretroviral Treatment

Preferred Regimens	
NNRTI based	Efavirenz ¹ /tenofovir/emtricitabine ²
PI based	Atazanavir/r + tenofovir/emtricitabine (TDF/FTC) ² Darunavir/r (QD) + TDF/FTC ²
INSTI based	Raltegravir + TDF/FTC ² Elvitegravir/cobicistat/TDF/FTC ^{2,3} Dolutegravir (QD) + abacavir/lamivudine (ABC/3TC) ^{2,4} Dolutegravir (QD) + TDF/FTC ²
Alternative Regimens	
NRTI based	Efavirenz ¹ + ABC/3TC ^{2,4} Rilpivirine ⁵ /TDF/FTC ² Rilpivirine ⁵ + ABC/3TC ^{2,4}
PI based	Atazanavir/r + ABC/3TC ^{2,4} Darunavir/r + ABC/3TC ^{2,4} Fosamprenavir/r (QD or BID) + ABC/3TC ^{2,4} or TDF/FTC ² Lopinavir/r (QD or BID) + ABC/3TC ^{2,4} or TDF/FTC ²
INSTI based	Raltegravir + ABC/3TC ⁴

¹ Efavirenz is teratogenic in nonhuman primates. Strongly consider alternative agent for women who plan to become pregnant or are not using effective and consistent contraception.

² 3TC can be used in place of FTC and vice versa.

³ Should be considered only for patients with estimated CrCl ≥70 mL/min.

⁴ Abacavir should not be used by patients who test positive for HLA-B*5701; use with caution if HIV RNA level is >100,000 copies/mL or if there is a high risk of cardiovascular disease.

⁵ Rilpivirine is not recommended if the pretreatment HIV RNA is >100,000 copies/mL; caution if the CD4 count is <200 cells/μL.

Abbreviations: /r = low-dose ritonavir; INSTI = integrase inhibitor; NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside/nucleotide analogue; PI = protease inhibitor

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at www.aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Note: Many other ART combinations are possible, and in some cases a different option may be most appropriate for the individual patient. The HHS *Guidelines* also list regimens that are “Acceptable,” those that “May be acceptable,” but are “less satisfactory” or lack definitive data, and several that “May be acceptable but should be used with caution”; see Table 5b in the HHS *Guidelines*.

Once-Daily Regimens

The use of convenient and simplified dosing is an obvious strategy for improving adherence, particularly with the availability of coformulations that reduce pill burden (see “Preferred Starting Regimens,” above). The HHS *Guidelines* emphasize the importance of simple regimens and currently include six once-daily combinations among “preferred” regimens for initial therapy, and list a number of other possibilities among “alternative” regimens.

Avoiding Drug Resistance

ARV medications never should be given as single agents, in two-drug regimens, in suboptimal regimens, or in lower dosages than recommended, because of the potential for development of resistance. High-level resistance to NNRTIs, as well as to emtricitabine and lamivudine, may develop quickly (i.e., within days to weeks) in these situations, and the same may be true for the INSTIs raltegravir and elvitegravir. It may take longer for high-level resistance to develop to other NRTIs and to ritonavir-boosted PIs, and perhaps also the INSTI dolutegravir. Patients must be instructed to take the full dosage of all medications on schedule and to avoid skipping doses or taking “days off” from their regimens. Careful medication dosing is important because resistance to one drug within a particular class may transfer to other drugs in the same class (cross-resistance). Cross-resistance can limit the options for future therapy significantly or necessitate the use of very complicated regimens in the future. Once resistant viral strains have developed, they may be transmitted to other people.

Acquired or “primary” resistance, in which a patient is infected with ARV-resistant virus, is common in parts of the United States. Because both multi- and single-class resistance has been found among ARV-naïve persons in many U.S. cities, it is recommended that individuals with newly diagnosed HIV infection and all others entering care should receive a baseline resistance test. This test should be obtained as early as possible, in order to maximize the likelihood of detecting transmitted mutations, and before initiation of ART (see chapter *Resistance Testing*).

Drug Interactions

Many of the ARVs interact with one another as well as with other common medications. When starting or changing an ARV regimen, review all the patient’s current medications carefully for possible drug interactions. See chapter *Drug-Drug Interactions with HIV-Related Medications* for a summary of this issue and for references and resources to review medication lists and combinations. For further information on drug interactions involving ARVs, see relevant tables in the HHS *Guidelines*.

Drugs and Drug Combinations That Should Not Be Used

Most clinicians in the United States avoid using the NRTIs zidovudine (except for pregnant women), stavudine, or didanosine if other options are available, because of the high rates of metabolic and other adverse effects associated with these agents. Stavudine, in particular, is likely to cause peripheral neuropathy and lipodystrophy. Drugs with additive or overlapping toxicities, such as stavudine and didanosine, should not be combined. Zidovudine and stavudine, which compete intracellularly and therefore cause antagonism, should not be used together.

Drugs with similar mechanisms of action and resistance mutations (e.g., lamivudine and emtricitabine, or efavirenz and nevirapine) offer no significant advantage when combined and may increase toxicities. Certain drug

combinations have suboptimal efficacy and are not recommended (e.g., tenofovir + didanosine as an NRTI backbone; three-NRTI regimens). Some ARVs require specific dosing intervals in particular patients. For example, once-daily dosing of lopinavir/ritonavir is not recommended for patients receiving concomitant efavirenz or nevirapine, and some once-daily PIs or combinations should not be used for treatment-experienced patients. For further information, see relevant tables in the *HHS Guidelines*.

Follow-Up of Patients Starting ART

Patients who start a new ARV regimen ideally should be seen at least twice within the first month to allow for an assessment of their adherence to therapy and the tolerability and adverse effects of the regimen.

When patients have been on a new regimen for 2-8 weeks, clinicians should check the following:

- HIV viral load, to monitor initial virologic response to therapy, then every 4-8 weeks until the viral load is below the level of detection
- CBC with platelets, for patients starting a zidovudine-containing regimen, to monitor for anemia
- LFTs, to monitor for hepatotoxicity (patients starting a nevirapine-containing regimen should be monitored closely for the first 18 weeks of treatment)
- Serum electrolytes, blood urea nitrogen, and creatinine (particularly for patients taking tenofovir)
- Fasting glucose and lipids (after 1-3 months)

CD4 cell count should be checked after about 3 months.

For further information, and for recommendations about monitoring stable patients, see chapter *Initial and Interim Laboratory and Other Tests*.

Regimen Failure

An ART regimen may fail for several reasons, including the following:

Incomplete virologic response

- Viral load is >200 copies/mL on consecutive tests after 24 weeks on therapy. (For some patients with multidrug resistance, it may not be possible to decrease plasma HIV viral load to undetectable levels, and stabilization of viral load below the previous baseline may be an appropriate goal of therapy.)

Virologic rebound

- Virus is repeatedly detected in plasma (>200 copies/mL) after suppression to undetectable levels. Confirmatory testing is required to rule out “blips” of virus (isolated elevations in viral load of less than several hundred copies/mL) that are not clinically significant and to ensure that the increase is not caused by infection, vaccination, or problems with test methodology. Note that some patients may have persistently detectable low-level viremia (<200 copies/mL); the clinical significance of this is not clear.

Immunologic failure

- Despite virologic suppression on ART, the CD4 cell count shows an inadequate response or a persistent decline.

Clinical progression

- Recurrent, persistent, or new HIV-related illness occurs after ≥ 3 months on ART. Note that new or recurrent symptoms of opportunistic illness occurring in the first weeks to months after starting ART, especially in patients with severe immunosuppression, may not reflect a failure of ART. Rather, these symptoms could be attributable to persistence of opportunistic infections that may require longer treatment, or they could be caused by an immune reconstitution inflammatory syndrome (see chapter *Immune Reconstitution Inflammatory Syndrome*).

Responding to Apparent Treatment Failure

- Carefully assess patient adherence, because inadequate adherence to ART is a common reason for regimen failure. In some cases, adherence support, treatment of adverse drug effects, substitution for poorly tolerated ARVs, or other measures to enhance adherence may result in virologic suppression (see chapter *Adherence*). In other cases, ARV resistance may have developed. Poor adherence may affect the decision to change therapy, and adherence issues should be addressed before a new regimen is initiated. If resistance is suspected, obtain an appropriate resistance test (or CCR5 tropism assay, if the patient is taking a CCR5 antagonist) while the patient is on the failing regimen; see below.
- The availability of effective alternative ARVs is a critical consideration in deciding whether or when to change therapies. The development of new ARVs and new ARV classes in recent years has made virologic suppression possible for most patients, even those with extensive resistance. For the few patients in whom treatment possibilities are limited or nonexistent, it may be necessary to weigh the value of partial virologic suppression with the current regimen against the likelihood of further resistance developing. Strongly consider consultation with an experienced HIV provider and the use of HIV resistance testing when considering changes in therapy. When no treatment options remain among currently approved drugs, refer the patient to an appropriate clinical trial, if possible.

Note that the optimal management of immunologic failure is uncertain and is an active area of research. Consult with an HIV expert and consider referral to a research study.

Resistance and Coreceptor Tropism Testing

If resistance is suspected, obtain an appropriate resistance test (see chapter *Resistance Testing*). Resistance testing is recommended, before changing regimens, in cases of virologic rebound during ARV therapy or suboptimal suppression of viral load on ARV therapy. Resistance testing often is crucial in identifying ARVs that are not likely to be effective against the patient's virus. It should be done while the patient is taking the failing regimen (or within 4 weeks of discontinuation) to maximize the likelihood that resistant viral populations will be present in detectable numbers. In virologic failure of a first regimen, it is fairly common to see resistance to only one or two drugs in a multidrug combination. The test results should be interpreted in the context of the patient's ARV history and the results of previous resistance tests.

Standard genotypes test give information about resistance that may affect NRTI, NNRTI, and PI agents. If INSTI (or fusion inhibitor) resistance is suspected, a specific genotype test must be ordered. For patients with virologic failure while taking a CCR5 antagonist, a coreceptor tropism assay should be obtained (though the result does not rule out the possibility of resistance to CCR5 antagonists).

Cross-resistance exists among ARVs, such that resistance to one drug in a class of agents often extends to other drugs in that class. For example, cross-resistance between efavirenz and nevirapine is almost complete, and resistance mutations to NRTIs, INSTIs, and PIs often decrease viral susceptibility to other drugs in those classes. As a result, selecting a new ARV regimen can be complicated because it requires knowledge of expected resistance patterns. The likelihood of sustained viral suppression is lower when resistant virus is present, unless three ARVs that are fully active against the patient's virus can be included in the subsequent regimen.

If treatment with a CCR5 antagonist is being considered, a tropism test must be obtained to verify that the patient has only CCR5-tropic virus (the currently available agent in this class is not effective in patients with any degree of CXCR4 virus). The standard test requires an HIV viral load of >1,000 copies/mL at the time of testing; a newer proviral DNA assay can identify coreceptor tropism in blood samples with HIV RNA levels below the limit of detection (this has not been clinically validated).

Suggestions for Changing an ARV Regimen for Suspected Drug Failure

The following recommendations are adapted from the HHS *Guidelines*.

Distinguish between the need to change a regimen because of drug intolerance or inability to adhere to the regimen and the failure to achieve the goal of sustained viral suppression. In the event of intolerance, single agents usually can be changed without resistance testing.

In general, do not change a single drug or add a single active drug to a failing regimen; it is important to use at least two or, preferably, three fully active ARVs (e.g., ARVs selected on the basis of resistance testing or because they are from a drug class to which the patient's virus has not been exposed). If resistance testing (performed while the patient is taking the failing regimen) shows resistance to only one agent in a regimen, it may be possible to replace only that drug; however, consultation with an expert is recommended.

In general, the goal of ART is to suppress HIV RNA to undetectable levels, in order to improve or maintain immune function. This usually is possible even for patients with resistance to multiple drugs as new ARV agents and new classes of ARVs have become available. Nevertheless, some patients have

limited options for new regimens that will achieve durable virologic suppression. In some of these cases, it may be reasonable to continue the same regimen if partial virologic suppression and clinical and immunologic stability are maintained. The risk of continuing patients on a partially suppressive regimen, however, is the emergence of additional resistance mutations.

Data on the value of restarting a drug that the patient has previously received are limited. Resistant virus can be archived and will reemerge for patients who are rechallenged with regimens on which they had previously developed resistance. As a result, resistance tests from previous regimens should be used with current resistance tests to determine what drugs might be active in a new regimen.

Making the decision to change therapy and choosing a new ARV regimen require that the clinician have considerable expertise in the care of people with HIV infection. Those less experienced in the care of persons with HIV are strongly encouraged to obtain assistance by consulting with or referring to an expert.

Follow-Up of Patients Not Started on ART

Patients who are not on ART

These patients should continue their regular visits for monitoring, prophylaxis, and other medical treatment (see section *Testing and Assessment* for chapters on physical examinations and laboratory tests). ART should be discussed again and offered at regular intervals to anyone who initially refuses treatment. Routine clinic visits present ongoing chances to discuss the benefits of ART and the risks of delayed treatment, and to educate patients about new medications and research findings. Decreases in patients' CD4 count or declines in their condition should be taken as opportunities to reassess their decisions about ARVs. If lack of readiness or

probable adherence difficulties are at issue, an adherence counselor (if available) or a mental health provider should be engaged to bolster the patients' support and coping mechanisms (see chapter *CD4 Monitoring and Viral Load Testing* and the HHS *Guidelines*).

Special Situations for ART

ART during acute or recent HIV infection

There are no definitive data that demonstrate long-term benefit if ART is started during early HIV infection, though emerging clinical data as well as theoretical considerations suggest early treatment may reduce the severity of immune system disruption and lessen both the short-term and the long-term impact of HIV infection. In addition early treatment may decrease the risk of HIV transmission during the highly infectious period of acute HIV. The HHS *Guidelines* recommend treatment of acute HIV (if identified during pregnancy, ART should be started as quickly as possible to reduce the risk of perinatal HIV transmission). Before starting an ARV regimen, patients must be counseled carefully about potential limitations, such as toxicity, pill burden, cost, and the possible development of drug resistance. Patients should be monitored with HIV viral load, CD4 counts, and other parameters, as with patients with established infection who are receiving ART. See chapter *Early HIV Infection*.

Pregnant women

Combination ARV regimens are recommended for all women during pregnancy, regardless of CD4 count or HIV RNA level. The goal of ART for pregnant women is to reduce the risk of transmission to the infant and to treat HIV infection in the mother, through maximal virologic suppression. Obviously, the decision of whether to start ART during pregnancy is the choice of the woman, and her choice must be respected. There are a number of

specific considerations about ART for pregnant women, including the timing of ART initiation (for those not already on treatment), specific ARVs that are recommended or that should be avoided (because of toxicity or teratogenicity concerns), pharmacokinetic variations and dosing requirements in pregnancy, and indications for resistance testing. See chapters *Reducing Perinatal HIV Transmission* and *Care of HIV-Infected Pregnant Women*; also refer to the HHS *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*.

Older persons

Older persons with HIV infection may experience earlier development of a number of conditions that are associated with aging, such as cardiovascular disease and neurocognitive impairment. Additionally, older persons may have dampened immunologic responses to ART. For these reasons as well as others, ART initiation in older persons probably should not be delayed. Current HHS *Guidelines* recommend ART for all patients older than 50 years of age.

Acute opportunistic infections

The presence of opportunistic infections is a strong signal of the need for ART and effective immune reconstitution. For some of these infections, ART is the primary therapy, and for others it is adjunctive. Although ART sometimes causes immune reconstitution inflammatory syndromes if initiated in the setting of acute opportunistic infection, clinical data for many such infections (including *Pneumocystis jiroveci* pneumonia and tuberculosis in persons with very low CD4 counts) suggest improved outcomes, including better survival, if ART is started early. Exceptions to this recommendation include cryptococcal meningitis, for which most experts recommend a short period of antifungal treatment before ART is started.

For further information, see chapter *Immune Reconstitution Inflammatory Syndrome* and the *Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America* (see “References,” below).

Hepatitis B coinfection

If treatment for either HIV or HBV is to be started, both infections generally should be treated simultaneously, by including in the ART regimen two NRTIs with activity against both viruses (tenofovir + emtricitabine or tenofovir + lamivudine), if possible. The use of a single NRTI with activity against both viruses (resulting in monotherapy for HBV) is not recommended. If tenofovir is contraindicated, another anti-HBV drug should be used in combination with lamivudine or emtricitabine. Flares of HBV may occur if tenofovir, emtricitabine, or lamivudine is discontinued; monitor closely or consider substitution of another anti-HBV drug. See chapter *Hepatitis B Infection* and the *HHS Guidelines* for additional information.

HIV-associated nephropathy

ART is a primary treatment for HIVAN and should be started urgently for patients with suspected HIVAN. See chapter *Renal Disease*.

Expert Consultation

The National HIV/AIDS Clinicians' Consultation Center is a valuable resource for any clinician seeking expert advice about ART, HIV clinical manifestations, laboratory evaluations, and other issues. Its National HIV Telephone Consultation Service (Warmline) is staffed by HIV-experienced physicians and pharmacists. The Warmline operates Monday through Friday, 9 a.m. to 8 p.m. eastern time and is available free of charge in the United States at 800-933-3413.

Patient Education

- Making the decision to start ART is rarely an emergency situation. Before starting patients on ART, health care providers must work with them to determine what goals of therapy are likely to be achieved, and which personal issues are pertinent for selecting the best regimen to fit their lifestyles,
- Providers should review the proposed drug regimen with their patients. Be sure patients understand the instructions about dosage, scheduling, food requirements or restrictions, drug storage, adverse effects, toxicities, and type of reactions that must be reported immediately, as well as remedies for common adverse effects.
- Providers should explain to patients that successful ART requires a commitment to taking the medications every day, as prescribed. If ARVs are taken incorrectly, HIV can quickly become resistant to the medications. This will mean even fewer choices and less-effective treatment in the future. It also may mean that patients could transmit resistant virus to a partner or, if they are pregnant, to an infant.
- Patients should know that HIV medications may reduce the risk of HIV transmission substantially but do not offer perfect protection against infecting others. Recommend prevention measures such as using latex barriers during sex (safer sex) and not sharing needles or other drug-using equipment, even with other HIV-infected persons (see chapter *Preventing HIV Transmission/Prevention with Positives* for more information).
- HCV, HBV, and other sexually transmitted diseases such as syphilis and gonorrhea can be transmitted between two HIV-infected partners.
- Patients should be advised to check with their provider before discontinuing ARVs.

If ARVs must be discontinued, it is usually best to stop all ARVs at once. The exception to this recommendation may be NNRTI-containing regimens. In this case, blood levels of the NNRTIs may be detectable for several weeks after discontinuation; if NRTIs are stopped, that may result in NNRTI monotherapy and the risk of NNRTI resistance. The optimal strategy for discontinuing NRTIs is not clear; some experts recommend continuing the NRTIs for a period of time after discontinuation of the NNRTI or switching from an NNRTI to a PI for some time before stopping all agents.

- Patients should be encouraged to advise their provider of all other medications that they take, including over-the-counter medications, herbal remedies, and nutritional supplements.
- Discuss contingencies in the event the client is unable to take ARVs for a day or more (e.g., illness, severe adverse effects, hospitalization, or other unexpected circumstances).

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Reducing Perinatal HIV Transmission

Carolyn K. Burr, EdD, RN

Background

This chapter describes strategies for reducing the risk of perinatal HIV, based on the U.S. Department of Health and Human Services (HHS) *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*. It is not intended to be a comprehensive discussion of these topics, and all HIV-infected pregnant women should be treated by an HIV-experienced obstetrician and an HIV specialist. For centers that do not have HIV specialists available, experts at the National Perinatal HIV Consultation and Referral Service are available for consultation through the Perinatal HIV Hotline (888-448-8765). For more information on other aspects of caring for HIV-infected pregnant women, see chapter *Care of HIV-Infected Pregnant Women*.

Unless otherwise referenced, the information in this chapter is based on the most recent HHS perinatal guidelines available at the time this chapter was published. Consult the AIDSinfo website (aidsinfo.nih.gov/guidelines) for the most current recommendations.

Overview of Prevention of Perinatal HIV Transmission

In the absence of antiretroviral (ARV) prophylaxis or other interventions, the rate of perinatal HIV transmission in the United States ranges from 16% to 25%. Antiretroviral therapy (ART) is highly effective in reducing the risk of perinatal transmission of HIV, to as low as <1%. It probably prevents HIV transmission in several ways, including by reducing the mother's viral load in blood and genital secretions and by providing pre- and postexposure prophylaxis for the infant. All pregnant women with HIV infection should be educated about the risks of perinatal HIV transmission and offered ART and other medical management to maintain or improve their own health and to reduce the risk of HIV transmission to their infants.

In 1994, the Pediatric AIDS Clinical Trial Group study 076 (PACTG 076) found that ARV treatment during pregnancy could significantly reduce the risk of HIV transmission to infants. The intervention, consisting of zidovudine (ZDV) given PO to the women during the last weeks of pregnancy and IV during labor

and delivery, as well as to the newborns for 6 weeks, reduced the rate of infant infection from 25.5% to 8.3%. The ZDV regimen quickly became the standard of care in the United States and other high-income countries. Subsequent studies showed that combination ARV regimens with suppression of maternal HIV viral load to undetectable levels further reduced the risk of perinatal infection.

Studies in resource-limited countries as well as in resource-abundant areas have examined various ARV strategies for reducing the risk of perinatal HIV transmission. The Petra study, a placebo-controlled trial in a breast-feeding population in Uganda, South Africa, and Tanzania, found a transmission rate of 8.9% among women who received PO ZDV plus lamivudine (3TC) intrapartum and for 1 week postpartum and whose infants also received 1 week of ZDV/3TC, compared with a rate of 15.3% in the placebo group. The HIV NET 012 trial in a breast-feeding population in Uganda compared the efficacy of a single dose of nevirapine (NVP) given to the mother at the onset of labor plus a single dose given to the newborn 48 hours postpartum with that of PO

ZDV given to the mother during labor and to the newborn. The transmission rate was 11.8% in the NVP arm, compared with 20.0% in the ZDV arm. The results of this study and the low cost of NVP prompted a number of resource-limited countries to institute NVP prophylaxis as the standard of care for preventing mother-to-child transmission of HIV. Numerous other trials have demonstrated the efficacy of various ARV strategies, combining different ARVs with different treatment durations and given to mothers, newborns, or both, in both breast-feeding and non-breast-feeding populations. Research has shown that ARV interventions even late in the peripartum or newborn periods may decrease the infant's risk of HIV infection. A retrospective study of subjects in New York found that the rate of perinatal HIV transmission was 9.3-10% if ZDV was given either to both the mothers intrapartum and their newborns or to the newborns only, compared with 26.6% if no ARV medication was given. This study underscores the importance of offering ARV interventions to pregnant women with HIV infection whenever they are identified during pregnancy or during labor and delivery, or as an intervention with the newborn.

In the United States, the PACTG 076 regimen remains an important component in the prevention of perinatal HIV transmission, and usually is incorporated into combination ART for pregnant women. For international settings, other guidelines have been developed by global agencies such as the World Health Organization (see "References," below) and by individual governments.

Mother-to-child transmission also can occur through breast-feeding. Recent studies have shown that ART given to the nursing mother and/or her infant decreases but does not eliminate the risk of HIV transmission to the infant. In the United States, because substitute feeding is safe, affordable, feasible, sustainable, and available, mothers in the United States should not breast-feed.

HIV Testing During Pregnancy

The success of interventions to reduce the risk of perinatal HIV transmission has been achieved through the routine HIV testing and counseling of all pregnant women.

Interventions to prevent transmission can be effective only if women know their HIV status and have access to treatment. HHS has recommended universal HIV counseling and testing for pregnant women since 1995. Many national professional and governmental organizations, including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the U.S. Preventive Services Task Force, endorse those recommendations. Current recommendations from the U.S. Centers for Disease Control and Prevention (CDC) feature the following three approaches to HIV testing during pregnancy:

- Routine testing as part of first-trimester prenatal screening tests for all pregnant women, using an "opt-out" policy whereby a pregnant woman is tested unless she specifically declines testing
- Routine "opt-out" testing with a rapid HIV test for women who present in labor with unknown or undocumented HIV status, in order to offer ARV prophylaxis during labor for those who test positive for HIV
- Expedited HIV testing for newborns of mothers of unknown HIV status so that they can receive postexposure ARV prophylaxis, if indicated

The CDC also recommends repeat HIV testing in the third trimester for women who receive health care in jurisdictions with an elevated incidence of HIV or AIDS among women, as well as for women at high risk of acquiring HIV (e.g., a history of injection drug use, exchange of sex for money or drugs, multiple sex partners, or a partner known to be HIV infected). Jurisdictions in which repeat third-trimester testing is recommended include Alabama, Connecticut, Delaware,

District of Columbia, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, Mississippi, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. A number of states mandate a third-trimester HIV test for all pregnant women.

Any pregnant woman with signs or symptoms of acute HIV infection should be evaluated (see *chapter Early HIV Infection*) and receive an HIV plasma RNA test as well as an antibody test.

State laws regarding HIV testing during pregnancy vary widely, and many are currently under review. A number of states have adopted the opt-out approach, whereas some still require written informed consent before an HIV test is done. Others require patient education and a chart note from the providers. Clinicians should be familiar with relevant state laws regarding HIV testing during pregnancy, opt-out or consent provisions, and regulations about rapid HIV testing during the intrapartum or newborn period. (Information on state laws regarding HIV testing during pregnancy can be found at the National HIV/AIDS Clinicians' Consultation Center's Compendium of State HIV Testing Laws at www.nccc.ucsf.edu.) Whatever the consent process, a woman should know that an HIV test is being done and should receive at least the information outlined below.

HIV Education and Counseling of Pregnant Women

Educating pregnant women about the importance of HIV testing is a critical element in preventing perinatal HIV transmission. However, extensive pretest counseling is not essential. A woman must be told that HIV testing is a standard component of prenatal care, that her clinician recommends the tests, and that all pregnant women should be tested for HIV because knowing about HIV infection is important for their health and the health of their babies. Research has

shown that a provider's strong endorsement of HIV testing is a major predictor of whether a woman receives an HIV test. Testing should be voluntary and free of coercion, and a woman should know that she can decline testing without the risk of being denied care. A woman's age, cultural background, educational level, and primary language may influence her knowledge about HIV transmission and her willingness to be tested; the clinician should consider these factors carefully when providing education and information.

The following minimum information should be provided through an educational session with a health care provider or through written or electronic media (e.g., brochures, videos):

- HIV is the virus that causes AIDS.
- Without treatment, approximately 25% of babies born to HIV-infected women will be infected, either during pregnancy, during labor and delivery, or by breast-feeding.
- A woman could be at risk of HIV infection and not know it.
- ART is highly effective in protecting the infant from being infected with HIV and can improve the mother's health.
- HIV testing is recommended for all pregnant women.
- Women who decline testing will not be denied care.

Women should be told that test results are confidential to the extent allowed by law and that medical and other services are available for women with HIV infection. Reporting requirements for the specific state should be explained.

HIV testing should be performed as early in pregnancy as possible to allow for interventions to prevent transmission and for effective management of a woman's HIV infection, if the woman is found to be HIV seropositive. The CDC recommends repeat HIV testing in the third trimester for women who have risk factors for HIV or who live in

areas with a high incidence of HIV in women; some states mandate third-trimester testing for all pregnant women.

If the client declines testing at any point, the clinician should inquire about her reasons and follow up at subsequent visits. If the provider is persistent, the woman may choose to have an HIV test at a later visit.

In the United States, the vast majority of pregnant women who are tested for HIV will be HIV seronegative. When giving test results to an HIV-negative woman, the clinician should take the opportunity to discuss risk-reduction strategies to help ensure that she remains uninfected by HIV. Women at risk of HIV infection should be referred for more extensive counseling because some research indicates that pregnancy may place them at greater risk of acquiring HIV infection, and acute HIV infection may confer greater risk of transmission to the fetus.

Counseling a pregnant woman with a positive HIV test result requires knowledge and sensitivity. The clinician should explain that, even though the woman may feel well, she is infected with the virus. The woman should be told about the importance of medical management of HIV for her own health and for the prevention of perinatal transmission, and she should be guided to the medical and social services available in her local community. She also should be referred to an HIV obstetric specialist who can work closely with her primary obstetric and HIV providers to manage her care during the pregnancy. The patient may be surprised or shocked upon receiving the HIV diagnosis, or she may have known her status but been reluctant to disclose it. The clinician should emphasize the importance of emotional and social support, assess the patient's social support resources, and offer her referrals as needed.

Expedited HIV Testing During Labor

As discussed earlier, beginning ART during pregnancy offers the greatest chance for preventing perinatal transmission of HIV, but interventions during the intrapartum and neonatal periods also offer opportunities to decrease the risk of HIV transmission. Expedited HIV testing for women who present in labor with unknown or undocumented HIV status can identify women who are infected with HIV so that interventions can be offered. Available rapid HIV antibody tests are both sensitive and specific and provide results in as little as 20 minutes. Fourth-generation antigen-antibody HIV tests also are becoming increasingly available through hospital laboratories using random access machines that deliver results in 30 minutes to 2 1/2 hours.

Women who should receive HIV testing during labor include the following:

- Those who have had little or no prenatal care
- Those who were not offered testing earlier in pregnancy
- Those who declined previously
- Those whose HIV test results are not available at the time of labor

Education and counseling for the woman in labor who needs an HIV test should incorporate the information for prenatal education discussed earlier, with consideration given to the special circumstances of labor. Special educational formats such as flip charts have been developed to help with patient education. Confidentiality should be assured for the information and consent process and for treatment. If an opt-out approach is used in the labor setting, a woman of unknown serostatus should be told that no HIV test is found on her chart, that HIV testing is part of routine care, and that she can decline if she wishes, but that experts recommend HIV testing because available interventions can

decrease her baby's risk of becoming infected with HIV if she is found to be seropositive.

Women who present in labor with unknown HIV serostatus should undergo expedited HIV antibody testing. If the results are positive, a confirmatory HIV test should be sent as soon as possible but maternal prophylaxis should be started immediately (intravenous ZDV).

This should be followed by combination ARV prophylaxis (ZDV + NVP) for the infant beginning as soon as possible after birth. ARV drugs should be initiated pending results of the confirmatory test. If the confirmatory HIV test result is positive, infant ARV drugs should be continued for 6 weeks. If the confirmatory test result is negative, the infant ARV drugs should be stopped.

Factors Influencing Perinatal HIV Transmission

Perinatal transmission is most likely to occur in the intrapartum period. Several factors influence the risk of transmission from mother to infant. One of these is the mother's HIV RNA level (viral load). Clinical trials and observational studies have shown a strong positive correlation between maternal HIV viral load during pregnancy or during delivery and the risk of perinatal HIV transmission, even among women receiving treatment with ARVs. However, HIV transmission may occur at any level of maternal HIV RNA, including (rarely) when the viral load is undetectable. HIV RNA levels in the blood and the genital tract generally correlate but discordance may occur. Low-level cervical-vaginal HIV shedding has been found even in women on ART with undetectable plasma HIV RNA, particularly in the presence of genital infections.

ARV prophylaxis is a critical factor in reducing HIV transmission. For women on effective combination ART with undetectable HIV RNA, the rate of perinatal HIV transmission is approximately 1%. Thus, ARV prophylaxis

with full suppression of HIV RNA is recommended for all pregnant women with HIV infection, regardless of HIV viral load. Note that ART may exert protective effects not only by lowering maternal HIV RNA but also (for ARVs with good transplacental passage) by providing pre- and postexposure prophylaxis for the infant.

Other maternal factors associated with increased risk of perinatal transmission include low CD4 cell count, sexually transmitted diseases, active genital herpes during labor, illicit drug use, cigarette smoking, and unprotected sex with multiple partners.

Obstetric factors also affect the risk of HIV transmission. Infection risk increases linearly with the increased duration of ruptured membranes, although the effect of ruptured membranes in women with low viral loads is not known. Invasive procedures performed at any time during pregnancy, such as amniocentesis, placement of scalp electrodes, artificial rupture of membranes, episiotomy, or operative (forceps) delivery may increase risk by exposing the fetus to maternal blood; these procedures should be avoided (though the risk of transmission in women on fully suppressive ART is not clear). In addition, the mode of delivery, whether vaginal or cesarean, can influence the risk of HIV transmission. Scheduled cesarean delivery decreases the rate of perinatal infection for women with an HIV RNA level of >1,000 copies/mL, but its efficacy is not clear for women whose labor has begun or for those whose membranes have ruptured; see "Intrapartum Management and Mode of Delivery," below, for further information.

Infant risk factors for HIV infection include premature birth, low birth weight, skin and mucous membrane lesions such as thrush, and breast-feeding. Breast-feeding increases the risk of HIV transmission by 5-20%. In the United States, where safe, affordable replacement feeding and clean water routinely are available, women with HIV should not breast-feed.

However, some women with HIV will be under tremendous cultural and familial pressure to breast-feed and will need the clinician's ongoing support to use substitute formula.

Because many factors that affect the risk of perinatal HIV transmission may be modified, clinicians should educate pregnant women carefully about the importance of ARV prophylaxis and other strategies to reduce the risk of maternal-fetal transmission of HIV.

Antiretroviral Therapy During Pregnancy

The goals of ART for the pregnant woman are the same as those for any person living with HIV:

- To suppress the level of HIV as low as possible for as long as possible
- To preserve and restore immune function
- To prolong life and improve quality of life
- To reduce risk of HIV transmission to sex partners

An additional, and crucial, goal of ART for pregnant women is to reduce the risk of perinatal HIV transmission through maximal HIV suppression.

The HHS recommendations discuss in detail the multiple issues that must be considered when balancing the woman's need for therapy for her own health and the need to decrease the risk of transmission to the infant. Combination ART is recommended for all HIV-infected pregnant women regardless of CD4 count or HIV viral load. Decisions about ART are complex and should be made by the woman and her health care provider after discussing the risks and benefits. Clinicians are urged to consult an HIV specialist and the most current HHS recommendations when making therapeutic decisions. The Perinatal HIV Hotline (888-448-8765) provides free clinical consultation on all aspects of perinatal HIV care. The following discussion addresses some of the issues in determining ART

strategies and is taken from the HHS *Perinatal ARV Guidelines*.

The HHS Perinatal HIV Guidelines Working Group recommends fully suppressive combination ART for all pregnant women, unless there are compelling reasons based on pregnancy-specific maternal and fetal safety issues to modify this approach. Key recommendations from the HHS *Perinatal ARV Guidelines* include the following:

- Assess the woman's HIV disease status and make recommendations about initiating or altering an ARV regimen, as part of the initial evaluation.
- Recommend ARV prophylaxis to all pregnant women regardless of HIV viral load or CD4 count.
- Discuss known benefits and potential risks of ART.
- If HIV RNA level is >500-1,000 copies/mL, perform drug-resistance testing prior to starting or changing ART.
- If HIV is diagnosed late in pregnancy, ART should be initiated promptly without waiting for results of resistance testing.
- Emphasize the importance of adherence to the regimen.
- Ensure that the woman has access to and coordination of services among perinatal, primary care, and HIV providers as well as mental health and drug abuse services and income support as needed.
- Considerations about continuing ART after pregnancy are the same as for nonpregnant individuals.

A fundamental principle of the *Guidelines* is that therapies of known benefit should not be withheld during pregnancy unless they may cause adverse effects to the woman, fetus, or infant, and these adverse effects outweigh the potential benefits. Thus, women should be advised of the potential risks and benefits of ART (to the woman, fetus, and infant) and of the limited long-term data on outcomes for

infants with in utero exposure to ARVs, but treatment decisions should be guided by the woman's clinical, virologic, and immunologic status and by the goal of preventing perinatal transmission. An additional benefit of ART is the reduction in risk of transmission to sex partners. Women should be educated and counseled on the importance of close adherence to the ART regimen (see chapter *Adherence*).

Drug-resistance testing should be conducted for all pregnant women before the initiation of therapy, and for women who are already on ART without fully suppressed HIV RNA.

All women receiving ARVs during pregnancy for prophylaxis or for treatment should receive a combination containing at least three agents, with the aim of viral suppression to undetectable levels (i.e., <20-75 copies/mL, depending on the assay). Monotherapy (e.g., with ZDV) and dual therapy are not as effective and generally are not recommended. Current *Guidelines* recommend that the regimen include two nucleoside reverse transcriptase inhibitors (NRTIs) and either a nonnucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). Regimen selection should be individualized on the basis of factors such as anticipated safety and efficacy, ARV history, results of resistance testing, and comorbidities (e.g., hepatitis B virus [HBV]) (see chapter *Antiretroviral Therapy* for considerations in selecting ARVs). It should be recognized that only limited information is available for many ARVs and ARV combinations regarding potential toxicities for the fetus or infant (see Table 5 of the *Guidelines*), and for dosage requirements with pregnant women.

The HHS *Perinatal ARV Guidelines* offer recommendations on the use of specific ARV agents during pregnancy. The table below shows "Preferred" and "Alternative" ARVs; others are classified as "Use in special circumstances" or "Insufficient data to recommend use." For more complete information, see Table 5 of the *Guidelines*).

Recommendations for ARV Use During Pregnancy

ARV Class	Preferred Agents	Alternative Agents
NRTI	- Lamivudine - Zidovudine	- Abacavir[#] - Emtricitabine - Tenofovir
NNRTI	Nevirapine*	
PI	- Atazanavir/ ritonavir - Lopinavir/ ritonavir (Kaletra)	- Darunavir/ ritonavir - Saquinavir/ ritonavir

* For women with CD4 counts of >250 cells/μL, NVP should be initiated only if benefit clearly outweighs risk, owing to the increased risk of potentially life-threatening hepatotoxicity in women with high CD4 counts. Women who are already taking NVP at the start of pregnancy and are tolerating it well may continue NVP, regardless of CD4 count.

[#] Risk of hypersensitivity reaction; should be given only to patients who test negative for HLA-B*5701. Test for HLA-B*5701 before starting abacavir.

Adapted from U.S. Department of Health and Human Services. *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

The guidelines' preferred NRTI component is ZDV/3TC, because of data showing safety and efficacy in pregnancy. Alternative NRTIs listed above may be used for women with intolerance to ZDV (e.g., severe anemia) or documented resistance to ZDV (see "Safety and Toxicity of Antiretroviral Medications During Pregnancy," below). Tenofovir + 3TC or FTC is the preferred NRTI pair for women with hepatitis B coinfection (see "Special Circumstances," below).

Of the NNRTIs, NVP may be started for women with CD4 counts of ≤250 cells/μL or continued for women who are already on NVP-containing regimens. NVP generally should not be started for treatment-naïve women with CD4 counts of >250 cells/μL because of an increased risk of symptomatic and potentially fatal hepatic and rash toxicity. Efavirenz is not recommended for use during the first 5-6 weeks of pregnancy because of concern for potential teratogenicity, but it can be continued in pregnant women already

taking an effective efavirenz-based regimen who present for antenatal care in the first trimester, and it can be considered for other women (after the first 6 weeks of pregnancy) if other agents are not appropriate (see “Safety and Toxicity of Antiretroviral Medications During Pregnancy,” below). There are insufficient pharmacokinetic and safety data to recommend the use of etravirine or rilpivirine during pregnancy.

Atazanavir + ritonavir and lopinavir/ritonavir are recommended PIs based on efficacy studies in adults and experience in pregnant women. For both of these (and for darunavir), serum levels may be low in the second and third trimesters; see the *Guidelines* for recommendations about dosage adjustments. The alternative PIs are ritonavir-boosted darunavir and ritonavir-boosted saquinavir, although pharmacokinetic data during pregnancy are limited. Nelfinavir has been used widely for pregnant women but current guidelines recommend its use only in “special circumstances” because, in nonpregnant adults, it has shown inferior efficacy compared with first-line agents. Indinavir also may be considered when preferred and alternative agents are not available. Fosamprenavir and tipranavir are not recommended because of lack of data in pregnancy, but they may be considered if other agents are not tolerated or are not appropriate.

The integrase inhibitor raltegravir may be considered if preferred or alternative agents are not appropriate. Pharmacokinetic and safety data in pregnancy are not sufficient to recommend the use of maraviroc or enfuvirtide, and they do not consider the newer agents rilpivirine, etravirine/cobicistat, or dolutegravir; these may be considered for use by women for whom drugs in other classes have failed but they should be prescribed in consultation with HIV and obstetric specialists.

ART Recommendations by Clinical Scenario

Recommendations for ARV Use by Pregnant Women

The HHS *Perinatal ARV Guidelines* offer recommendations on ART for pregnant women based on four clinical scenarios; these are categorized by the woman’s ART status when she presents for care (see Table 6 of the *Guidelines*). Note that current adult and adolescent guidelines recommend ART for all, regardless of CD4 cell count (see chapter *Antiretroviral Therapy*).

HIV-infected pregnant women currently receiving ART

Women already receiving ART should, in general, continue to receive it during pregnancy if it is suppressing viral replication. If the woman has detectable virus (e.g., >500–1,000 copies/mL) on therapy, HIV drug-resistance testing should be performed, and the regimen should be optimized to maximize the likelihood of achieving virologic suppression. Women presenting in the first trimester should be counseled about the risks and benefits of ART during this period. Discontinuation of therapy could lead to increased viral load and potential for transmission to the fetus.

Pregnant women receiving NVP-containing regimens should continue them, regardless of CD4 count, if they are virologically suppressed and tolerating the regimen. For women who become pregnant while taking efavirenz, current *Guidelines* state that, because the risk of neural tube defects is limited to the first 5 to 6 weeks of pregnancy and pregnancy is rarely recognized before 4 to 6 weeks of pregnancy, efavirenz can be continued (assuming the regimen is maximally suppressive).

HIV-infected pregnant women who are ARV naive

All pregnant women should start potent combination ART. The drug regimen should be based on the recommendations of the *Perinatal ARV Guidelines* (see above and Table 5 of the *Guidelines*). As in other scenarios,

drug-resistance testing should guide ARV selection.

Starting ART early in pregnancy may be more effective in reducing perinatal HIV transmission but the potential benefits of early ART must be weighed against potential fetal effects of first-trimester exposure. Starting ART after the first trimester can be considered in women with high CD4 T-lymphocyte (CD4-cell) counts and low HIV RNA levels.

Inclusion of NRTIs with good placental passage (zidovudine, lamivudine, emtricitabine, tenofovir, or abacavir) is recommended.

ART should be continued intrapartum. ZDV should be administered to HIV-infected women by continuous IV infusion if they have HIV RNA levels of >400 copies/mL (or unknown HIV RNA levels) near delivery, regardless of ART regimen or mode of delivery.

After delivery, consider the indications for continuing ART and the woman's willingness and ability to do so (note that ART currently is recommended for all adults and adolescents); see "Postpartum Follow-Up of HIV-Infected Women," below, and chapter Antiretroviral Therapy.

HIV-infected pregnant women who previously have received ART or prophylaxis but are not currently receiving any ARV medications

In some instances, a pregnant woman has been on ART for her own treatment or for prophylaxis during a previous pregnancy and subsequently discontinued the medications. ARV drug-resistance testing should be conducted prior to initiating ART. The regimen should be chosen on the basis of previous ART experience and the reasons for stopping and results of past and current resistance testing, with avoidance of drugs and combinations with adverse maternal effects. The selection of an ART regimen for women with advanced HIV disease or a history of extensive prior therapy can be challenging, and consultation with an HIV specialist is

recommended. Principles of ARV selection are as described above.

For women who present late in pregnancy, ART should be started promptly, without waiting for results of resistance testing. The use of raltegravir during late pregnancy for women who have high viral loads has been suggested because of its ability to suppress viral load rapidly (an approximately 2-log₁₀ copies/mL decrease by week 2 of therapy). However, the efficacy and safety of this approach have not been evaluated and only anecdotal reports are available. Until more data become available on the safety of raltegravir use during pregnancy, this approach cannot be recommended for treatment-naïve women.

Intrapartum ZDV infusion should be given as described above if the HIV viral load is >400 copies/mL near the time of delivery.

HIV-infected women who have received no ARV before labor and their Infants

HIV-infected pregnant women who have not received ARV prior to labor should be given ZDV as a continuous infusion during labor. The mother's need for continuing ARV treatment postpartum should be evaluated. Infants born to women who had no ART during pregnancy should begin ARV prophylaxis as close to birth as possible. In addition to receiving ZDV for 6 weeks, the infant should also be given three doses of NVP in the first week of life (at birth, 48 hours later, and 96 hours after the second dose).

Pharmacokinetic Considerations During Pregnancy

Physiologic changes that occur during pregnancy (e.g., prolonged gastrointestinal transit time; increase in body fat and water; and changes in cardiac, circulatory, hepatic, and renal function) may affect the kinetics of drug absorption, distribution, and elimination. Few pharmacokinetic studies have been conducted on levels of ARVs during pregnancy, but available data suggest that altered dosing for some PIs (e.g., atazanavir/ritonavir,

darunavir/ritonavir, lopinavir/ritonavir) may be required (see Table 5 of the *Guidelines*).

Special Circumstances

Hepatitis B Coinfection

Screening for HBV infection with hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), and hepatitis B surface antibody (anti-HBs) is recommended for all pregnant women who have not been screened during the current pregnancy. The HBV vaccine series should be administered to pregnant women who screen negative for hepatitis B.

For pregnant women coinfecting with HIV and HBV, providers should treat both infections at once, by including a two-NRTI combination that is active against both infections. The NRTI combination tenofovir + 3TC or FTC is preferred for pregnant women with HIV/HBV, in combination with an NNRTI or PI. Liver transaminases should be monitored for signs of hepatotoxicity or HBV flare. Treatment may be complicated, and consultation with an expert is recommended. Also see the relevant discussion in the HHS *Perinatal ARV Guidelines*, and chapter *Hepatitis B Infection* in this manual.

HBV-infected pregnant women who are not immune to hepatitis A should be vaccinated. Infants born to coinfecting women should receive HBV immune globulin and start the HBV vaccine series within 12 hours after birth (with subsequent vaccine doses per usual protocol).

Hepatitis C Coinfection

Treatment for hepatitis C virus (HCV) is not recommended during pregnancy. Recommendations for ART during pregnancy are the same for women who are HIV/HCV coinfecting as for those without HCV coinfection. Liver transaminases should be monitored for signs of hepatotoxicity.

Coinfecting pregnant women should be tested for immunity to hepatitis A and HBV; if not

immune, they should be vaccinated. Infants born to coinfecting women should be evaluated for HCV infection.

See the relevant discussion in the HHS *Perinatal ARV Guidelines*, and chapter *Hepatitis C Infection* in this manual.

Safety and Toxicity of Antiretroviral Medications During Pregnancy

Limited data are available on the safety of ARVs during pregnancy, particularly when ARVs are used in combination. The existing safety and toxicity information is derived from animal and human studies, clinical trials, registry data, and anecdotal experience.

Several drugs are of special concern when used during pregnancy (see HHS *Perinatal ARV Guidelines*; Table 5), including the following:

- Efavirenz:** Efavirenz is classified by the U.S. Food and Drug Administration (FDA) as a Pregnancy Class D drug because malformations have occurred in monkeys receiving efavirenz during the first trimester. Several cases of neural tube defects in humans after first-trimester exposure to efavirenz have been reported. As mentioned above, the *Guidelines* state that alternative ARVs should be strongly considered in women who are planning to become pregnant or are not using effective contraception with male partners. For pregnant women who present for antenatal care in the first trimester, discontinuation of efavirenz is not necessary, because the risk of neural tube defects is limited to the first 5–6 weeks of pregnancy and pregnancy is rarely recognized before 4–6 weeks.
- Nevirapine:** Women, including pregnant women, who begin NVP therapy when their CD4 count is >250 cells/μL have nearly a 10 times higher incidence of hepatotoxicity than women initiated on NVP at lower CD4 counts. Symptoms of hepatotoxicity include fatigue, malaise, anorexia, nausea, jaundice, liver tenderness, and hepatomegaly. NVP should be initiated as part of an ARV

regimen for pregnant women with CD4 counts of >250 cells/ μ L only if the benefits clearly outweigh the risks (see Table 5 of the *Guidelines*). Women with higher CD4 cell counts who are already taking and tolerating NVP may continue it.

- **Didanosine + stavudine:** The combination of didanosine and stavudine may cause fatal lactic acidosis and hepatic steatosis and should be avoided unless no alternative is available. Patients may present with symptoms 1-6 weeks in duration that include nausea, vomiting, abdominal pain, dyspnea, and weakness; clinicians should be alert for early signs and symptoms of lactic acidosis and evaluate them promptly.

In addition, PIs have been associated with an increased risk of new-onset diabetes, worsening diabetes, and diabetic ketoacidosis. Of course, pregnancy itself is a risk factor for hyperglycemia. Clinicians should monitor the glucose levels of pregnant women taking PIs and should educate them about the symptoms of hyperglycemia. The HHS *Perinatal ARV Guidelines* recommend that pregnant women on ART should be screened with a standard 50 g glucose loading test at 24-28 weeks (see chapter *Care of HIV-Infected Pregnant Women*).

Information on ARV toxicity during pregnancy should be consulted carefully before treatment choices are made. The HHS *Guidelines* provide information on each ARV drug, including preclinical and clinical data, pharmacokinetic and toxicity data, and recommendations regarding use during pregnancy. These guidelines are updated routinely as information is received (see Table 5 and Appendix A of the *Guidelines*). Numerous other medications also are contraindicated for use during pregnancy, and potential toxicity should be considered carefully before any medication is given to a pregnant woman.

Adverse Events Related to ARV Drugs During Pregnancy

A number of studies have identified an increased risk (up to double) of preterm delivery in women who take combination therapy during pregnancy (whether started before or during pregnancy), while other studies have not. Given the conflicting data, the *Guidelines* advise clinicians to be aware of a possible small increased risk of preterm birth among women who receive ART. However, the benefit of ART for the mother's health and for prevention of perinatal transmission is clear, and combination ART should not be withheld. Until more is known, pregnant women who are taking combination regimens should be monitored closely for complications and toxicities and should be educated about the signs of premature labor.

Antiretroviral Pregnancy Registry

The Antiretroviral Pregnancy Registry collects observational data on HIV-infected pregnant women taking ARV medications to determine whether patterns of fetal or neonatal abnormalities occur. This is a project initiated by the pharmaceutical industry and overseen by an advisory committee comprising representatives from the CDC, National Institutes of Health, FDA, pediatric and obstetric providers, and others. Providers who care for pregnant women taking ARVs are encouraged to enroll patients in the registry at the time of initial evaluation. Information is confidential and patients' names are not used. More information can be obtained by visiting the registry website (www.apregistry.com/) or by calling 800-258-4263, 8:30 a.m. to 5:30 p.m. eastern time.

Intrapartum Management and Mode of Delivery

In 2012, a significant change was made in the *Guidelines* recommendation regarding intrapartum management of the woman with HIV infection. For women on ART with HIV

RNA levels of <400 copies/mL near delivery, IV ZDV during labor can be considered but is not required (though they should continue their usual ARV medications). IV ZDV is recommended for HIV-infected women with HIV RNA levels of ≥ 400 copies/mL (or with unknown viral loads) near delivery, regardless of antepartum regimen or mode of delivery. IV ZDV should be given to the woman during labor as a 1-hour loading dose of 2 mg/kg followed by a continuous infusion of 1 mg/kg per hour until delivery. Women on ART should continue their regimen on schedule as much as possible during labor, except that women receiving ZDV or a ZDV-containing fixed-dose combination whose viral load is ≥ 400 copies/mL should be given IV ZDV, with other components continued orally. For women on a stavudine-containing regimen, the stavudine component should be discontinued while IV ZDV is being administered.

For women on ART who have detectable viral load at the time of delivery, the addition of the single-dose NVP protocol (single dose to the woman during labor, single dose to the neonate) is not recommended in the United States, because clinical trials have not shown benefit and there is a risk of NVP resistance. For the neonate, an expanded infant prophylaxis regimen may be indicated (see “Follow-Up of HIV-Exposed Infants,” below).

Studies conducted before the availability of viral load testing found that cesarean delivery performed before the onset of labor or rupture of membranes significantly reduced the risk of perinatal transmission. However, in the United States and other settings where HIV-infected pregnant women typically receive potent combination ART, rates of HIV transmission rates are very low (<1%, unadjusted for mode of delivery) and it is difficult to determine whether delivery by cesarean section further decreases the risk of peripartum transmission.

For a woman with a viral load of <1,000 copies/mL, cesarean delivery is not routinely recommended; decisions on mode of delivery

should be individualized and based on discussions between the woman and her obstetric clinician. The woman and her health care providers should decide about mode of delivery before the onset of labor, based on her current viral load, her health status, and the outcome of discussions about other concerns, which should include counseling about the risks and benefits of cesarean delivery. If cesarean delivery is planned for standard obstetrical indications it should be scheduled for 39 weeks' gestation.

For a woman with HIV RNA levels of >1,000 copies/mL at or near the time of delivery, the HHS *Perinatal ARV Guidelines* and the American College of Obstetricians and Gynecologists recommend delivery by scheduled cesarean section at 38 weeks' gestation.

IV ZDV should be started 3 hours before a scheduled cesarean delivery. Prophylactic antibiotics are recommended at the time of cesarean delivery for HIV-infected women to decrease the risk of maternal infection.

It is not clear whether cesarean delivery provides any benefits in preventing perinatal HIV transmission once labor has begun or membranes are ruptured. Management of a woman for whom a scheduled cesarean was planned but who presents in labor or with ruptured membranes should be individualized on the basis of her HIV viral load, current ART regimen, length of time since membrane rupture, duration of labor, and other clinical factors.

The HHS *Perinatal ARV Guidelines* outline several scenarios in which the clinician must decide whether cesarean delivery is needed; see Table 8 of the *Guidelines* for further information. The data on the benefits of cesarean delivery are complex and must be considered alongside the increased risk to the mother after surgery. The clinician should consult an obstetric/HIV specialist to discuss specific situations.

A woman who presents in labor without a documented HIV status should receive an expedited HIV antibody test and, if the result is positive, should be presumed to be infected until the confirmatory HIV test result is received. She should receive IV ZDV immediately to prevent perinatal transmission, and her infant should start infant prophylaxis pending the mother's confirmatory results (see "Follow-Up of HIV-Exposed Infants," below). She will need confirmation and staging of her HIV infection (e.g., CD4 cell count, HIV RNA viral load) as well as referral to care for her own health and ongoing psychological support.

Questions remain about the management of labor when a vaginal delivery is planned. Because the duration of ruptured membranes is a risk factor for perinatal transmission, pregnant women with HIV infection should be counseled to go to a hospital for care at the first signs of labor or rupture of membranes. If the membranes rupture spontaneously before labor occurs or early in labor, the clinician should consider interventions to decrease the interval to delivery, such as administration of oxytocin. Procedures that potentially increase the neonate's exposure to maternal blood, such as the use of scalp electrodes or artificial rupture of membranes, should be avoided. Operative interventions with forceps or vacuum extractor and episiotomy should be performed only in select circumstances.

For management of postpartum hemorrhage owing to uterine atony, note that Methergine has significant interactions with PIs and with NNRTIs, and may interact with the pharmacokinetic booster cobicistat. Methergine should not be administered to women taking PIs, if possible. If alternative treatments are not available and Methergine must be used, it should be given at the lowest possible dosage and for the shortest possible duration. If Methergine is given to women taking NNRTIs, its dosage may need to be increased or additional uterotonic medications may be needed.

Postpartum Follow-Up of HIV-Infected Women

Women with HIV infection who have recently delivered need access to a comprehensive array of services for themselves and their infants. The clinician should refer the postpartum woman not only to her primary obstetric and HIV providers for family planning and HIV management but also to a pediatric HIV specialist for care of her infant. She should be referred as needed for mental health, substance abuse, and social support services. The clinician should be alert for indications of postpartum depression and should offer treatment promptly, if indicated. Adherence to ARV regimens may be particularly difficult for a woman in the immediate postpartum period because of postpartum physical and psychological changes and the demands of caring for a newborn; accordingly, the woman may require new or continued support services.

Women who are diagnosed through preliminary rapid HIV testing in labor will need thorough evaluation and management including confirmatory HIV testing and immediate linkage for medical and social services. They should not breast-feed unless the results of the confirmatory tests are received as negative.

Women should be evaluated regarding their ongoing need and desire for ART postpartum. Long-term ART generally should be recommended for all women, regardless of nadir CD4 count, in accordance with current HHS adult and adolescent guidelines. If ART was given only or primarily to reduce the risk of perinatal transmission, a discussion about continuing ART should include factors such as the woman's health status, her CD4 counts, the HIV status of her partner(s), and adherence issues. If the woman elects to discontinue ART postpartum, her need for treatment and willingness to restart ART should be reevaluated on an ongoing basis.

If ART is being discontinued, all drugs should be stopped at the same time if they have

similar half-lives. NNRTIs have longer half-lives than other agents, so an NNRTI should be discontinued for a period of time (the duration of this time has not been defined) before other ARVs, in order to avoid a period of NNRTI monotherapy and the development of NNRTI resistance mutations. Alternatively, a PI may be substituted for the NNRTI several weeks before stopping all the ARV agents. Note that, for women with HBV coinfection, discontinuation of NRTIs with anti-HBV activity (e.g., 3TC, emtricitabine, tenofovir) may result in a flare of HBV; consult with an expert before discontinuing ART.

Contraceptive counseling is an important aspect of postpartum care. Women should be offered dual-method contraception if pregnancy is not desired in the short-term future or if the ART regimen contains potentially teratogenic drugs such as efavirenz. Note that there are significant interactions between some hormonal contraceptives and PIs, NNRTIs, and elvitegravir/cobicistat. (See chapters *Care of HIV-Infected Pregnant Women* and *Health Care of HIV-Infected Women Through the Life Cycle*.)

Breast-feeding is not recommended in the United States or other parts of the world where replacement feeding is affordable, feasible, acceptable, sustainable, and safe. Women may experience culture-based and family pressure to breast-feed and may need support to use replacement feeding.

Follow-Up of HIV-Exposed Infants

The HIV-exposed neonate born to a mother with HIV infection should receive ZDV syrup at a dose based on the infant's gestational age. Infants at ≥ 35 weeks' gestation infant should be given ZDV syrup at a 4 mg/kg/dose PO BID, beginning as soon as possible after birth, preferably within 6-12 hours, and continuing for 6 weeks. Dosing for premature infants is detailed in the *Guidelines*. In the United States, the use of ARV drugs other than ZDV and NVP

cannot be recommended for premature infants because of lack of dosing and safety data.

Newborns should be discharged home with a supply of PO ZDV syrup. The use of ZDV for the neonate is recommended regardless of whether the mother has a history of resistance to ZDV. Two-drug therapy – specifically, ZDV by standard protocol for 6 weeks plus 3 doses of NVP given at birth, 48 hours later, and 96 hours after the second dose – is recommended for infants of mothers who did not receive ART before delivery or received ZDV only intrapartum. Few data are available to guide use of other combination therapies for neonates; consult with a pediatric HIV expert. Every HIV-exposed infant should be referred to a pediatric HIV specialist for diagnostic testing and monitoring of health status.

For an infant born to a mother whose HIV status is unknown, expedited HIV testing of the mother or the infant should be done as soon as possible. If the result for either is positive, ZDV prophylaxis for the infant should be started immediately. A confirmatory HIV test (e.g., Western blot) should be done at the same time and prophylaxis should be discontinued if the result is negative. If positive, the infant should be tested with an HIV DNA polymerase chain reaction (PCR) assay or an HIV RNA assay. If the newborn's HIV viral load test result is positive, prophylaxis should be discontinued and the infant should be referred urgently to a pediatric HIV specialist for management of HIV infection using combination ART.

Traditional HIV antibody testing cannot be used with infants because maternal antibodies may persist for up to 18 months. Diagnosis of HIV infection in infants requires virologic testing (HIV DNA or HIV RNA). Virologic testing should be performed by age 14-21 days, then at 1-2 months, and at 4-6 months. HIV can be diagnosed in an infant on the basis of two positive results from virologic tests done on separate blood samples at any time.

HIV can be excluded presumptively in an infant with two or more negative results from virologic tests, with one done at ≥ 14 days of age and one done at ≥ 1 month of age, or one negative virologic test result at ≥ 2 months of age, or one negative HIV antibody test result at ≥ 6 months of age. HIV can be excluded definitively with two or more negative virologic test results, with one test done at age ≥ 1 month and one done at ≥ 4 months. However, these tests may not be accurate in infants who are receiving combination ART. Some experts recommend retesting, using an antibody test, at age 12-18 months as a confirmatory test.

Infants should have a baseline complete blood count and differential and should be monitored for anemia while they are taking ZDV. Monitoring for anemia should be based on the infant's gestational age, ZDV dose, clinical condition, and maternal ARV history. Infants on ZDV/3TC prophylaxis should have a hemoglobin and neutrophil count at 4 weeks after initiation of ARVs.

Pneumocystis jiroveci pneumonia (PCP) prophylaxis for HIV-exposed infants is recommended starting at 6 weeks when the ZDV prophylaxis regimen is completed and continued until they are determined presumptively or definitively to be HIV seronegative. Initiation of PCP prophylaxis should be stopped or avoided altogether when HIV has been presumptively excluded.

Parents and family caregivers must be taught how to monitor the infant for signs of illness until an HIV diagnosis is made or ruled out. They also need to know that the infant's exposure to ARV agents in utero is an important part of the infant's medical history and should be shared with future health care providers. Although no enduring consequences of ARV exposure have been confirmed, the child may be at risk of long-term problems.

Patient Education

- The clinician should provide the pregnant woman with the most current information on the risk of perinatal HIV transmission and the importance of ARV prophylaxis.
- The clinician and the patient should have a detailed discussion about ART, both for the patient's own health and for decreasing the risk of perinatal transmission.
- The clinician should review with the patient the critical importance of her adherence to ART regimens before prescribing a regimen.
- The clinician should review possible adverse effects of the ARVs and give the patient specific instructions about managing them if they are mild or seeking medical advice if they are more serious, such as ongoing fatigue, persistent nausea and vomiting, or signs of hyperglycemia.
- The clinician should explain the signs and symptoms of early labor to the patient and emphasize the importance of seeking medical care if she has signs and symptoms of early labor or premature rupture of membranes.
- Early in the third trimester, the clinician and the patient should discuss the risks and potential benefits of cesarean section based on her viral load and clinical status.
- Intrapartum management, including the possible need to use intrapartum ZDV, should be discussed with the patient so that she knows to tell the delivery team about her HIV status when she presents in labor.
- The clinician should discuss infant feeding plans with the mother and reinforce that she should not breast-feed. The clinician may need to provide ongoing support for formula feeding.
- The clinician should advise HIV-infected mothers against premastication of the infant's food and promote safer feeding options.

- The clinician should discuss follow-up plans and make referrals for the patient and her infant. If possible, the woman should meet the pediatric HIV team before delivery or in the postpartum period. The importance of ARV prophylaxis and follow-up for the newborn should be emphasized.

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Care of HIV-Infected Pregnant Women

Background

This chapter describes the elements involved in caring for the pregnant woman with HIV infection, whether the woman was known to be HIV infected before conception or was found to be HIV infected during pregnancy. It is not intended to be a comprehensive discussion of this topic, and an HIV-experienced obstetrician and an HIV specialist should be involved in the management of all HIV-infected pregnant women. For centers that do not have HIV specialists available, experts at the National Perinatal HIV Consultation and Referral Service are available for consultation through the Perinatal HIV Hotline (888-448-8765).

The goals of HIV management during pregnancy are to maintain and support the woman's health, provide optimal antiretroviral treatment (ART) to preserve or restore her immune system and suppress viral replication, and to offer interventions that decrease the risk of perinatal HIV transmission. According to the U.S. Department of Health and Human Services perinatal guidelines, *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*, all HIV-infected pregnant women should be given ART during pregnancy to prevent mother-to-child transmission of HIV, and ART also is recommended for all women for their own health, regardless of pregnancy status (see chapter *Reducing Perinatal HIV Transmission*).

The first task in caring for an HIV-infected woman who is pregnant or considering pregnancy is to provide counseling that will allow her to make informed reproductive choices. Taking a careful reproductive history and providing preconception counseling should be part of any woman's routine primary care. To make informed choices about pregnancy, the patient needs education and information about the risk of perinatal transmission of HIV, potential complications of pregnancy, continuation or modification (or possibly, initiation) of ART, and the support she will need to optimize maternal and fetal outcomes. See chapter *Health Care of HIV-Infected Women Through the Life Cycle* for a more detailed discussion of preconception evaluation.

An appropriate ART regimen should be started before pregnancy to attain a stable, maximally suppressed maternal viral load prior to conception. This will support the woman's own health and greatly reduce the risk of HIV transmission either to a fetus or to a sex partner. Antiretroviral (ARV) resistance testing should be performed before ART is initiated. For women who intend to conceive, particular ARVs should be avoided, including those with increased risk of causing teratogenicity (e.g., efavirenz) or metabolic complications such as lactic acidosis (e.g., didanosine and stavudine). See chapter *Reducing Perinatal HIV Transmission*. It should be noted that most fetal organogenesis occurs in the early weeks of pregnancy, before most women know that they are pregnant. Thus, any medication with potential teratogenicity or fetal toxicity, whether an ARV or another drug, should not be administered to women who intend to become pregnant or may become pregnant. Certain medications (e.g., ribavirin) also should be avoided by male partners of women who may become pregnant.

Folate supplementation to reduce the risk of neural tube defects in the developing fetus should be started at least 1 month before conception, if possible, because the neural tube forms in the early weeks of pregnancy (see below).

Evaluation and Counseling of Pregnant Women

All HIV-infected pregnant women should receive thorough education and counseling about perinatal transmission risks, strategies to reduce those risks, and potential effects of HIV infection or HIV treatment on the course or outcomes of pregnancy.

- The goals of therapy for pregnant women receiving ART, as for all persons being treated for HIV infection, are to suppress the HIV viral load maximally (preferably to undetectable levels) for as long as possible, to improve quality of life, to restore or preserve immune function, and to prevent transmission to sexual (or injection drug equipment-sharing) partners. For pregnant women, an additional, and critical, goal is to reduce the risk of perinatal transmission as much as possible.
- Therapy-associated adverse effects, including hyperglycemia, anemia, and hepatic toxicity, may have a negative effect on maternal and fetal health outcomes. Pregnant women should be advised about possible ARV-related adverse effects and should be monitored regularly for these events.
- HIV-infected women should receive evaluation and appropriate prophylaxis for opportunistic infections (OIs), as well as the vaccinations indicated for persons with HIV infection (see below).
- Some medications, both ARVs and other drugs, may cause fetal anomalies or toxicity when taken during pregnancy. These should be avoided in pregnant women, unless the anticipated benefit outweighs the risk. Consult with an HIV or obstetric specialist, a pharmacist, or the drug labeling information before prescribing medications for pregnant women.
- Options for mode of delivery should be discussed early. The benefits and risks of vaginal vs. cesarean delivery are outlined in the perinatal guidelines. If the HIV viral

load is >1,000 copies/mL at 36 weeks of pregnancy, a scheduled cesarean delivery at 38 weeks' gestation is recommended to further reduce the risk of transmission.

Other evaluation and support measures for pregnant women should include the following:

- Screening for other potential maternal health problems, such as diabetes and hypertension
- Maternal nutritional evaluation and support, including initiation of a prenatal multivitamin containing folate (0.4 mg PO QD) to reduce the risk of fetal neural tube defects; for women receiving trimethoprim-sulfamethoxazole, some experts recommend higher folate doses in the first trimester; consult with an HIV-experienced obstetric specialist.
- Screening for psychiatric and neurologic disease
- Counseling about the risks of tobacco smoking; smoking cessation support as indicated (see chapter *Smoking Cessation*)
- Counseling about the risks of alcohol or drug use and support for discontinuation of these activities as needed
- Intimate partner violence screening
- Review of medications, including over-the-counter and nutritional agents, and discontinuation of medications with the potential for fetal harm
- Immunizations (e.g., influenza, Tdap, hepatitis B) as indicated
- Institution of the standard measures for evaluation and management (e.g., assessment of reproductive and familial genetic history, screening for infectious diseases or sexually transmitted diseases [STDs])
- Planning for maternal-fetal medicine consultation, if desired or indicated
- Selection of effective and appropriate postpartum contraceptive methods, if desired

Comprehensive Care of Pregnant Women with HIV Infection

Comprehensive care is important for pregnant women with HIV infection to achieve a healthy pregnancy and delivery. A multidisciplinary approach is the most effective way to address the medical, psychological, social, and practical challenges. For example, while her medical care is being managed by her obstetrician and an HIV specialist, the pregnant woman may need help from a social worker to find appropriate social services for food, housing, child care, and parenting issues. The pregnant woman may need counseling and psychological support for herself and her partner, as well as referrals for substance abuse and detoxification programs. Peer counselors may be of particular assistance. Some patients may need legal or domestic violence services during and after pregnancy. Cooperation and communication between the obstetrician or nurse/midwife and the primary HIV provider are imperative throughout the pregnancy and early postpartum period. Referral to a maternal-fetal medicine specialist may be needed in complicated obstetric cases.

Prenatal Care

All pregnancy-related complications seen in HIV-uninfected women, such as hypertensive disorders, ectopic pregnancy, psychiatric illness, multiple gestation, preterm delivery, and STDs, also can occur in HIV-infected women. These problems must be recognized quickly and treated appropriately to avoid life-threatening complications. Ideally, HIV-infected pregnant women are managed by both an experienced obstetrician-gynecologist and an HIV specialist. Communication between these specialists about medications, expectations, and complications is vital for the health and well-being of both mother and baby. If complications occur or abnormalities are detected, they should be evaluated and treated as indicated by the condition, and referral should be made to a maternal-fetal medicine specialist, if possible. Antenatal fetal surveillance and testing to identify fetal abnormalities should be carried out using guidelines established by the American College of Obstetricians and Gynecologists.

The suggested testing and monitoring practices for pregnant women with HIV infection, from the first trimester to labor and delivery, are presented in Tables 1 and 2.

Table 1. Recommended Evaluation and Routine Monitoring of the Pregnant Woman with HIV Infection

Evaluation		Frequency
History		
HIV History	Date of diagnosis	Initial
	Signs and symptoms	Initial and at every visit
	Nadir CD4 and current CD4 cell count; HIV viral load	Initial
	ARV history, including regimen efficacy, toxicity, and ARV resistance	Initial
	Opportunistic infections and malignancies	Initial and at every visit
	History of STDs	Initial
	Adherence	Initial and at every visit
Obstetric History	Number of pregnancies; complications and outcomes (GPAL [gravida, para, abortion, living children]); mode of deliveries	Initial
	History of genetic disorders	Initial
	Use of ARV prophylaxis during previous pregnancies	Initial
	HIV status of children	Initial
Current Pregnancy	Last menstrual period (LMP)	Initial
	Pregnancy: intended or not	Initial
	Contraceptive methods used, if any	Initial
	Gestational age (can be calculated in a woman with regular menses by counting weeks from LMP)	Initial and at every visit
	Estimated date of delivery	Initial
	Signs or symptoms of maternal complications: elevated blood pressure, headache, significant edema, gastrointestinal or genitourinary symptoms, vaginal discharge or bleeding, decreased fetal movement (fetal movement is usually first detected at 18-24 weeks of pregnancy)	Initial and at every visit
	Screen for depression	Initial
	Screen for intimate-partner violence	Initial and at every visit

Evaluation		Frequency
Physical Examination		
General	Vital signs and weight	Initial and at every visit
	Funduscopy, breast examination	Initial and as indicated
Gynecologic/ Obstetric (usually performed by the obstetric provider)	Pelvic examination, STD screening, examination for perineal or vaginal lesions (discoloration, condyloma, ulcerative lesions, vaginal discharge), cervical lesions, discharge or bleeding	Initial and as indicated
	Fundal height, correlating with gestational age (concordant between 18 and 30 weeks)	Every visit starting the second trimester
	Fetal heart beat and rate: may be audible with Doppler devices as early as 12 weeks	Initial and at every visit
	Fetal movements and position in third trimester	Every visit starting at 24 weeks
Laboratory and Other Studies		
HIV	HIV antibody test (if not already documented)	Initial
	HIV viral load and CD4 count (total and percentage); results obtained at 35-36 weeks guide decisions on the mode of delivery	Viral load at initial visit, 2-4 weeks after starting or changing ART, every 4 weeks until undetectable, then at least every 3 months CD4 count at initial visit and at least every 3 months
	Genotype if ARV naive or detectable HIV RNA while on ART	Initial and as indicated
	Cytomegalovirus (CMV) immunoglobulin G (IgG)	Initial
	<i>Toxoplasma</i> IgG	Initial
	G6PD level in appropriate ethnic or racial groups if PCP prophylaxis with dapsone is anticipated	Initial
General	Complete blood count (CBC)	Initial and every 3 months or more frequently, based on ARV regimen or symptoms; check weeks 24-28
	Chemistries, liver enzymes (LFTs)	Initial and every 3 months or more frequently, based on ARV regimen or symptoms If on NRTIs, monitor electrolytes and hepatic enzymes monthly in third trimester
	Fasting lipids and glucose	Initial and as indicated
	Blood group	Indicated
	Rh antibody screen	Indicated

	Evaluation	Frequency
Pregnancy Specific	Ultrasound	First trimester: confirm gestational age and potential timing for cesarean delivery if necessary Second trimester: assess fetal anatomy for women on combination ART during first trimester
	Screening for chromosomal abnormalities	Screen for neural tube and abdominal wall defect, trisomy 21, and trisomy 18; first-trimester testing may include laboratory and ultrasound exam, whereas patients in their second trimester are evaluated by multiple marker screening Abnormal result requires further investigation – consider amniocentesis only if abnormality is detected on multiple marker screening or level-2 sonogram and the woman is on suppressive ART (to decrease risk of HIV transmission); voluntary and requires counseling
	Diabetes screening	Consider at 20 weeks; check glucose 1 hour after 50 g glucose load; perform 3-hour glucose tolerance test if screen is abnormal If 3-hour test result is abnormal, perform regular glucose monitoring, especially in women taking protease inhibitors (PIs)
	Rubella antibody	Initial
	Varicella IgG for those without history of chickenpox or shingles	Initial
	Screening for syphilis: rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL)	Initial and during weeks 32-36
	Consider bacterial vaginosis (BV) screening (BV increases risk of preterm labor)	Week 24-28
	Screening for streptococcus B (if result is positive, intrapartum chemoprophylaxis is indicated)	Week 32-36
	Screening with herpes simplex virus-2 serology in high-risk patients is recommended by some experts	Initial
	Urinalysis and clean-catch urine culture	Initial and as indicated
	Papanicolaou test	Initial and as indicated (colposcopy is done on pregnant women, but biopsy is avoided; management resumes postpartum, after the 6-week postpartum visit)

	Evaluation	Frequency
Hepatitis Serologies	Hepatitis A virus (HAV) antibody (IgG)	Initial
	Hepatitis B virus (HBV): HBsAg, HBcAb , HBsAb	Initial
	Hepatitis C virus (HCV) antibody	Initial
TB Screening	Tuberculin skin test (purified protein derivative [PPD]), more reliable if CD4 count is >200 cells/ μ L (induration >5 mm is positive); or interferon-gamma release assay (IGRA); note there is limited experience with IGRAs in pregnant women	Initial
Disease Specific	Consider hemoglobin electrophoresis, if anemic or at increased risk of hemoglobinopathies	Initial
	Serum screening for Tay-Sachs disease – both partners – if at increased risk	Initial
	Urine toxicology screen	Initial and as indicated

Table 2. Recommended Evaluation and Routine Monitoring of the Pregnant Woman with HIV Infection: Labor and Delivery

Test	Comment
Record Review	- Documentation of HIV serostatus, blood type and Rh, hepatitis serologies, RPR - Review of ART, if any, during pregnancy - Review of HIV viral load results during pregnancy
Physical Evaluation	- Vital signs and fetal heart rate - Frequency and intensity of contractions - Fetal lie, presentation, attitude, and position - Vaginal examination: rule out HSV lesions; detect ruptured membranes; determine cervical effacement, dilatation, and position - Avoid procedures that increase risk of perinatal HIV transmission (e.g., fetal scalp electrodes, scalp sampling, or assisted rupture of membranes)
Admission Laboratory Tests	- Complete blood count - Liver function tests - RPR or VDRL, if not done recently - Repeat hepatitis B and C testing, if at risk of acquisition of hepatitis B or C, to prevent perinatal transmission of these infections - Others, as required by specific state laws

Immunizations and Opportunistic Infection Prophylaxis

Immunizations During Pregnancy

Generally, immunizations should be given before pregnancy, if possible. However, immunizations should be considered during pregnancy when the risk of exposure to an infection is high, the risk of infection to the mother or fetus is high, and the vaccine is unlikely to cause harm. The inactivated influenza virus and Tdap vaccines both meet this criteria and are generally recommended during pregnancy, as are certain others (see Table 3). Some vaccinations (particularly live-

virus vaccines such as measles/mumps/rubella and varicella vaccines) are contraindicated, and others should be given only if the anticipated benefit of the vaccination outweighs the risk. Special considerations for immunizations in HIV-infected individuals are discussed in chapter *Immunizations for HIV-Infected Adults and Adolescents*.

Because vaccinations may cause a transient increase in the HIV viral load and theoretically may increase the risk of perinatal HIV transmission, vaccination should be given after pregnant women are on ART.

Table 3. Immunizations and Postexposure Prophylaxis in Pregnant Women with HIV Infection

Immunization	Comment
Hepatitis A virus (HAV)	Recommended for susceptible patients at risk of becoming infected, those with chronic HBV or HCV, those traveling to endemic areas, injection drug users, and those in the setting of a community outbreak.
Hepatitis B virus (HBV)	Generally recommended for susceptible patients at risk of HBV infection during pregnancy.
Human Papilloma Virus (HPV)	Not recommended during pregnancy.
Influenza	Inactivated influenza vaccine is recommended for all pregnant women, before or during flu season. Live attenuated vaccines should not be used.
Measles/Mumps/Rubella (MMR)	Contraindicated.
Pneumococcus	Generally recommended. Limited data on safety during pregnancy for both the PPSV23 and PCV13 vaccines: no reports of adverse effects with PPSV23; limited experience with PCV13.
Tetanus-diphtheria-pertussis (Tdap)	Recommended during each pregnancy. Can be given at any time in pregnancy, but optimally between 27 and 36 weeks' gestation (to maximize maternal antibody response and passive antibody transfer to the infant). In addition, family members and caregivers should receive Tdap vaccination.
Varicella • Primary vaccination • Zoster vaccination	Contraindicated

Immunization	Comment
Immune globulins (for postexposure prophylaxis in susceptible individuals)	
Measles	Recommended after measles exposure.
Hepatitis A	Recommended after exposure (close contact or sex partner), or in case of travel to endemic areas.
Varicella-zoster virus immune globulin (VariZIG)	Recommended for susceptible individuals after close contact with someone with varicella or herpes zoster (give as soon as possible, and within 10 days of exposure).
Hepatitis B immune globulin (HBIG)	Recommended for susceptible individuals after needlestick or sexual exposure to a person with hepatitis B infection.

Opportunistic Infection Prophylaxis

Some OIs can have an adverse effect on pregnancy. In turn, pregnancy can affect the natural history, presentation, treatment, and significance of some OIs. Women should be monitored carefully for OIs during pregnancy, with special attention given to nonspecific symptoms such as fatigue, back pain, and weight loss, which may be attributable to HIV-related illness rather than to pregnancy. Respiratory symptoms in particular merit rapid, aggressive investigation. Clinicians should follow the most current recommendations of the U.S. Centers for Disease Control and Prevention (CDC), National Institutes of Health, and Infectious Diseases Society of America, *Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*, which give special consideration to pregnant women for each OI discussed. The indications and recommendations for OI prophylaxis generally should follow the guidelines for adults (see chapter *Opportunistic Infection Prophylaxis*). However, because of the risks of teratogenicity or harm to the developing fetus, some drugs routinely used for prophylaxis of OIs in nonpregnant adults are contraindicated during the first trimester of pregnancy, whereas others should not be used at any time during pregnancy.

Special Considerations for OI Prophylaxis During Pregnancy

Trimethoprim-sulfamethoxazole use

In pregnant women, folate deficiency increases the risk of neural tube defects in the developing fetus. Trimethoprim inhibits the synthesis of metabolically active folic acid and thus increases the risk of folate deficiency and congenital anomalies. Pregnant women, or women who may become pregnant, who are taking trimethoprim-sulfamethoxazole (TMP-SMX, Septra, Bactrim, cotrimoxazole) should be given folate supplementation to reduce the risk of neural tube defects. However, folate also counteracts the activity of TMP, and may compromise the therapeutic efficacy of TMP-SMX. The recommended dosage of folic acid usually is 0.4 mg/day, but the optimal dosage in women on TMP-SMX is not clear. Some experts recommend higher dosages during the first trimester, when the fetus is at greatest risk for teratogenic effect. TMP-SMX is the recommended drug for women who require prophylaxis against PCP during pregnancy; alternatives to TPM-SMX during first trimester include aerosolized pentamidine and atovaquone.

Genital herpes

Women with HIV infection are more likely than HIV-uninfected women to experience outbreaks of genital herpes. If HSV is transmitted to the infant, neonatal infection can be severe, even if it is detected and treated early. In addition, there is increased genital shedding of HIV in those with active genital HSV lesions though it is not known whether this remains true in women treated with effective ART. Some experts recommend obtaining HSV-2 serologies in a woman whose clinical history is unclear. Treatment for symptomatic HSV infections should be offered during pregnancy, and suppressive therapy should be given to women with frequent recurrences. Suppressive therapy with acyclovir or valacyclovir also should be offered to any woman with an HSV recurrence during pregnancy, starting at 36 weeks' gestation. If a woman has an active outbreak of genital HSV or experiences prodromal symptoms at the time of labor or membrane rupture, delivery by cesarean section is indicated. Prophylaxis for pregnant women who are seropositive for HSV-2 but who do not have a history of genital lesions is not recommended.

Tuberculosis

Prophylaxis is recommended for any woman with a positive PPD skin test result (≥ 5 mm induration), a positive IGRA result, or a history of exposure to someone with active tuberculosis, after active disease has been ruled out. Patients receiving isoniazid also should receive pyridoxine to reduce the risk of neurotoxicity.

Toxoplasmosis

All HIV-infected persons should be tested for IgG antibodies to *Toxoplasma* soon after HIV diagnosis, and this should be a part of antenatal testing for pregnant women with HIV infection. Women with a negative IgG titer should be counseled to avoid exposure to *Toxoplasma* (e.g., by avoiding raw or undercooked meats, unwashed or uncooked

vegetables, and cat feces). Women with previous exposure to *Toxoplasma* (positive IgG titer) should be given prophylaxis during pregnancy, if the CD4 count is <100 cells/ μ L. For women who require prophylaxis, TMP-SMX is the preferred agent (see considerations for TMP-SMX, above).

HIV-infected pregnant women who have evidence of primary or reactivated *Toxoplasma* infection should be managed by a specialist.

Antiretroviral Therapy

The current HHS guidelines recommend treating HIV infection in all pregnant women, using the same principles and modalities as used for nonpregnant individuals. HIV-infected pregnant women should receive potent combination ART regimens comprising at least three ARVs. The choice of ARV regimen should be based on what is likely to be optimal for the woman's health, the potential effect on the fetus and infant, resistance test results, the woman's previous experience, if any, with ART, and her stage of pregnancy. ARV resistance testing should be performed before initiating or changing therapy, but should not delay the initiation of ART in late stages of pregnancy. Combination ART in pregnancy should include ZDV or another NRTI with good placental passage. ARV agents with potential teratogenic effects should be avoided in the early weeks of pregnancy (however, efavirenz may be continued during pregnancy, provided the regimen is tolerated and is providing effective virologic control). Women who have very high CD4 cell counts and are taking ART only for the prevention of perinatal transmission may delay initiation of therapy until after the first trimester, though effectiveness in preventing transmission may be decreased. For women already taking ART at the time they become pregnant, the regimen should be reevaluated for its appropriateness during pregnancy to avoid potentially toxic medications and to ensure maximal virologic

suppression. Generally, any ART regimen that is effective and tolerated by the woman may be continued during pregnancy. If necessary, the ART regimen may be changed but therapy should continue without interruption.

Discontinuation of ART could lead to an increase in viral load, which could result in a decline in immune status and an acceleration of disease progression, thereby increasing the risk of HIV transmission to the fetus.

For further information about ART during pregnancy, see chapter *Reducing Perinatal HIV Transmission* and the HHS *Perinatal ARV Guidelines*. The guidelines include recommendations regarding ARV regimens, modes of delivery (vaginal vs. cesarean section), and potential adverse events, as well as a detailed discussion of individual ARV agents. Additionally, the treatment of pregnant women with HIV/HBV coinfection and HIV/HCV coinfection is discussed.

Antiretroviral Pregnancy Registry

To improve tracking of pregnancy-related adverse events and fetal effects, an Antiretroviral Pregnancy Registry has been established as a collaborative project among the pharmaceutical industry, pediatric and obstetric providers, the CDC, and the National Institutes of Health. The registry collects observational data on HIV-infected pregnant women taking ARV medications to determine whether patterns of fetal or neonatal abnormalities occur. Pregnant women taking ARVs can be placed in this confidential follow-up study by calling 800-258-4263, 8:30 a.m. to 5:30 p.m. eastern time; the fax number is 800-800-1052. Information is confidential and patients' names are not used. Providers are encouraged to add to the available information on fetal risk by using this registry at first contact with a pregnant woman receiving ART. More information can be obtained at www.APRRegistry.com.

Pregnancy-Specific Complications and Management

Nutrition risk and inadequate weight gain

Maternal nutrition and weight must be monitored throughout the pregnancy. A food diary may be a useful tool in assessing intake, and nutritional counseling is recommended.

Nausea and vomiting

Women with signs of dehydration should be assessed and treated appropriately in collaboration with the obstetrician or nurse/midwife. Any medication used for nausea and vomiting must be assessed for drug-drug interactions with all HIV-related medications the patient is taking.

Hyperglycemia

Pregnancy is a risk factor for hyperglycemia, and women treated with PIs may have an even higher risk of glucose intolerance than other pregnant women and must be monitored carefully. New-onset hyperglycemia and diabetes mellitus, and exacerbation of existing diabetes, all have been reported in patients taking PIs. Clinicians should educate women taking PIs about the symptoms of hyperglycemia and closely monitor glucose levels. Women with HIV-infection should receive standard glucose screening at 24-28 weeks' gestation. Women who were taking a PI-based regimen prior to pregnancy may be screened earlier according to recommendations for women at high risk of glucose intolerance. The newborn should be checked for neonatal hypoglycemia at 1 and 4 hours after birth.

Lactic acidosis

Lactic acidosis is a rare but life-threatening complication that has been reported in pregnant women taking nucleoside reverse transcriptase inhibitors, particularly didanosine and stavudine. The combination of didanosine and stavudine should be avoided during pregnancy. Clinical suspicion

of lactic acidosis should be prompted by vague symptoms such as malaise, nausea, or abdominal discomfort or pain.

Hyperbilirubinemia

Women taking atazanavir or indinavir frequently develop elevated indirect bilirubin, but it is not known whether treatment during pregnancy exacerbates physiologic hyperbilirubinemia in newborns. Women who are taking indinavir may have an increased risk of nephrolithiasis, but evidence of harm to their newborns has not been demonstrated. Indinavir should be used during pregnancy only when preferred and alternative agents are not acceptable, and it must be boosted with low-dose ritonavir.

Pain management

Pain management during labor and delivery may be complicated by drug interactions with ARV agents and by the higher medication tolerance in women who have addictions. Additional pain medication may be needed for women with histories of drug use.

Invasive perinatal procedures

The risk of HIV transmission to the fetus during invasive procedures (e.g., amniocentesis, chorionic villus sampling, and percutaneous or umbilical cord blood sampling) must be weighed carefully against the possible benefits of these procedures. Current HHS guidelines suggest that women undergoing such procedures should be on effective ART, preferably with undetectable HIV RNA. The use of fetal scalp electrodes and artificial rupture of membranes should be avoided if possible, and forceps or vacuum extractors and episiotomy should be used only if there are clear obstetric indications.

Postpartum considerations

Because HIV can be transmitted to the infant through breast-feeding, breast-feeding is contraindicated in the United States and other resource-adequate countries where safe

replacement feeding is available. Breast-feeding information should be removed from patient educational material pertaining to labor and delivery. Lactation suppression techniques can be used as needed to reduce lactation discomfort. Clinicians should recognize that women in some cultural groups are expected to breast-feed and they may need additional support to use formula rather than breast-feed.

ART should be continued, unless the woman refuses ARVs. Maternal and infant medication adherence must be discussed with the new mother. Adherence barriers for the mother during the postpartum period may be different from those during pregnancy (e.g., because of changes in daily routine, sleep/wake cycles, and meals).

New mothers should be observed carefully for signs of bleeding or infection.

If the mother's glucose tolerance test result was abnormal during pregnancy, she should be reevaluated 6-12 weeks postpartum and should be screened yearly for diabetes.

At the infant's 2-week follow-up visit, the HIV pediatric clinician should address the mother's concerns, screen for postpartum depression, assess adherence to her own and the infant's ARV medications, and ensure follow-up for the 6-week postpartum visit with the obstetric provider and soon thereafter with the primary HIV care provider. These visits provide an opportunity to address the woman's contraceptive needs and options, if this was not done previously (see chapter *Health Care of HIV-Infected Women Through the Life Cycle*).

Contraception

Many contraceptive choices are available for HIV-infected women; considerations are discussed in chapter *Health Care of HIV-Infected Women Through the Life Cycle*. Consistent condom use should be emphasized, and for women who wish to avoid pregnancy a "dual-protection" strategy, condom use plus another method of birth control, should be

emphasized. This strategy effectively prevents pregnancy, prevents transmission of HIV to sex partners, and prevents the acquisition of sexually transmitted diseases. It is important to provide women with all contraceptive options including long-acting reversible contraceptive methods such as the intrauterine device and implants.

Patient Education

- Reinforce regularly and clearly the notion that, when the mother cares for herself, she is caring for her infant. Talk with the patient about stress, the importance of adequate mild-to-moderate exercise, and sufficient rest.
- Emphasize that regular prenatal care is extremely important to prevent complications of pregnancy.
- Use of a prenatal vitamin supplement is important, but cannot replace healthy food intake. Develop a plan with the patient for attaining the desired weight gain during pregnancy, while maintaining a healthy nutritional intake.
- Cigarette, alcohol, and drug use contribute to poor maternal nutrition and can harm the developing fetus. Illicit drug use increases the risk of transmitting HIV to the infant. Injection drug use can transmit HBV, HCV, and CMV to the mother and to the baby. Encourage cessation of cigarette, alcohol, and drug use, and offer referrals for treatment, as needed.
- Be sure the woman understands all planned procedures and treatments and understands their potential risks and benefits both to herself and to the fetus.
- Discuss the risks and benefits (to the woman and fetus) of each medication to be taken during pregnancy, including those for which there are limited data on teratogenicity.
- Discuss ART as a benefit to the woman's health and as part of the strategy to reduce the risk of perinatal HIV transmission to the fetus or newborn. Also discuss the effect of ART on reducing risk of HIV transmission to sex partners.
- For women at risk, diligent use of “safer sex” during pregnancy is important for preventing infection with STDs and CMV, which can cause more complications when HIV is present. STDs can harm fetal development and may increase the risk of HIV transmission to the baby. New genital herpes infections during pregnancy can cause severe complications and even death in neonates.
- For women with negative *Toxoplasma* titers, explain the need to avoid undercooked meat, soil, and cat feces.
- Teach the pregnant woman how to obtain medical attention quickly at the first signs of OI or other complication. Discuss what to watch for and how to get help when emergencies arise in the evenings or on weekends or holidays.
- Help the patient clarify her child care options and support systems for raising a family.

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Health Care of HIV-Infected Women Through the Life Cycle

Background

Women with HIV infection have the same reproductive and life cycle health needs and concerns as women without HIV infection. However, for women with HIV infection, certain gynecologic problems may be more common or more frequent. In addition, issues regarding antiretroviral therapy (ART), contraception, and preconception counseling require special attention. This chapter addresses some of the unique health care needs of HIV-infected women across the lifespan, from menarche through postmenopause, and describes the essential elements of care. For further information, see chapters *Reducing Perinatal HIV Transmission*, *Care of HIV-Infected Pregnant Women*, and *Antiretroviral Medications and Hormonal Contraceptive Agents*.

Epidemiology and Factors Affecting HIV Transmission

Heterosexual transmission of HIV is more efficient from man to woman than from woman to man. Transmission can occur through intact vaginal tissue; no damage to the vaginal lining is required. Women have specific risks of HIV acquisition at different phases of the lifespan:

- Young adolescents have immature genital tracts and increased cervical ectopy (increased vulnerability to HIV and other sexually transmitted diseases [STDs])
- Women of reproductive age may desire pregnancy and childbearing (potentially increasing risky sexual behaviors)
- Married or partnered women may be monogamous with male partners who have risk factors for HIV infection (women may lack awareness of partner's risk behaviors)
- Postmenopausal or posthysterectomy women may have vaginal atrophy (decreasing the anatomic barrier to HIV), or may have no fear of pregnancy or have a perception that they are at low risk of infection (increasing risky sexual behaviors)
- Additionally, woman-to-woman transmission may occur if risk factors are present

Psychosocial/Emotional Factors Unique to Women

Women may inherit social roles and responsibilities as caretakers for extended family members and often for friends, and may not give sufficient priority to their own medical care. Furthermore, heterosexual women frequently are faced with unequal power and socioeconomic relationships with their male partners. These women may be more likely to exchange sex for money, less likely to successfully negotiate protected sex, and less likely to leave a relationship they perceive as risky. They may be fearful about disclosing their HIV status.

Sexual abuse appears to increase the risk of HIV transmission to HIV-uninfected women. For HIV-infected women, intimate partner violence and sexual coercion appear to occur at about the same rates as for HIV-uninfected women (>60% in one review). However, HIV-infected women appear to be subjected to more frequent and more severe abuse. HIV-infected women should be screened for intimate partner violence and referred to intervention services, if indicated. The U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force recommend several screening tools (see "References," below). The Abuse Assessment Screen (AAS) is one tool recommended by the

CDC. It originally was intended for screening pregnant women but has since been used more widely.

Abuse Assessment Screen

- Have you ever been emotionally or physically abused by your partner or someone important to you?
- Within the last year, have you been hit, slapped, kicked, or otherwise physically hurt by someone? If yes, by whom? How many times?
- Since you have been pregnant, have you been hit, slapped, kicked, or otherwise physically hurt by someone? If yes, by whom? How many times and where?
- In the last year, has anyone forced you to have sexual activities? If so, whom? How many times?
- Are you afraid of your partner or anyone you listed above?

ART Issues Particular to Women

In general, women on ART have virologic and immunologic responses comparable to those of men; however, several studies have shown that women discontinue ART more frequently than men. Women have higher rates of adverse effects from a number of antiretroviral (ARV) medications, in part because serum levels of at least some ARVs are higher in women. Pregnancy may require changes in ART, either because of pharmacokinetic changes or because of toxicity. See Table 1.

Table 1: Special Considerations for Use of Antiretrovirals with Women

ARV Issues for Women	Considerations
ARV adverse effects	Some ARV adverse effects may be more severe in women: • Abacavir hypersensitivity • Anemia (zidovudine) • Bone loss, especially after menopause • Hepatotoxicity (nevirapine) • Lactic acidosis (particularly with stavudine + didanosine) • Lipoaccumulation: central fat accumulation in breasts, abdomen; lipoatrophy: face • Neuropathy (stavudine, didanosine) • Severe rash (nonnucleoside reverse transcriptase inhibitors [NNRTIs], darunavir, tipranavir)
Pregnancy	Teratogenicity: • Efavirenz (EFV) is associated with neural tube defects in primates with in utero exposure. Consider alternatives, if feasible, in women who 1) are planning to become pregnant or 2) are sexually active with male partners and not using effective contraception. In women who become pregnant while taking EFV, EFV may be continued because the risk of neural tube defects is restricted to the first 5-6 weeks of pregnancy and pregnancy is rarely recognized before 4-6 weeks of pregnancy. Efavirenz is classified by the U.S. Food and Drug Administration (FDA) as a Pregnancy Category D drug. Pharmacokinetic (PK) changes: • Serum levels of some ARVs may be decreased during pregnancy (e.g., unboosted protease inhibitors [PIs], and boosted PIs including atazanavir/ritonavir, darunavir/ritonavir, and lopinavir/ritonavir). • Some ARVs should be avoided and certain ARVs may require dosage adjustment in the third trimester. • PK studies in pregnancy are not available for some ARVs. See chapter <i>Reducing Perinatal HIV Transmission</i>
Contraception	There are significant interactions between some hormonal contraceptive agents and certain ARVs; see “Contraception,” below.

Baseline Reproductive History

Taking a careful reproductive history should be a part of routine primary care for any woman. Important information to gather includes the following:

- Age of menarche
- Menstrual history: last menstrual period (LMP), amenorrhea, menstrual irregularity, uterine fibroids, endometriosis
- Obstetrical history: G-P-A-L
- G (gravida, or number of pregnancies), P (parity, or number of births), A (abortion; number of miscarriages or terminations), L (number of living children)
 - Pregnancy complications and outcomes: full-term, premature births, mode of deliveries
 - Use of ART during pregnancy
 - HIV status of children
- Sexual activity: vaginal, oral, anal; condom use; number of partners; sex of partners; HIV status of partners
- Plans and desires for childbearing
- Contraception, past and current
- Date of last Papanicolaou (Pap) test and results; history of abnormal Pap test results
- Gynecologic procedures: colposcopy/biopsy, loop electrosurgical excision procedure (LEEP), cervical surgery, tubal ligation, partial or total hysterectomy; and indication for these

- History of STDs, bacterial vaginosis, vulvovaginal candidiasis, herpes, warts; especially recurrence
- Current symptoms: vaginal discharge, vulvar/vaginal/anal pain, dysuria, dyspareunia (pain with intercourse), lesions, intermenstrual bleeding, postcoital bleeding

Elements of Gynecological Care

Women with HIV infection should receive routine screening for gynecologic cancers and infections. The incidence, prevalence, and persistence of human papillomavirus (HPV) infection and cervical, vaginal, vulvar, and anal dysplasia are more common in women with HIV infection, especially among women with low CD4 counts. It is not clear that initiation of suppressive ART improves clinical outcomes of women with dysplasia (see chapter *Cervical Dysplasia*). Other common gynecological problems include recurrent yeast vaginitis, pelvic inflammatory disease; vaginal, vulvar, and anal warts; and perineal/perianal herpes.

Women also should be evaluated for risk of breast cancer, for contraceptive needs, and for preconception counseling

Table 2: Routine Gynecologic Screening and Counseling for Women

Medical Service	Comments
Cervical and anal cancer screening	Women with HIV infection should have more frequent screening than uninfected women: • Screen all HIV-infected women for cervical cancer (cervical Pap test) at initial visit, at 6 months, then annually unless abnormal. • For HIV-infected women (any age) with ASCUS or higher-grade abnormality, colposcopy generally is recommended; alternatively, the Pap can be repeated in 6-12 months. • Consider anal cancer screening (anal Pap test) for all HIV-infected women if high resolution anoscopy is available to evaluate abnormal findings. • See chapters <i>Cervical Dysplasia</i> and <i>Anal Dysplasia</i> • Perform pelvic examination. • Include vulvar and anal examination • Assess for potentially dysplastic lesions • CDC recommendations for HPV vaccination of children and young women should be followed.
STD screening	Gonorrhea, chlamydia, syphilis at least annually, and more frequently depending on risk factors or symptom exam findings
Breast cancer screening	Mammography • Mammogram every 1-2 years recommended for women 50-69 years of age • Consider annual mammogram for women 40-50 years of age • Consider starting earlier if risk factors are present • For women ≥ 70 years of age, decisions about whether to continue screening should take into account the woman's life expectancy and clinical status Clinical breast examination • Annually • Breast self-examination (BSE) monthly (assess technique)
Contraceptive counseling	• Assess life dynamics and need for contraception at every visit. • Stop only after hysterectomy or sterilization. • See "Contraception," below.
Preconception counseling	Annually or more often for all women of reproductive age • Ask about pregnancy desires at every visit • See "Preconception Counseling," below

Contraception

Many contraceptive choices are available for HIV-infected women; some considerations are presented in the table below. For more information about interactions between ARVs and hormonal agents, see chapter *Antiretroviral Medications and Hormonal Contraceptive Agents*. Depending on the woman's (and her partner's) risk factors, consistent condom use should be emphasized, with or

without other methods of contraception, to prevent the transmission of HIV and the acquisition or transmission of other STDs. Dual contraception (e.g., use of condoms plus additional contraception) is the optimal contraceptive strategy for serodiscordant heterosexual couples since it reduces the risk of transmission of HIV and other STDs as well as providing effective contraception.

Table 3: Advantages and Disadvantages of Various Contraceptives

Contraceptive Type	Advantages	Disadvantages
Barrier Methods		
Male and female condom	Only contraceptive method that also protects against transmission of HIV and STDs	- Requires partner cooperation and correct technique - High failure rate when used incorrectly or inconsistently
Diaphragm and cervical cap		- Requires correct technique - High failure rate when used incorrectly or inconsistently - Use of diaphragms with spermicide can disrupt the cervical mucosa, which may increase risk of HIV transmission to uninfected sex partners
Hormonal Methods*		
Oral	- Very effective contraception if used as prescribed - Lighter menstrual flow	- Do not prevent STD or HIV transmission - May have significant drug-drug interactions with PIs, some NNRTIs, and elvitegravir/cobicistat that may affect the efficacy and toxicity of estradiol or the progestin, and of certain PIs* - Alternative or additional methods recommended for women taking certain PIs or NNRTIs, or elvitegravir/cobicistat.
Injectable depot medroxyprogesterone acetate (DMPA, Depo-Provera)	- Effective contraception for 3 months - May cause amenorrhea	- Concern about osteoporosis with long-term use - Irregular bleeding, especially initially - Weight gain - Limited and conflicting data show possible increased risk of HIV transmission (from HIV-infected woman to male partner) or acquisition (by uninfected woman from HIV-infected man) for women on DMPA (note: no study participants were on ART)
Transdermal (patch)	- Effective contraception if used as prescribed - Lighter menstrual flow	No data on pharmacokinetic interactions with ARVs, but of possible significance; use same precautions as with oral hormonal agents (see above)
Vaginal ring	Effective contraception if used as prescribed	- Lighter menstrual flow - No data on pharmacokinetic interactions with ARVs, but of possible significance; use same precautions as with oral hormonal agents (see above)
Intrauterine devices (IUDs) (copper IUD and levonorgestrel-containing IUD)	- Effective for long-term use - No evidence of increased HIV viral shedding - Progestin-releasing IUD may cause lighter menstrual flow	- Possible blood loss with Copper T IUD - Insertion of IUD not recommended for women with advanced immunosuppression
Etonogestrel implant	- Effective - Amenorrhea	No data on pharmacokinetic interactions with ARVs, but of possible significance; Use same precautions as with oral hormonal agents (see above)

Contraceptive Type	Advantages	Disadvantages
Emergency contraception: - Levonorgestrel - Ulipristal acetate - Copper T IUD	- Effective - Appropriate for women who present 4-5 days after intercourse	- Efavirenz lowers levonorgestrel levels; use alternative method - No data on pharmacokinetic interactions with ARVs, but of possible significance; use same precautions as with oral hormonal agents (see above) - Heavy blood loss
Surgical Methods		
Bilateral tubal ligation (female)	Effective; permanent	- Does not prevent transmission of HIV or other STDs - No future fertility (usually not reversible)
Vasectomy (male)	Effective; permanent	- Does not prevent transmission of HIV or other STDs - No future fertility (usually not reversible)
Spermicides		
Spermicides		- Not currently recommended - Nonoxynol-9 causes mucosal damage to vagina - Do not prevent transmission of HIV or other STDs

* See chapter *Antiretroviral Medications and Hormonal Contraceptive Agents* and Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Preconception Counseling

As discussed above, every visit with an HIV-infected woman in her reproductive years presents an opportunity to discuss pregnancy desires and options, including gathering information about her partner. It is important to assess the couple's sexual history, sexual decision making, and control of reproductive options. The goals of preconception counseling are to improve the health of the woman prior to conception and identify, and when possible intervene around, risk factors for adverse maternal and fetal outcomes. When a woman desires pregnancy, it is important to discuss the topics listed below, with the goals of educating her and decreasing risk of HIV transmission to an HIV-uninfected partner or to the fetus. Ideally, the partner will take part in the discussion.

- Options for conception that decrease risk of HIV transmission to an HIV-uninfected partner (see below)
- Recommendations for ART before and during pregnancy, at delivery, and postpartum

- Optimization of maternal health status and suppression of HIV viral load before pregnancy
- Effect of HIV and ARVs on pregnancy and outcomes
- Effect of non-HIV-related factors (e.g., age, drug use) and other medical conditions (e.g., hypertension, diabetes, depression) on pregnancy course
- Counseling on safer sexual practices
- Counseling on other aspects of health promotion (e.g., smoking and alcohol cessation, drug treatment)
- Perinatal HIV transmission risk and prevention: ARVs for mother and infant, mode of delivery, avoidance of breast-feeding
- Treatment and care of an HIV-exposed or HIV-infected infant
- Long-term planning including advance directives and guardianship of a child if one or both parents were to become ill or die

Any history of infertility or low fertility in either the patient or her partner should be

evaluated and options for having children should be discussed, including current information on gamete donation, other assisted reproductive techniques, and adoption.

If the heterosexual couple is serodiscordant, techniques to minimize the risk of transmission to the uninfected partner should be discussed. These same techniques should be explained to couples when both partners are HIV infected, if there is a risk of transmitting different HIV “strains.” Some of the recommended techniques include the following:

- If the male partner is HIV uninfected: the woman does self-insemination of ejaculate using a syringe (no HIV exposure risk to the male partner)
- Maximal suppression of the HIV viral load of the infected partner with ART
- Screening for and treatment of STDs
- Assisted reproductive technology
 - Sperm washing with polymerase chain reaction (PCR) testing and intrauterine insemination (IUI), in vitro fertilization (IVF), or intracytoplasmic sperm injection (ICSI), if the male partner is HIV infected and the female partner is HIV uninfected

The couple should be fully educated about other options, including the following:

- Preexposure prophylaxis (PrEP) for the uninfected partner
- Estimating the time of ovulation and limiting unprotected intercourse to this period, with or without use of PrEP. This approach should be considered only if HIV viremia is maximally suppressed and intercourse is limited to times when conception is most likely.
- Postexposure prophylaxis for an uninfected partner

The CDC has issued interim guidelines on use of PrEP by heterosexually active individuals as well as a fact sheet on PrEP (see “References,”). Both address the use of PrEP during attempts to conceive. Few clinical data are available at this time to guide practice; when treating serodiscordant couples who wish to conceive using PrEP, providers should review current guidelines and consult with experts in the field.

If an HIV-infected woman who is considering pregnancy initiates ART, an appropriate regimen should be started before pregnancy, avoiding agents with increased risk of teratogenicity (e.g., efavirenz), hepatotoxicity (e.g., nevirapine, in women with CD4 counts of >250 cells/ μ L), or metabolic complications such as lactic acidosis (e.g., didanosine and stavudine). See chapter *Reducing Perinatal HIV Transmission* and the U.S. Department of Health and Human Services *Perinatal HIV Guidelines* (see “References,” below). It should be noted that most fetal organogenesis occurs in the early weeks of pregnancy, before most women know that they are pregnant. Thus, any medication with potential teratogenicity or fetal toxicity, whether an ARV or another drug, should be avoided for use by women who are intending to become pregnant or who may become pregnant. Certain medications (e.g., ribavirin) should be avoided by male partners of women who may become pregnant.

Folate supplementation to reduce the risk of neural tube defects in the developing fetus should be started at least 1 month before conception, if possible, because the neural tube forms in the early weeks of pregnancy (see chapter *Care of HIV-Infected Pregnant Women*).

Menopause

There is evidence that HIV-infected women may be more likely to undergo premature physiologic menopause. Earlier onset of menopause also is associated with non-HIV factors such as ethnicity and a history of intravenous drug use. Menopausal women are more at risk of premature bone loss, osteopenia, and osteoporosis; this risk may be increased by HIV infection and certain ARVs. If indicated, bone density screening (DEXA) should be considered.

Hormone replacement therapy (HRT), especially of long duration, has been associated with an increased risk of breast cancer and cardiovascular and thromboembolic events, and its routine use is not recommended. HRT may be considered for women who experience severe vasomotor symptoms and vaginal dryness, but should be used only for a limited period of time and at the lowest effective dosage.

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Palliative Care and HIV

Background

Palliative care is not curative care, but is supportive, symptom-oriented care. It may be needed at any point in the course of disease progression to relieve patients' suffering and promote quality of life. Palliative care is important for patients with any medical condition, even if they are not actively in hospice. It may be used in conjunction with disease-specific care or as the sole approach to care. Palliative care includes the following:

- Management of symptoms (e.g., fatigue, pain)
- Treatment of adverse effects (e.g., nausea, vomiting)
- Psychosocial support (e.g., depression, advance care planning)
- End-of-life care

The U.S. Health Resources and Services Administration (HRSA) HIV/AIDS Bureau Working Group on Palliative Care in HIV has provided the following working definition of palliative care:

Palliative care is patient- and family-centered care. It optimizes quality of life by active anticipation, prevention, and treatment of suffering. It emphasizes use of an interdisciplinary team approach throughout the continuum of illness, placing critical importance on the building of respectful and trusting relationships. Palliative care addresses physical, intellectual, emotional, social, and spiritual needs. It facilitates patient autonomy, access to information, and choice.

(Excerpted from: HRSA Working Group on HIV and Palliative Care.
Palliative and Supportive Care. HRSA Care ACTION, July 2000)

Palliative care for patients with HIV infection comprises a continuum of treatment consisting of therapy directed at AIDS-related illnesses (e.g., infection or malignancy) and treatments focused on providing comfort and symptom control throughout the lifespan. This care may involve multidimensional and multidisciplinary services, including HIV medicine, nursing, pharmacy, social work, complementary or alternative medicine, and physical therapy.

Palliative Care in the Era of Antiretroviral Therapy

With advances in HIV-specific therapy and care, HIV infection is no longer a rapidly fatal illness. Instead, patients who are able to tolerate antiretroviral therapy (ART) usually experience a manageable, chronic illness.

The death rate from AIDS, however, continues to be significant: approximately 15,000 deaths per year in the United States. In many parts of the world, patients still are not able to obtain specific treatments for HIV or for opportunistic illnesses, and supportive or palliative care may be the primary mode of care available to patients with advanced AIDS. Regardless of access to disease-specific treatment, people living with HIV continue to experience symptoms from HIV disease and its comorbid conditions, and those taking ART may experience adverse effects. Integrating palliative care and disease-specific care is important for treating patients with HIV in order to promote quality of life and relieve suffering.

S: Subjective

The patient with advanced HIV disease complains of one or more of the following:

- Agitation
- Anorexia
- Chronic pain
- Constipation
- Cough
- Decubitus ulcers or pressure sores
- Delirium
- Dementia
- Depression
- Diarrhea
- Dry mouth
- Dry skin
- Dyspnea
- Fatigue
- Fever
- Hiccups
- Increased secretions (“death rattle”)
- Nausea
- Pruritus
- Sleep disturbance
- Sweats
- Vomiting
- Weakness
- Weight loss

O: Objective

Conduct a complete symptom-directed physical examination.

To evaluate pain, please refer to chapter *Pain Syndrome and Peripheral Neuropathy*.

**A/P: Assessment and Plan
Treatment**

Common symptoms of persons with late-stage HIV infection and their possible causes are listed in Table 1. Also included are disease-specific treatments and palliative interventions. Depending on the situation, either or both of these types of treatments may be appropriate. Consider the patient’s disease stage and symptom burden, the risks and benefits of therapies, and the patient’s wishes.

When assessing each of the patient’s symptoms, include the psychiatric review of symptoms (depression, anxiety, psychosis), and consider the following aspects of each symptom:

- Onset, progression, frequency, severity
- Degree of distress and impact on function
- Aggravating and alleviating factors
- Previous treatments and their efficacy
- What the patient believes is causing the symptom
- Coping strategies and supports
- The patient’s personal goals of care with this particular symptom

Practitioners should note that some of the palliative treatments may have substantial long-term adverse effects and should be used to alleviate symptoms only in late-stage or dying patients.

Table 1. Common Symptoms in Patients with AIDS and Possible Disease-Specific and Palliative Interventions

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
CONSTITUTIONAL			
Fatigue, weakness	• AIDS • Opportunistic infection • Anemia • Hypoandrogenism	• ART • Treat specific infections • Erythropoietin, transfusion • Testosterone/androgens in men with concomitant hypogonadism; for women, androgens are investigational and not approved by the U.S. Food and Drug Administration for this use	• Psychostimulants: give in the morning; also useful as treatment for depression and sedation owing to opioids; avoid in patients with anxiety and agitation (e.g., methylphenidate, dextroamphetamine, modafinil; pemoline is not first-line because of hepatotoxicity risk) • Corticosteroids (prednisone, dexamethasone)
Weight loss/anorexia	• HIV • Malignancy	• ART • Specific treatment of malignancy • Nutritional support	• Testosterone/androgens in men with hypogonadism (see above) • Oxandrolone for 2-4 week courses; an anabolic steroid that may be a useful adjunct, can help increase lean body mass but also has virilizing effects • Megestrol acetate can improve appetite and fatigue but has not been shown to improve nutritional status; possible adverse effects include deep vein thrombosis, glucose intolerance, and hypoandrogenism in men • Dronabinol is a cannabinol derivative that helps increase appetite but over the long term (≥ 12 months) does not significantly increase weight • Recombinant human growth hormone can improve lean body mass, but is associated with significant side effects (headache, edema, myalgias) and is expensive; consider for patients with severe wasting if no other therapies are effective • Corticosteroids can help increase appetite in the short term but not increase weight, and the duration of effect is short-lived

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
Fevers, sweats	- Disseminated <i>Mycobacterium avium</i> complex and other infections (opportunistic or other) - Lymphoma and other malignancies - Immune reconstitution inflammatory syndrome - Medication reaction	- Specific treatment of opportunistic infection or malignancy - ART - Discontinue causative medication (if drug reaction)	- Acetaminophen - NSAIDs (ibuprofen, naproxen, indomethacin) - Anticholinergics can be useful for sweats (hyoscyamine, glycopyrrolate) - H2 antagonists can be useful for sweats (ranitidine, famotidine; dose at least 12 hours apart from atazanavir or rilpivirine; note that cimetidine should be avoided in patients taking fosamprenavir or delavirdine because of drug interactions)
PAIN			
Nociceptive, somatic, visceral	- Opportunistic infections - HIV-related malignancies, nonspecific	Specific treatment of disease entities	- See chapter <i>Pain Syndrome and Peripheral Neuropathy</i> for detailed treatment options - Refer to the World Health Organization (WHO) analgesic ladder: NSAIDs and opioids - Corticosteroids can be useful for treating inflammatory-mediated pain, often as an adjunct to opioids (may worsen some conditions) - Benzodiazepines or muscle relaxants for muscle spasms (clonazepam, diazepam, baclofen) - Nonpharmacologic therapies (e.g., massage, physical therapy)
Neuropathic	- HIV-related peripheral neuropathy - Cytomegalovirus - Varicella-zoster virus - Medications (e.g., stavudine, isoniazid, vincristine)	- ART - Discontinue offending medication - Change antiretroviral or other regimen	- See chapter <i>Pain Syndrome and Peripheral Neuropathy</i> for detailed treatment options - Refer to the WHO analgesic ladder: NSAIDs and opioids - Neuropathic pain medications: - Tricyclics (nortriptyline, imipramine) - Anticonvulsants (gabapentin, pregabalin, lamotrigine) - Muscle relaxants (e.g., baclofen) - Benzodiazepines can be useful adjuncts (clonazepam, diazepam) - Corticosteroids can be useful for treating inflammatory-mediated pain, often as an adjunct to opioids (may worsen some conditions) - Acupuncture

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
GASTROINTESTINAL			
Nausea, vomiting	• Antiretroviral medications • Esophageal candidiasis • Cytomegalovirus esophagitis	• Specific treatment of disease entities • Change antiretroviral regimen	• Dopamine antagonists (prochlorperazine, haloperidol) • Prokinetic agents (metoclopramide) • Serotonin antagonists (granisetron, ondansetron, dolasetron) • Antihistamines (diphenhydramine, promethazine, meclizine) • Anticholinergics (hyoscyamine, scopolamine) • Somatostatin analogues in patients with bowel obstruction, to reduce gut motility; can be used with anticholinergics (octreotide) • Benzodiazepines (lorazepam) • Marijuana, dronabinol can help increase appetite
Diarrhea	• <i>Mycobacterium avium</i> complex • Cryptosporidiosis • Cytomegalovirus colitis • Microsporidiosis • Other intestinal infections • Malabsorption • Medications (e.g., protease inhibitors)	• Specific treatment of disease entities • Discontinue offending medication	• Bismuth, methylcellulose • Psyllium • Kaolin • Diphenoxylate + atropine • Loperamide • Calcium carbonate • Ferrous sulfate • Tincture of opium for severe chronic diarrhea unresponsive to other therapies • Crofelemer for ARV-related diarrhea • Octreotide for profuse, refractory watery diarrhea; expensive and needs subcutaneous administration
Constipation	• Dehydration • Malignancy • Anticholinergic medications • Opioids • Reduced activity	• Hydration • Radiation and chemotherapy • Medication adjustment	• Activity/diet modification • Prophylaxis for patients taking opioids with docusate + senna • Peristalsis-stimulating agents: • Anthracenes (senna) • Polyphenolics (bisacodyl) • Softening agents: • Surfactant laxatives (docusate) • Bulk-forming agents (bran, methylcellulose) • Osmotic laxatives (lactulose, sorbitol) • Saline laxatives (magnesium hydroxide)

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
RESPIRATORY			
Dyspnea	• <i>Pneumocystis jiroveci</i> pneumonia • Bacterial pneumonia • Anemia • Pleural effusion, mass, or obstruction • Decreased respiratory muscle function	• Specific treatment of disease entities • Erythropoietin, transfusion • Drainage, radiation, or surgery	• Use of fan, open windows • Relaxation techniques, massage, guided imagery • Oxygen supplement titrated to comfort, if the patient is hypoxic • Bronchodilators (albuterol, ipratropium, inhaled steroids) if there is bronchospasm • Opioids, particularly morphine, to decrease sense of air hunger and respiratory rate • Benzodiazepines (e.g., lorazepam) to reduce the anxiety that often accompanies dyspnea
Cough	• <i>Pneumocystis jiroveci</i> pneumonia • Bacterial pneumonia • Tuberculosis • Acid reflux • Postnasal drip	• Specific treatment of disease entities	• Cough suppressants (dextromethorphan, codeine, hydrocodone, morphine, aerosolized lidocaine) • Bronchodilators (albuterol, ipratropium, inhaled steroids) if there is bronchospasm • H2 blockers or proton-pump inhibitors (ranitidine, omeprazole) if there is acid reflux (caution: interactions with atazanavir, rilpivirine) • Decongestants (pseudoephedrine, phenylephrine, steroid nasal sprays) for postnasal drip
Increased secretions ("death rattle")	• Fluid shifts • Ineffective cough • Sepsis • Pneumonia	• Antibiotics as indicated	• Atropine, hyoscyamine, transdermal scopolamine, glycopyrrolate • Fluid restriction, discontinue intravenous fluids
Hiccups	• Aerophagia (swallowing air) • <i>Candida</i> and other causes of esophagitis, including GERD • Vagus and phrenic nerve irritation • CNS mass lesions • Uremia • Alcohol intoxication • Anesthesia	• Treatment of underlying etiology (e.g., antifungals for <i>Candida</i> esophagitis, acid reducers for GERD)	• Metoclopramide can promote gastric emptying • Chlorpromazine (antipsychotic) can reduce the CNS response, start at low dosage to reduce the risk of dystonia and drowsiness • Baclofen can reduce the CNS response

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
DERMATOLOGIC			
Dry skin	• Dehydration • End-stage renal disease • End-stage liver disease • Malnutrition • Medications (e.g., indinavir)	• Hydration • Dialysis • Nutritional support • Discontinue offending medication	• Avoid soaps, most of which dry the skin further • Emollients with or without salicylates • Emollients with urea (e.g., Ultra Mide 25) • Emollients with lactate (e.g., Lac-Hydrin) • Lubricating ointments or creams (e.g., petrolatum, Eucerin)
Pruritus	• Fungal infection • End-stage renal disease • End-stage liver disease • Dehydration; dry skin • Eosinophilic folliculitis • Opioid side effect	• Antifungal agents (e.g., itraconazole for eosinophilic folliculitis) • Dialysis • Hydration • Topical corticosteroids	• Avoid soaps and hot baths/showers • Warm compresses • Treatments for dry skin, as above • Topical agents (menthol, phenol [e.g., Sarna lotion], calamine, doxepin, capsaicin) • Antihistamines (hydroxyzine, doxepin, diphenhydramine) • Corticosteroids (topical or systemic) • Opioid antagonists (naloxone, naltrexone) can be useful for treating uremic and biliary-associated pruritus • Antidepressants • Anxiolytics • Thalidomide in intractable pruritus, but beware of side effects, including neuropathy
Decubitus ulcers, Pressure sores	• Poor nutrition • Decreased mobility, prolonged bed rest	• Increase mobility • Enhance nutrition	• Prevention (nutrition, mobility, skin integrity) • Wound protection (semipermeable film, hydrocolloid dressing) • Debridement (normal saline, enzymatic agents, alginates)

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
NEUROPSYCHIATRIC			
Delirium/ agitation	• Electrolyte imbalances, glucose abnormalities • Dehydration • Hypoxia • Toxoplasmosis • Cryptococcal meningitis • CNS masses and metastases • Sepsis • Medication adverse effects (e.g., benzodiazepines, opioids, efavirenz, corticosteroids) • Intoxication or withdrawal	• Correct imbalances • Hydration • Oxygen supplementation • Specific treatment of disease entities • Discontinue offending medications	• Neuroleptics (haloperidol, risperidone, chlorpromazine) to induce sedation in severe agitation • Benzodiazepines (e.g., lorazepam, diazepam, midazolam) in the “terminal restlessness” of the last few days of life to relieve myoclonus, seizures, restlessness (Note: in some patients, these may have adverse effects)
Dementia	• HIV-associated dementia • Other dementia (e.g., Alzheimer dementia, Parkinson dementia, multi-infarct dementia)	• ART	• Psychostimulants (methylphenidate) • Memantine (NMDA antagonist) has been used in patients with Alzheimer dementia but has unclear benefit for patients with HIV-associated dementia • Low-dose neuroleptics (haloperidol, chlorpromazine) can be useful in psychotic delirium

Symptom	Possible Causes	Disease-Specific or Curative Treatment	Palliative Treatment
Depression	- Chronic illness - Reactive depression, major depression	Antidepressants	- Antidepressants are useful when the patient has a life expectancy of several months or more: SSRIs, SNRIs, mirtazapine (useful in lowest dosages for insomnia), bupropion, (though beware of lowering the seizure threshold); note that tricyclic antidepressants are not considered first- or second-line therapy owing to side effects, though they may be useful for treating refractory melancholic or delusional depression (see chapter <i>Major Depression and Other Depressive Disorders</i> for further information, including dosages) - Psychostimulants are useful for patients who have urgent, severe depression or are weeks from death (methylphenidate, pemoline, dextroamphetamine, modafinil)

Abbreviations: ART = antiretroviral therapy; CNS = central nervous system; GERD = gastroesophageal reflux disease; NMDA = N-methyl- D-aspartate; NSAID = nonsteroidal antiinflammatory drug; SNRI = serotonin norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor

Adapted from Selwyn PA, Rivard M. *Palliative care for AIDS: Challenges and opportunities in the era of highly active antiretroviral therapy*. Innovations in End-of-Life Care. 2002;4(3). Available at www2.edc.org/lastacts/archives/archivesmay02/ovessay.asp. Accessed December 1, 2013.

Advance Care Planning

Advance care planning involves planning for future medical care. Two main documents are produced:

- Advance directive (living will)
- Health care proxy (a person to speak for the patient or make decisions if the patient is too sick to do so)

The clinician should initiate these conversations and make referrals to helpful resources.

Patient Education

- Discuss advance care planning with patients, and the option of hospice care, if appropriate.
- Provide patients and their family members with detailed information so that they understand the illness and associated treatments.
- Instruct patients to discuss their pain or other bothersome symptoms with their health care provider.
- Encourage patients to talk with their health care provider if they are feeling anxious, depressed, or fearful.
- Discuss with patients what their death might be like. Some patients may feel relieved to be able to talk openly about their last days. Assure them that their pain will be controlled and that their health care provider will be there to help them.

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Adherence

Background

For HIV-infected patients with wild-type virus who are taking antiretroviral therapy (ART), adherence to ART is the major factor in ensuring the virologic success of an initial regimen and is a significant determinant of survival. Adherence is second only to the CD4 cell count as a predictor of progression to AIDS and death. Adherence rates approaching 100% are needed for optimal viral suppression, yet the average ART adherence in the United States is approximately 70%. Individualized assessment of and support for adherence are essential for patients to be successful with ART.

Patients with suboptimal adherence are at risk not only of HIV progression, but also of the development of drug resistance (see chapter *Resistance Testing*) and consequent narrowing of options for future treatment. In one cohort study, it was estimated that drug-resistant mutations will occur in 25% of patients who report very high but not perfect (92-100%) adherence to ART. It is important to note, though, that the relationship between suboptimal adherence and resistance to antiretroviral (ARV) medications is very complex and is not thoroughly understood.

Characteristics of the ARV regimen and individual patient pharmacokinetic variables also influence the likelihood of both virologic suppression and the development of resistance mutations. For example, in patients with wild-type virus on initial ART regimens, it appears that more drug resistance occurs in regimens that are based on an unboosted protease inhibitor or a nonnucleoside reverse transcriptase inhibitor, where the genetic barrier to resistance is relatively low, than in regimens that include a ritonavir-boosted protease inhibitor. In patients with suboptimal adherence, these factors can influence outcomes of therapy more strongly.

S: Subjective

Studies indicate that health care providers' assessments of their patients' adherence often are inaccurate, so a calm and open approach to this topic is very important.

Adherence assessment is most successful when conducted in a positive, nonjudgmental atmosphere. Patients need to know that their provider understands the difficulties associated with taking an ARV regimen. Within a trusting relationship, a provider may learn what is actually happening with the patient's adherence rather than what the patient thinks the provider wants to hear. See Table 1 for examples of questions to assess adherence in patients who are on ART. For patients who are considering initiation of ART, it is important to lay the groundwork for optimal adherence in advance, and to anticipate barriers to adherence; see Table 2 for exploratory questions.

Common reasons for nonadherence include the following: experiencing adverse drug effects, finding the regimen too complex, having too many pills, having difficulty with the dosing schedule (not fitting into the daily routine), forgetting to take the medications, being too busy with other things, oversleeping and missing a dose, being away from home, not understanding the importance of adherence, and being embarrassed to take medications in front of family, friends, or coworkers. Other contributors to incomplete adherence include psychosocial issues (e.g., lack of social support, homelessness), psychiatric illness, and active substance abuse. It is important to look for these and other potential barriers to adherence. (See chapter *Initial History*.)

O: Objective

Evaluate the following:

- CD4 cell count
- HIV viral load (indicating the effectiveness of ART in suppressing viremia; an indirect indicator of adherence)
- Current drug list (including over-the-counter medications, vitamins, and herbal remedies); check for potential adverse drug-drug interactions with ARV medications
- Pharmacy refill records or missed doses remaining in pill organizers (e.g., medi-sets pill boxes, bubble packs)

A: Assessment

Assess adherence at each visit using questions such as those in Tables 1 and 2, and assessment scales such as those found in Tables 4, 5, and 6 (Appendix). Ask these questions in a simple, nonjudgmental, structured format and listen carefully to the patient to invite honesty about issues that may affect adherence. Asking about adherence over the last 3 to 7 days gives an accurate reflection of longer-term adherence.

Ideally, a multidisciplinary team that includes primary providers as well as nurses, pharmacists, medication managers, and social workers works together to evaluate and support patient adherence.

Table 1. Important Questions to Ask Patients Taking ART

- Do you manage your own medications? If not, who manages them for you?
- What HIV medications do you take and what is their dosage? When do you take these?
- What is your average daily schedule like? How well does taking your HIV medications at this time fit into your daily schedule?
- How do you remember to take your medications?
- How many doses of your HIV medication have you missed in the past 72 hours, past week, past 2 weeks, and past month?
- On a scale of 1 to 10, where would you say you are? A score of 1 indicates that you do not take your medicines as directed at all; for example, not every day or not at the same time every day; 10 indicates that you take your medications perfectly every day, at the same time every day. (Visual analog scales are also used to assess adherence; see Appendix.)
- If not a 10, what causes you not to be a 10?
- When are you most likely to miss doses?
- Do you have any adverse effects from your HIV medications? If so, what are they?
- Are you comfortable taking medications in front of others?
- What is most difficult about taking your medications?
- How do you like working with your pharmacy?

Table 2. Important Questions to Ask Patients Considering Initiation of ART

- What is your attitude toward ART?
- Do you believe that ART is effective?
- What are your biggest concerns about starting ART?
- What do you hope these medications will do for you?
- Are you ready to take the medication every day, around the same time each day?
- What is your level of commitment and motivation to take the medication every day for the rest of your life?
- Who knows about your HIV status?
- What other medications are you taking: prescription, over-the-counter, herbals?
- Are you a morning or afternoon person?
- What is your daily routine, including waking and bed times?
- How many meals and snacks do you eat per day, and at what times?
- Do you use alcohol, marijuana, cocaine, or injectable drugs? If so, how much do you use and how long have you used them?
- What are your ARV regimen preferences? What are some of the most important things you want to avoid in an ARV regimen (e.g., specific side effects, number of pills, frequency of dosing)?

The patient’s self-report has been shown to be the most effective measure of adherence. Although, according to some studies, self-report of good adherence has limited value as a predictor

of good adherence; self-report of suboptimal adherence should be taken seriously and considered a strong indicator of nonadherence.

Before initiating (or changing) ART, it is important to assess the patient's readiness for ART. Patient factors that have been associated with poor adherence in the United States and western Europe include:

- Active alcohol or drug use
- Competing priorities (e.g., housing, childcare, food, work)
- Depression
- Lack of belief in treatment efficacy
- Lack of social support
- Lack of support from a partner
- Low literacy
- More advanced HIV infection
- Unstable housing
- Young age

Most of these factors are modifiable. Before starting ART, appropriate interventions should be made, and sources of adherence support should be identified to help patients overcome potential barriers to adherence.

It is important to note that sociodemographic variables such as sex, HIV risk factors, and education level generally are not associated with adherence. In addition, a history of substance or alcohol abuse is not a barrier to adherence.

Assess the patient's support system, and ask who knows about his or her HIV status. Supportive family members or friends can help remind patients to take their medications and assist with management of adverse effects. For patients who have accepted their HIV infection as an important priority in their lives, taking medications can become routine despite other potential adherence barriers such as alcohol or drug use.

Assess patients' willingness to accept and tolerate common adverse effects of ART. Patients may identify some adverse effects that they wish to avoid completely and others that they are willing to accept and manage; this may help

in tailoring the selection of ARV medications to the individual patient. Describe strategies for the management of adverse effects before starting a regimen (see chapters *Patient Education* and *Adverse Reactions to HIV Medications*), and emphasize that adverse effects often can be treated quite effectively, and that they should notify their providers if they experience them.

For patients taking ART, it is important to assess adherence at every clinic visit. Tools such as those in the Appendix to this chapter may be useful in predicting adherence. Adverse effects are a common cause of suboptimal adherence to ART. Continue to ask whether the patient has adverse effects from the ARV medications and assess his or her ability to accept and tolerate these. Work closely with the patient to treat adverse effects, and consider changes in ART if adverse effects are not tolerated. Continue to offer support to improve or maintain optimal adherence.

Before prescribing ARVs, some clinicians have their patients conduct adherence trials using placebo tablets or jelly beans to measure the patients' readiness to start therapy and their ability to adhere to a regimen. Such a trial allows patients to experience what a regimen will entail in real life, how therapy will affect their daily lifestyles, and what changes will be needed to accommodate the regimen. The shortcoming of placebo trials is that patients are not challenged with adverse effects as they might be with an actual regimen.

P: Plan

Start the ARV regimen when the patient is ready (recognizing that in some cases the need for ART is urgent). Starting it too early may result in poor acceptance of ART by the patient, inadequate adherence, failure of the regimen, and increased risk of ARV resistance. Comorbid conditions that may interfere with adherence, such as mental health issues or depression, may need to be treated initially. It is important to consider the patient's preferences and to involve her or him in selecting the drug regimen. The

regimen must fit into the patient's daily routine, and the patient must believe in the potential success of ART. It is extremely important to simplify the ARV regimen to the extent possible with once-daily regimens and the lowest number of pills (and lowest total expense to the patient), while maintaining efficacy and minimizing adverse effects; this will help to maximize adherence and avoid pill fatigue. Starting ART is rarely an emergency situation, so taking time to identify the patient's wishes for care, making a thorough readiness assessment, selecting the ARV regimen, and planning for adherence support are important measures for maximizing the likelihood of treatment success. (See Table 3 for additional suggestions.)

Table 3. Strategies for Improving Adherence to ART

- Use a multidisciplinary team approach
- Establish a trusting relationship with the patient
- Establish readiness to start ART
- Assess and simplify regimens if possible
- Involve the patient in ARV regimen selection
- Identify potential barriers to adherence prior to starting ART
- Provide mental health and substance abuse resources for the patient if needed
- Provide resources to obtain prescription drug coverage
- Assess adherence at every clinic visit
- Use educational aids including pictures, pillboxes, and calendars
- Identify the type of nonadherence and the reasons for nonadherence
- Anticipate and treat adverse effects
- If resources allow, select from among available effective interventions

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2103.

Patients who can identify their medications (in their own words) and describe the proper dosing and administration have higher adherence rates. Providing patient education before writing a prescription helps ensure adherence to ARV regimens. Education

can be provided in oral, written, or graphic form to assist the patient's understanding of the medications and their dosing. Basic information, including number of pills, dosages, frequency of administration, dietary restrictions, possible adverse effects, tips for managing adverse effects, and duration of therapy, will help patients to understand their ARV regimens. Patients should understand that the success of ART depends upon taking the medications every day and that very high adherence levels (in some cases perhaps >95%) are important in preventing virologic failure.

Close follow-up by telephone, clinic visits, or other contact with the patient during the first few days of therapy is useful in identifying adverse effects, assessing the patient's understanding of the regimen, and addressing any concerns before they become significant adherence barriers. Individualized interventions should be designed to optimize outcomes for each patient. Pharmacists, peer counselors, support groups, adherence counselors, behavioral intervention counselors, and community-based case managers are useful in supporting adherence for the HIV-infected patient. Multidisciplinary teams that include nurses, case managers, nutritionists, and clinical pharmacists, in which each care provider focuses on adherence at each contact with the patient, are extremely effective, and peer support groups, in which patients share with one another their strategies for improving adherence, may be beneficial.

Many physical devices can be used to support adherence. The following are simple, inexpensive, and easy to incorporate into the routine of the HIV patient:

- Medication organizers include pillboxes and medi-sets. These are available in several shapes and sizes to fit the needs of the individual patient. They can be filled weekly so that the patient can easily determine whether a dose of medication was missed.
- Reminder devices include alarm watches, beepers, and cell phone alarms. They are ef-

fective in reminding the patient when to take medications. Medication diaries may be used for the patient to record doses that were taken.

- Visual medication schedules are calendars featuring photos or images of the patient's medications to remind the patient which drugs to take and at what dosages.
- Interventions for successful adherence are an ongoing effort, not one-time events. Studies have suggested that adherence rates decline when patient-focused interventions are discontinued. Therefore, positive reinforcement at each clinic visit or contact is extremely important. Reinforce what the patient has done well and assist the patient in identifying and problem-solving areas for improvement. Whenever possible, share positive information about the patient's health, such as improvements in quality of life, CD4 cell count, and viral load, to encourage a high level of adherence.

Special Populations and Issues

Mental Illness

Patients with mental health issues may have difficulty with adherence. In this population, it is particularly important to incorporate ARV medications into structured daily routines. Medication cassettes, reminder signs, and calendars have been very effective for these patients. Nursing care providers and family members may be instrumental in filling medication boxes or ordering prescription refills.

Pediatrics

Adherence can be a challenge for young children who rely on parents and caregivers to provide their medications, but adolescents are more likely than younger children to have poor adherence. To improve adherence in this population, it is important to support the family. The Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection* (available at aidsinfo.nih.gov/guidelines) address some of the adherence issues and considerations for this patient population.

Low Literacy

Health literacy is an important predictor of treatment adherence, particularly in low-income populations and some immigrant populations. Adherence interventions are necessary in this population to accommodate individuals who have difficulty reading and understanding medical instructions. Providers often fail to recognize this disability. In addition, adherence support is needed for patients who have difficulty navigating the health care system.

Resource-Limited Settings

Research has shown that the level of adherence in resource-limited countries is at least as good as in resource-rich settings and that rates of virologic suppression are equivalent or better. Lack of access to a consistent supply of ARV medications, including financial barriers that may cause interruptions in treatment, appears to be the primary obstacle to adherence in resource-limited settings.

Patient Education

- Educate patients about the importance of adherence and the need to take their ARV medications exactly as prescribed and to take every dose, every day.
- Advise patients that, if they miss an ARV dose on a rare occasion, that usually will not result in failure of the regimen. On the other hand, if they frequently miss or skip doses of their ARV medications, the regimen may become ineffective, and the HIV may develop resistance to ARVs.
- Tell patients to notify the clinic if they miss doses of the ARV medications.
- Work with patients to devise ways to improve their adherence, and reinforce good adherence behavior.
- Advise patients in advance that some people have adverse effects from the medications, and tell them to notify the clinic if they develop adverse effects. Discuss ways to reduce these effects.

Appendix

Table 4. Visual Analog Scale Used in a Research Study to Assess Adherence to HIV Medication Regimens

Script for Interviewing Patients About Adherence																							
Interviewer	Now I'm going to ask some questions about your HIV medications. Most people with HIV have many pills or other medications to take at different times during the day. Many people find it hard to always remember to take their pills or medicines. For example: • Some people get busy and forget to carry their pills with them. • Some people find it hard to take their pills according to all the instructions, such as "with food" or "on an empty stomach," "every 8 hours," or "with plenty of fluids." • Some people decide to skip taking pills to avoid adverse effects or to just not take pills that day. We need to understand what people with HIV are really doing with their pills or medicines. Please tell us what you are actually doing. Don't worry about telling us you don't take all your pills or medicines. We need to know what is really happening, not what you think we "want to hear." Which antiretroviral medications have you been prescribed to take within the last 30 days?																						
INTERVIEWER: LIST CODES FOR ALL ANTIRETROVIRALS THAT SUBJECT WAS PRESCRIBED TO TAKE IN LAST 30 DAYS. IDENTIFY UP TO 4 DRUGS.																							
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DRUG A:	DRUG C:																						
DRUG B:	DRUG D:																						
Interviewer	Now, I am going to ask you some questions about these drugs. Please put an "X" on the line below at the point showing your best guess about how much (DRUGS A-D) you have taken in the last 3-4 weeks. We would be surprised if this were 100% for most people.																						
HAND INSTRUMENT AND PEN TO RESPONDENT																							
Interviewer	• 0% means you have taken no (DRUG A) • 50% means you have taken half your (DRUG A) • 100% means you have taken every single dose of (DRUG A)																						
Adherence Self-Assessment Instrument																							
Instructions for Patient:	Put an "X" on the line below at the point showing your best guess about how much of each drug you have taken in the last 3 to 4 weeks. • 0% means you have taken none of the drug • 50% means you have taken half of the drug • 100% means you have taken every single dose of the drug																						
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Adapted from Machtinger EL, Bangsberg DR. *Adherence to HIV Antiretroviral Therapy*. In: Coffey S, Volberding PA, eds. *HIV InSite Knowledge Base* [textbook online]; San Francisco: UCSF Center for HIV Information; May 2005. Available at hivinsite.ucsf.edu/InSite?page=kb-03-02-09. Accessed December 1, 2013.

Table 5. Morisky Scale to Assess Adherence to HIV Medications: Dichotomous Response Options

Subjects were asked: "Thinking about the medications PRESCRIBED to you by your doctor(s), please answer the following questions."	NO	YES
Do you ever forget to take your medications?		
Are you careless at times about taking your medications?		
When you feel better, do you sometimes stop taking your medications?		
Sometimes, if you feel worse when you take your medications, do you stop taking them?		

Adapted from Morisky DE, Green LW, Levine DM. *Concurrent and predictive validity of a self-reported measure of medication adherence.* Med Care 1986;24:67-74.

Table 6. Morisky Scale to Assess Adherence to HIV Medications: 5-Point Response Options

Subjects were asked: "Thinking of the medications PRESCRIBED to you by your doctor(s), please answer the following questions."					
<i>Response options: never = 0; rarely = 1; sometimes = 2; often = 3; always = 4</i>	0	1	2	3	4
Do you ever forget to take your medications?					
Are you careless at times about taking your medications?					
When you feel better, do you sometimes stop taking your medications?					
Sometimes, if you feel worse when you take your medications, do you stop taking them?					

Adapted from Morisky DE, Green LW, Levine DM. *Concurrent and predictive validity of a self-reported measure of medication adherence.* Med Care 1986;24: 67-74.

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Diarrhea

Background

Diarrhea is a common complaint among HIV-infected individuals, and has a variety of causes. Episodes may be acute and brief, intermittent or recurrent, or, in some cases, chronic and severe. If diarrhea persists, it may cause dehydration, poor nutrition, and weight loss. Diarrhea may diminish patients' quality of life significantly, and may interfere with adherence to and efficacy of antiretroviral (ARV) medications.

Diarrhea is defined in various ways, but commonly as more than 4 loose or watery stools per day for more than 3 days. Duration is classified as follows:

- Acute: <2 weeks
- Persistent: 2-4 weeks
- Chronic: >4 weeks

The causes of diarrhea, both infectious and noninfectious, found in HIV-infected individuals with normal or mildly depressed CD4 cell counts are likely to be similar to those in HIV-uninfected persons. Among the noninfectious causes of diarrhea, adverse effects of ARVs and other medications are particularly common. Persons with advanced immunodeficiency are more likely to have infections, including opportunistic infections, as the cause of diarrhea.

Infectious diarrhea typically involves either the small or the large intestine, and the patient's history often suggests the site of the problem. Infections of the small intestine (enteritis) commonly produce generalized or periumbilical abdominal cramps, large-volume diarrhea without blood, and frequently dehydration. Large-intestine infections (colitis) often produce lower abdominal pain, an unproductive urge to defecate, and frequent small-volume stools with blood and pus.

S: Subjective

The patient complains of diarrhea. Take a thorough history, including the following:

- Onset of diarrhea: sudden or gradual
- Frequency (times per day, last episode)
- Stool consistency (soft vs. liquid)
- Stool color (gray, white, or greasy stools: possible cholelithiasis or pancreatitis; dark stools: possible gastrointestinal bleeding)
- Bloody stools (may indicate invasive organisms, inflammation, ischemia, or neoplasm)
- Rectal bleeding
- Straining at stool
- Pain with defecation, rectal discharge (consider sexually transmitted diseases, herpes simplex virus)
- Nausea or vomiting (within 6 hours of ingesting food, consider foodborne illness, gastroenteritis)
- Weight loss: quantify amount and time frame
- Abdominal pain or cramping; location if present
- Fever (consider invasive pathogens: *Shigella*, *Campylobacter*, *Salmonella*, *Clostridium difficile*)
- Other associated symptoms (e.g., bloating, flatus)

- Allergies (to foods or medications)
- Aggravating factors (e.g., dairy products, fatty or spicy foods)
- Alleviating factors (e.g., fasting)
- Treatments tried (e.g., over-the-counter antidiarrheals)
- Contact with others with similar symptoms
- Previous episodes of diarrhea
- History of cytomegalovirus (CMV), *Mycobacterium avium* complex (MAC), or other infections involving the gastrointestinal tract
- Family history of inflammatory bowel disease, celiac disease
- Oral-anal sexual contact (males and females)
- Receptive anal intercourse
- Exposure to unsafely prepared food (e.g., raw, undercooked, spoiled), unpasteurized milk or juices
- Exposure to possibly contaminated water (swimming in or drinking from well, lake, or stream) (consider parasites, including *Giardia*)
- Exposure to non-toilet-trained infants and children (e.g., at a daycare facility), pets, farm animals, reptiles (consider *Giardia*, *Salmonella*)
- Recent travel (enterotoxigenic *Escherichia coli*, *Shigella*, *Rotavirus*, *Salmonella*, *Campylobacter*, *Giardia*, *Entamoeba histolytica*)
- Antibiotic use or exposure in recent weeks or months or recent hospitalization (consider *C. difficile*)
- ARV medications, especially ritonavir-boosted protease inhibitors; check relationship of diarrhea onset to initiation of ARVs
- Other current and recent medications (prescribed or over-the-counter), including supplements and herbal preparations

- Dietary factors, especially “sugar-free” foods (containing nonabsorbable carbohydrates), fat substitutes, milk products, and shellfish, or heavy intake of fruits, fruit juices, or caffeine
- Alcohol and recreational drug use; withdrawal

O: Objective

Record vital signs, including temperature, orthostatic heart rate, blood pressure measurements, and weight. Compare these with recent or baseline values. Perform a thorough physical examination, including evaluation of the following:

- Hydration status (skin turgor, mucous membrane moistness)
- Nutritional status (body habitus, muscle mass, skin and hair integrity)
- Oropharynx (lesions, candidiasis, ulcerations, Kaposi sarcoma)
- Optic fundi (signs of CMV infection)
- Abdomen (distention, bowel sounds, tenderness, organomegaly, masses, adenopathy)
- Rectum (masses, tenderness, bloody stool)

Review recent CD4 cell counts. Low CD4 counts increase the risk of chronic or systemic illnesses and opportunistic infections.

A: Assessment

The differential diagnosis of diarrhea is broad and includes the following infectious and noninfectious causes. The CD4 cell count is important in stratifying risk of infection with opportunistic pathogens; some organisms cause disease only with severe immunosuppression.

Infectious Causes

Table 1. Infectious Causes

Severity	Differential Diagnosis
Active diarrhea, any CD4 count	• Viruses (especially Norwalk virus) • Viral hepatitis • Herpes enteritis • <i>C. difficile</i> (suspect in patients who have recently undergone treatment with antibiotics, or hospitalization) • <i>Salmonella</i> • <i>Shigella</i> • <i>Campylobacter</i> • <i>E. coli</i> O157:H7
Chronic diarrhea, any CD4 count	• <i>C. difficile</i> (suspect in patients who have been treated with antibiotics) • <i>Giardia lamblia</i> • <i>E. histolytica</i>
Chronic diarrhea, CD4 count <300 cells/μL	• Microsporidia • <i>Cryptosporidium parvum</i> • MAC (CD4 count <50 cells/μL) • <i>Isospora belli</i> • CMV (CD4 count <50 cells/μL)

Adapted from: *Infectious Causes of Diarrhea in Patients with HIV*, Table 8-8. In: Bartlett JG, Cheever LW, Johnson MP, et al., eds. *A Guide to Primary Care of People with HIV/AIDS*. Rockville, MD: U.S. Department of Health and Human Services, Health Resources and Services Administration; 2004. Available at hab.hrsa.gov/deliverhivaidscare/files/primary2004ed.pdf. Accessed December 1, 2013.

Noninfectious Causes

- Medication adverse effects, common with many medications including some ARVs:
 - Protease inhibitors (especially ritonavir and nelfinavir)
 - Didanosine buffered tablets (no longer available in the United States)
 - Cobicistat (present in Stribild)
- Irritable bowel syndrome
- Inflammatory bowel disease (ulcerative colitis, Crohn disease)
- Lymphoma
- Lactose intolerance
- Celiac disease
- Small intestinal bacterial overgrowth
- Pancreatic insufficiency
- Diverticulitis
- Fecal incontinence
- Laxative abuse

P: Plan
Diagnostic Evaluation

For suspected infections, perform laboratory studies including complete blood count with differential, serum electrolyte panel, and liver function tests. Check stool for white blood cells and blood. Perform stool studies as indicated by the patient’s presentation (bacterial culture, ova and parasites, microsporidia, cryptosporidia, *Giardia* antigen, *C. difficile* toxin assay). Order additional studies as suggested by the history (e.g., blood cultures, MAC cultures, hepatitis serologies, retinal examination for CMV). If noninfectious causes are suspected, perform evaluation for these etiologies as indicated (e.g., fecal fat concentration [for steatorrhea], stool osmolar gap [for osmotic diarrhea], anti-tissue transglutaminase [TTG] antibody [for celiac disease], or D-xylose [for pancreatic insufficiency]).

If the patient is febrile, perform a complete fever workup as appropriate (see chapter *Fever*).

Check the CD4 cell count and HIV viral load, if not checked recently.

If stool study results are negative (ova and parasite negative in three successive samples) and the patient has severe symptoms, particularly in the case of advanced immunodeficiency, refer to a gastroenterologist for colonoscopy or flexible sigmoidoscopy with biopsy. Endoscopy with biopsy is the best procedure for identifying certain conditions, including CMV colitis and inflammatory bowel disease. If all study results are negative but the diarrhea persists, consider repeat endoscopy in 6-8 weeks regardless of the level of immunodeficiency. Pathogens may be difficult to identify.

Treatment

Once a diagnosis is made, initiate appropriate treatment. For seriously ill patients, presumptive treatment may be started while diagnostic tests are pending. If the cause of the diarrhea cannot be identified, consult with an HIV expert or a gastroenterologist.

- For moderate to severe acute diarrhea, including dysentery (bloody diarrhea), empiric treatment can be given pending stool study results or in settings with limited resources for workup. If bacterial pathogens are suspected, use oral fluoroquinolones (e.g., ciprofloxacin 500 mg BID or levofloxacin 500 mg QD) for 5 days. Monitor effectiveness and adjust therapy according to the results of diagnostic studies and clinical response. Specific treatment with antimicrobials is guided by the pathogens identified in stool studies or on biopsy.

- For suspected small intestinal bacterial overgrowth consider treatment with an appropriate antimicrobial (e.g., rifaximin 1,200-1,600 mg per day for 7-10 days).
- For mild persistent diarrhea with no identified pathogen, treat with an antidiarrheal agent (see below). For patients whose diarrhea is suspected to be caused by ARV agents or other medications, symptomatic treatment also may be tried. Diarrhea owing to protease inhibitors often decreases after a few weeks without treatment. For persistent, daily ARV-associated diarrhea, antidiarrheal agents may be given on a scheduled basis (rather than as needed). If the diarrhea cannot be controlled, a change in ARV regimen should be considered.

Symptomatic treatments

- Antimotility agents such as loperamide (Imodium) in over-the-counter or prescription strengths and atropine/diphenoxylate (Lomotil) are useful for many patients. The suggested dosage is 2 tablets after each loose bowel movement, not to exceed 8 tablets per day. These agents should not be used if patients have bloody diarrhea or if the presence of *C. difficile* is suspected.
- Pharmaco-nutritional approaches include the use of calcium supplementation (500 mg BID or TID). Patients with diarrhea related to protease inhibitors may find that taking calcium with each dose of protease inhibitors can decrease or prevent diarrhea. Note that magnesium supplements may worsen diarrhea.

- Pancrelipase can be useful in managing chronic diarrhea caused by malabsorption. It comes in different formulations with differing amounts of pancreatic enzymes; usual dosage is 2-3 capsules TID with meals, titrated downward according to response.
- Cholestyramine or psyllium (e.g., Metamucil) may reduce diarrhea by slowing peristalsis and adding bulk to stools. Avoid administering cholestyramine with other medications because it may impair their absorption.
- Crofelermer, an antisecretory antidiarrheal agent, is approved by the U.S. Food and Drug Administration for treatment of noninfectious diarrhea in HIV-infected adults on antiretroviral therapy (ART). The dosage is 135 mg BID. Infectious causes should be ruled out before treatment with crofelermer.
- A combination of these treatments may be needed to control chronic diarrhea, and they can be continued for patients after an infectious process has been ruled out.

Nutrition and hydration

Encourage frequent intake of soft, easily digested foods such as bananas, rice, wheat, potatoes, noodles, boiled vegetables, crackers, and soups. Encourage hydration with fruit drinks, tea, “flat” carbonated beverages, and water. Patients should avoid high-sugar drinks, caffeinated beverages, alcohol, high-fiber foods, greasy or spicy foods, and dairy products. Many patients may benefit from a trial of a lactose-free, low-fiber, or low-fat diet. Patients should use nutritional supplements as needed or as recommended by a dietitian. In case of chronic or severe diarrhea, or significant weight loss, refer to a dietitian for further recommendations.

Patients with severe diarrhea must maintain adequate hydration, by mouth if possible. In severe cases, IV administration of fluids may be necessary. Oral rehydration solutions

include the World Health Organization formula, Pedialyte, Rehydralyte, Rice-Lyte, and Resol. Homemade alternatives include the following:

- Combine 1/2 teaspoon of salt, 1 teaspoon of baking soda, 8 teaspoons of sugar, and 8 ounces of orange juice; add water to make 1 liter and drink.
- Drink 1 glass containing 8 ounces of apple, orange, or other juice; 1/2 teaspoon of corn syrup or honey; and a pinch of salt; then drink 1 glass containing 8 ounces of water and 1/4 teaspoon of baking soda.
- Mix 1/2 cup of dry, precooked baby rice cereal with 2 cups of water (boil first in areas with poor water quality); add 1/4 teaspoon of salt and drink.

Patient Education

- Diarrhea can have many causes. Instruct patients to notify their health care provider if they develop new or worsening symptoms.
- Instruct patients to take their medications exactly as directed and to call their health care provider if they experience worsening diarrhea or other symptoms such as fever, nausea, vomiting, or pain.
- Patients must stay nourished and well hydrated even if they are having diarrhea. Instruct patients to eat small, frequent meals and to avoid dairy products, greasy food, and high-fat meals.
- Instruct patients to maintain good handwashing practices during diarrheal illnesses to prevent infection in close contacts or household members.
- Some diarrheal illnesses are reportable; advise patients that they may be contacted by the local health department.

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Ear, Nose, Sinus, Mouth

Background

HIV-infected individuals frequently experience infections and neoplasms that affect the ears, nose, sinuses, and mouth. The degree of immunosuppression, as reflected by a patient's CD4 cell count, can affect the severity, likelihood of recurrence, and response to therapy for various infections and neoplasms.

Patients may present with ear, nose, sinus, or mouth complaints early in the course of HIV infection, perhaps even before they are aware of their infection. Some conditions arise more commonly in patients with advanced HIV infection. Certain conditions (e.g., oral candidiasis) should prompt consideration of HIV testing in patients without known infection.

Ears

HIV-infected patients may experience recurrent acute otitis media and serous otitis media. Nasopharyngeal lymphoid hyperplasia, sinusitis, or allergies may contribute to dysfunction of the eustachian tubes. Unilateral and bilateral sensorineural hearing loss has been reported and may be caused by HIV infection involving the central nervous system (CNS) or the auditory nerve. Hearing loss also may be caused by syphilis, other CNS infections, chronic otitis media, neoplasms, and certain medications (including nucleoside analogues in rare cases). The pathophysiology, causative organisms, and incidence of external-ear infections appear to be the same in HIV-infected patients as in HIV-uninfected individuals.

S: Subjective

The patient may complain of ear pain, decreased hearing or hearing loss, a feeling of fullness in the ear, vertigo, or a popping or snapping sensation in the ear.

Obtain information regarding the following during the history:

- Medications (prescription and over-the-counter) and herbal supplements, current and past
- Current or recent sinus infection
- Associated symptoms
- Drainage or blood from the ear
- Head or ear trauma

O: Objective

CD4 count is an important measure of immunosuppression and a recent CD4 count is important in determining whether the patient is at risk of opportunistic infections as causes of ear complaints.

Perform visual and otoscopic inspection, including evaluation for skin abnormalities, lesions, cerumen impaction or foreign body, lymphadenopathy, and adenotonsillar hypertrophy.

If hearing loss is reported or suspected, evaluate hearing and refer the patient for an audiogram. Perform a neurologic examination and test for syphilis (e.g., rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL] test) and other possible causes.

A/P: Assessment and Plan

Otitis Externa/Interna

Proceed as with an immunocompetent patient. A chronic or atypical presentation in an HIV-infected patient warrants a thorough evaluation, including cultures, biopsy, radiographic scans, and referral to an ear, nose, and throat (ENT) specialist.

Hearing Loss

A patient with hearing loss should be referred for evaluation or treated, depending on the cause. Avoid ototoxic medications (e.g., furosemide, aminoglycosides).

Nose and Sinuses

Nasal and paranasal sinus conditions occur frequently in HIV-infected patients. Sinusitis, nasal obstruction, allergic rhinitis, and nasal lesions are common. Epistaxis can occur in patients with platelet disorders (e.g., idiopathic thrombocytopenic purpura [ITP]).

S: Subjective

The patient may complain of “stuffy nose,” rhinorrhea, epistaxis, frontal or maxillary headaches (worse at night or early morning), pain in the nostrils, persistent postnasal drip, mucopurulent nasal discharge, general malaise, aching or pressure behind the eyes, or toothache-like pain.

Obtain information regarding the following during the history:

- Medications (prescription and over-the-counter) and herbal supplements, current and past
- Current or recent sinus infection
- Previous sinus surgery
- Recent or current upper respiratory infection (URI)
- Nasal bleeding or discharge
- Facial trauma
- Allergic rhinitis
- Positional pain; worse when patient bends forward?
- Tobacco use
- Fever
- Headache
- Mucopurulent nasal drainage

O: Objective

CD4 count is an important measure of immunosuppression and a recent CD4 count is a key element in determining whether the patient is at risk of opportunistic infections as causes of nasal and sinus complaints.

Examine the nose and sinuses. Check the nasal mucosa with a light and a speculum, looking for areas of bleeding, purulent drainage, ulcerated lesions, or discolored areas. Palpate or percuss the sinuses for areas of tenderness, look for areas of swelling over the sinuses, and visualize the posterior pharynx for mucopurulent drainage. Transillumination may be helpful. Examine the teeth and gums for caries and inflammation of the gingivae. Check maxillary teeth with the use of a tongue blade (5-10% of maxillary sinusitis is attributable to dental root infection). Refer to a dentist for tooth sensitivity or caries.

A: Assessment

- Possible causes of epistaxis include coagulopathy, ITP, lesions of herpes simplex virus (HSV), and Kaposi sarcoma (KS) or other tumors. Suspect ITP if the platelet count is low and bleeding is difficult to control.
- Acute infection of one or more of the paranasal sinuses is common. *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* are seen in both HIV-uninfected and HIV-infected patients, whereas *Staphylococcus aureus* and *Pseudomonas aeruginosa* are found more often in HIV-infected patients. Fungi may be the causative agents, especially in patients with severe immunosuppression.
- Chronic sinusitis occurs frequently in patients with HIV infection and may be polymicrobial or anaerobic. In patients with low CD4 cell counts, fungal sinusitis may occur.
- Nasal obstruction may be caused by adenoidal hypertrophy, chronic sinusitis, allergic rhinitis, or neoplasm.
- Tumors may be caused by KS, squamous papilloma, or lymphoma; biopsy is necessary for determining the cause.
- Painful, ulcerated vesicles in the nasal mucosa may be caused by HSV or other infections.

P: Plan

Acute Sinusitis

Combination therapy with antibiotics, decongestants, mucolytics, saline nasal spray, and topical nasal steroids may be effective. See chapter *Sinusitis* for details. Note: For patients taking antiretroviral (ARV) regimens that include ritonavir or cobicistat, fluticasone (Flonase) nasal spray should not be used, and budesonide (Rhinocort Aqua) should be avoided if possible; see “Potential ARV Interactions,” below.

Chronic Sinusitis

Treat with a systemic decongestant (e.g., guaifenesin) or a saline nasal spray BID. Patients with exacerbations of sinusitis should be treated as for acute sinusitis. For more detailed information, see chapter *Sinusitis*. With patients taking ritonavir-boosted PIs, avoid fluticasone and budesonide nasal sprays; see “Potential ARV Interactions,” below.

Allergic Rhinitis

Patients should avoid exposure to known or suspected allergens. Nasal steroids may be very effective, but avoid fluticasone and budesonide nasal sprays with patients taking ritonavir or cobicistat (see “Potential ARV Interactions,” below). Second-generation nonsedating antihistamines such as cetirizine, fexofenadine, and loratadine are not as effective as nasal steroids, but may give additional symptom relief. Note that ritonavir may increase the serum levels and half-life of cetirizine. Daily nasal lavage with normal saline often is beneficial.

Nasal Obstruction

Perform magnetic resonance imaging (MRI) or computed tomography (CT) scan with biopsy for mass lesions or asymmetric nasal lymphoid tissue. Refer to an ENT specialist.

Epistaxis

Epistaxis caused by coagulopathy or tumor is managed the same as for immunocompetent patients with these conditions. Cauterization of an identified bleeding point or packing may be necessary. ITP should be managed in collaboration with a hematologist; antiretroviral therapy (ART) typically is used for chronic management, and corticosteroids or other therapies may be used for acute management.

Potential ARV Interactions

Caution: Protease inhibitors (PIs), particularly ritonavir-boosted PIs, and cobicistat [e.g., in coformulated elvitegravir/cobicistat/tenofovir/emtricitabine (Stribild)] may increase serum glucocorticoid levels if used concurrently with nasal steroids. Fluticasone (Flonase) nasal spray should not be used with ritonavir-boosted PIs or cobicistat unless expected benefits outweigh possible risks, and should be avoided, if possible, in patients taking unboosted PIs. Budesonide (Rhinocort Aqua) nasal spray should be avoided with ritonavir-boosted PIs and cobicistat. Interactions of PIs and cobicistat with other nasal steroids have not been well studied.

Ritonavir and cobicistat may increase serum levels of cetirizine and may prolong its half-life; start with low dosage and monitor for adverse effects.

Mouth and Throat

The oral cavity is one of the most common areas of symptoms in patients with HIV infection. Conditions that arise in the oral cavity may result from infectious, benign inflammatory, neoplastic, or degenerative processes.

S: Subjective

The patient may complain of white patches and red areas on the dorsal surface of the tongue and the palate, decreased taste sensation, white lesions along the lateral margins of the tongue, ulcers, nonhealing lesions at the corners of the mouth, sore gums, loose teeth, dysphagia, or odynophagia.

Obtain information regarding the following during the history:

- Medications (prescription and over-the-counter) and herbal supplements (note that some medications may cause aphthous ulcers)
- Usual oral hygiene (toothbrushing, tongue brushing or scraping, flossing, use of mouthwash)
- Date of last dental examination
- Use of tobacco (cigarettes, chewing tobacco)
- Involuntary weight loss

O: Objective

Because the CD4 count reflects degree of immunosuppression, a recent CD4 count is helpful in determining whether the patient is at risk of opportunistic infections as causes of oral complaints.

Thorough examination of the mouth and throat with a tongue depressor and a good light is mandatory. Observe for white patches or plaques on the mucous membranes that can be partially removed by scraping with a tongue blade (candidiasis). Examine the dorsal surface of the tongue and hard and soft palates for red, flat, subtle lesions (erythematous candidiasis). Look for ribbed, whitish lesions on the lateral aspects of the tongue that cannot be scraped off (oral hairy leukoplakia). Check for ulcerations, inflamed gums, and loose teeth (see section *Oral Health*). Look for discoloration or nodular lesions on the hard palate (Kaposi sarcoma). Check the pharynx for adenotonsillar hypertrophy. Rule out HIV-unrelated causes of pharyngitis, including streptococci or respiratory viruses.

A/P: Assessment and Plan

Perform biopsy, culture, and potassium hydroxide (KOH) preparation of lesions as indicated.

Oral Candidiasis (Thrush)

Oral candidiasis is most likely to occur when the CD4 count is <200 cells/ μ L, but it can occur at any CD4 level and in HIV-uninfected individuals. It may appear as creamy white plaques on the tongue or buccal mucosa or as erythematous lesions on the dorsal surface of the tongue or the palate. The most common treatment strategy is empiric therapy with topical or systemic antifungal agents. For more details, see chapter *Candidiasis, Oral and Esophageal*.

Angular Cheilitis

Angular cheilitis is also caused by *Candida* species, and it is characterized by fissuring at the corners of the mouth. For information on treatment, see chapter *Candidiasis, Oral and Esophageal*.

Oral Hairy Leukoplakia

Oral hairy leukoplakia (OHL) is caused by Epstein-Barr virus and appears as raised, ribbed, “hairy” white lesions along the lateral margins of the tongue. Lesions are primarily asymptomatic, and treatment generally is not needed. Lesions often resolve with effective ART. For more details, see chapter *Oral Hairy Leukoplakia*.

Kaposi Sarcoma

KS appears as red, blue, or purplish lesions that are flat or nodular, and solitary or multiple. Lesions appear most commonly on the hard palate but also occur on the gingival surfaces and elsewhere in the mouth. A definitive diagnosis requires biopsy and histologic examination. KS often resolves with ART and successful immune reconstitution. If lesions do not respond to ART or if they are severe or numerous, refer to an oncology specialist for chemotherapy. For more details, see chapter *Kaposi Sarcoma*.

Gingivitis

See chapter *Necrotizing Ulcerative Periodontitis and Gingivitis* for details.

Herpes Simplex Virus

HSV lesions occur on the palate, gingivae, or other mucosal surfaces. They appear as single or clustered vesicles and may extend onto adjacent skin of the lips and face to form a large herpetic lesion. Lesions tend to be more common, persist longer, recur more often, and be larger and more numerous in HIV-infected patients, especially those with significant immunosuppression, than in healthy individuals. Empiric treatment with valacyclovir, famciclovir, or acyclovir is appropriate. For more details, see chapter *Herpes Simplex, Mucocutaneous*.

Aphthous Ulcers

Aphthous ulcers are eroded, well-defined lesions surrounded by erythema, ranging in size from <6 mm to several centimeters in diameter. The ulcers can appear anywhere in the oral cavity or pharynx and may be recurrent; they are extremely painful. Treatment may involve topical steroids or other methods. For more details, see chapter *Oral Ulceration*.

Oral Warts (Human Papillomavirus)

Oral warts may appear as solitary or multiple nodules. The lesions may be smooth, raised masses resembling focal epithelial hyperplasia, or small papuliferous or cauliflower-like projections. See chapter *Oral Warts*.

***Neisseria gonorrhoeae* Pharyngitis**

Neisseria gonorrhoeae may be transmitted by orogenital exposure; the patient may have mild symptoms (e.g., sore throat) or be asymptomatic. Physical examination may reveal an erythematous pharynx or exudates. Anterior cervical lymphadenopathy also may be present. Most cases of *N. gonorrhoeae* pharyngeal infection will resolve spontaneously without treatment and usually do not cause adverse sequelae. However, treatment should be initiated to reduce the spread of the infection (see chapter *Gonorrhea and Chlamydia*). Regular screening is recommended for patients at risk of *N. gonorrhoeae* infection.

Medication-Related Causes of Mouth or Throat Lesions

- Candidiasis: antibiotics
- Xerostomia: antihistamines, anticholinergics, tricyclics, antipsychotic
- Gingival hyperplasia: phenytoin, calcium channel blockers

Other Conditions

Most of the above complications also can occur in the esophagus. See chapters *Esophageal Problems*; *Candidiasis, Oral and Esophageal*; and *Cytomegalovirus Disease*.

If patient is having mouth pain, anorexia, or problems with taste, treat the condition appropriately and refer to an HIV-experienced dentist for evaluation and further treatment as needed. Refer to a dietitian for assistance with dietary needs (e.g., nutritional supplements).

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Esophageal Problems

Background

Esophageal problems in HIV-infected patients include difficulty swallowing (dysphagia) or midline retrosternal pain when swallowing (odynophagia). Pain may be diffuse throughout the esophagus or localized in specific areas.

Several conditions may cause esophageal problems. Of the infectious causes of dysphagia in HIV-infected patients, *Candida* is the most common (50-70%). Drug-induced dysphagia, gastroesophageal reflux disease (GERD), vomiting, and hiatal hernia also can cause esophagitis. Less commonly, esophageal cancer or another cause of stricture may produce symptoms. Neuromuscular or neurological causes may be seen in patients with advanced AIDS.

If untreated, esophageal problems may result in esophageal ulcers, scarring of the esophagus, dehydration, and weight loss.

S: Subjective

The patient may complain of difficulty swallowing, a feeling of something being “stuck in the throat,” retrosternal pain when eating, “hiccups,” indigestion (“heartburn”), retrosternal burning, acid reflux, nausea, vomiting, or abdominal pain. Ascertain the following during the history:

- Medications (prescription and over-the-counter) and herbal supplements, current and past
- Concurrent gastrointestinal (GI) symptoms, such as abdominal pain or diarrhea
- Recent dietary history
- Location and characteristics of pain (diffuse or focal)
- Oral thrush
- Aphthous ulcers
- Cytomegalovirus (CMV)
- *Candida* esophagitis
- Gastroesophageal reflux disease (GERD)
- Hiatal hernia
- Presence of dysphagia to solids, liquids, or both
- Hematemesis or melena

O: Objective

Include the following in the physical examination:

- Measure vital signs (temperature may be elevated with certain infections, such as CMV, but not with herpes simplex virus [HSV], candidiasis, or idiopathic ulcers).
- Record weight (and compare with previous weights).
- Assess for oral candidiasis, lesions, and masses.
- Examine optic fundi to evaluate for CMV retinitis (in patients with CD4 counts of <50-100 cells/ μ L).
- Palpate for thyroid enlargement.
- Palpate the neck and supraclavicular and infraclavicular areas for lymphadenopathy.
- Assess the abdomen for masses, tenderness, and organomegaly.
- Perform a rectal examination to obtain stool for occult blood.
- Perform a neurologic examination.
- Check the CD4 cell count and HIV viral load to determine the level of immunosuppression and assess the risk of opportunistic infections as causes of esophageal complaints.

A: Assessment

Common causes of esophageal problems are as follows:

- Candidiasis (common with a CD4 count of <200 cells/ μ L or recent exposure to steroids or antibiotics)
- Most medications, including antiretroviral agents, can cause nausea and GI-related symptoms; the following medications are commonly associated with difficulty swallowing or heartburn: aspirin, nonsteroidal antiinflammatory drugs, potassium chloride, iron, tetracycline, theophylline, anticholinergic agents, calcium channel blockers, meperidine, and progesterone tablets
- Foods can irritate the esophagus, including citrus fruits, mints, coffee, chocolate, and spicy foods
- GERD

Less-common causes of esophageal problems include:

- CMV, HSV, idiopathic or aphthous ulcers
- Kaposi sarcoma, lymphoma, tuberculosis, *Mycobacterium avium* complex (MAC), histoplasmosis
- Cardiac chest pain

P: Plan

Diagnostic Evaluation

Diagnosis often can be made on clinical grounds; in this case, empiric treatment may be initiated (see below). If the diagnosis is unclear, consider endoscopy or radiographic imaging (e.g., computed tomography or barium swallow).

If the patient has dysphagia, odynophagia, unexplained weight loss, GI bleeding, anemia, or atypical symptoms, refer promptly for GI evaluation and endoscopy, or other evaluation as suggested by symptoms.

Treatment

Determine whether the patient is able to swallow pills before giving oral medications. If pills are not tolerated, the patient may need liquids or troches.

For patients with severe oral or esophageal pain, viscous lidocaine 1% 5-10 mL 2-4 times daily (with swallowing precautions) or Magic Mouthwash (viscous lidocaine 1%, tetracycline, diphenhydramine, and nystatin compounded 1:1:1:1) may be tried.

Other treatments may depend on the underlying cause:

- **Esophageal candidiasis:** Fluconazole is the drug of choice. If symptoms resolve within 7-10 days, no further testing is required. See chapter *Candidiasis, Oral and Esophageal* for more treatment options and for dosing information.
- **Medication related:** Remove the offending drug(s), and institute a trial of H2 blockers or proton pump inhibitors (PPIs) as appropriate (caution: see “Potential ARV Interactions,” below).
- **Food related:** Modify the diet and institute a trial of H2 blockers or PPIs as appropriate (caution: see “Potential ARV Interactions,” below).
- **“Heartburn” or GERD:** Patients whose primary symptoms are more typical of “heartburn” or reflux, especially those with a history of GERD, should receive a trial of H2 blockers or a PPI as appropriate (these may decrease absorption of atazanavir and rilpivirine; see “Potential ARV Interactions,” below). Reevaluate after 2-4 weeks; if symptoms are controlled, treat for 4-8 weeks, then reduce the dosage to the lowest effective amount.

Patients may require maintenance therapy for an indefinite period because of the high likelihood of recurrence. If symptoms do not respond to full-dose acid-blocking therapy, refer for GI evaluation.

- **GERD:** For nonpharmacologic treatment, in cases of obesity, counsel patients to lose weight, stop smoking, elevate the head of the bed, eat smaller meals, avoid eating food 2-3 hours before bedtime, and reduce fat in the diet to $\leq 30\%$ of calorie consumption.
- **CMV:** Treat with anti-CMV medications (e.g., oral valganciclovir). See chapter *Cytomegalovirus Disease* for details.
- **HSV:** Treat with antiviral medications, including acyclovir, famciclovir, and valacyclovir. See chapter *Herpes Simplex, Mucocutaneous*.
- **Aphthous ulcers:** These may respond to oral corticosteroids (consult with a specialist before this is undertaken). Alternatively, a combination of H2 blockers and sucralfate may be effective. In some circumstances, thalidomide 200 mg Q24H may be used. (**Note:** Thalidomide is teratogenic, and women of childbearing potential are not candidates for this therapy unless the potential benefits clearly outweigh the risks and appropriate prevention of pregnancy is undertaken.) Up to 40-50% of patients with aphthous ulcers experience relapse and require repeat treatment.
- **Neoplastic disease:** Treating this condition requires referral to an oncologist.

Esophageal conditions that do not resolve with treatment require referral to a GI specialist for diagnostic endoscopy, with biopsy and brushing for histopathology and cultures as appropriate.

Diet

It is important that patients maintain adequate caloric intake, preferably with foods and liquids that can be swallowed easily. Nutritional supplements along with soft, bland, high-protein foods are recommended. Refer to a nutritionist as needed.

Potential ARV Interactions

Caution: H2 blockers and PPIs interfere with the absorption of atazanavir and rilpivirine. For atazanavir, specific dosing strategies are required, and some combinations are contraindicated. For rilpivirine, PPIs are contraindicated and H2 blockers require specific dose timing. Polyvalent cations (e.g., magnesium, calcium, iron) contained in antacids, supplements, and other medications may lower serum levels of integrase inhibitors and require separate administration. See package inserts for dosage recommendations.

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Eye Problems

Background

The immunosuppression caused by HIV infection increases the incidence of eye infections. However, the risk of serious eye problems associated with advanced immunosuppression, such as blindness caused by cytomegalovirus (CMV) retinitis, is much lower in patients treated with effective antiretroviral therapy (ART). Common problems not unique to HIV-infected patients include dry eye, blepharitis, keratitis, and presbyopia. Infections that may affect the eye include herpes simplex virus (HSV), herpes zoster virus (HZV), and syphilis. More severely immunocompromised patients (CD4 count <100 cells/ μL) may experience CMV retinitis, Toxoplasma retinochoroiditis, cryptococcal chorioretinitis, and other conditions. Retinal detachment can result. Kaposi sarcoma (KS) also can affect the eye.

Immune reconstitution inflammatory syndrome (IRIS) may affect the eye in patients with advanced HIV disease soon after the initiation of effective ART. IRIS may lead to exacerbation of a previously treated opportunistic infection or a new presentation (often with unusual manifestations) of a previously subclinical infection. In the case of CMV, IRIS may present as retinitis, or less commonly as uveitis or vitreitis. IRIS retinitis typically occurs in patients whose CD4 counts have increased from <50 cells/ μL to 50-100 cells/ μL while receiving ART.

Drug-induced ocular toxicity can be caused by many medications, including rifabutin, ethambutol, and cidofovir, and less often by high-dose didanosine (ddI, Videx), IV ganciclovir, IV acyclovir, and atovaquone.

S: Subjective

The patient complains of dry eyes, blurred vision, floaters, sharp pains, flashing lights, central vision loss (“black holes”), vision field defects (“can only see half the page”), or peripheral vision loss (“looks like I’m in a tunnel”).

Ascertain the following during the history:

- Pain: clarify type and characteristics
- Unilateral or bilateral problem
- Visual defects (central or peripheral vision loss or distortion), scotomata (an area of lost or depressed vision surrounded by an area of less-depressed or normal vision); occurs with reading, distance, or both?
- Time course of symptoms
- Fever
- Headache
- Previous eye or vision problems

- Medications (prescription and over-the-counter) and herbal supplements, current and past
- Use of corrective lenses
- Date of last eye examination
- Recent or current varicella-zoster virus (VZV) or HSV infection

O: Objective

Evaluate recent CD4 cell count and HIV viral load to determine whether the patient is at risk of opportunistic infections as causes of eye complaints. Also, do the following:

- Consider the patient’s age.
- Check vital signs, including blood pressure and temperature.
- Administer a visual acuity examination using the Snellen chart. Test the patient’s ability to read small print, such as classified ads.

- Consider using an Amsler grid to locate areas of retinal pathology.
- Examine the eyelids for lesions, inflammation, and swelling.
- Examine the external eye for edema, ptosis, conjunctival injection, and corneal clarity.
- Test cranial nerves II, III, IV, and VI.
- Perform funduscopic examination with pupillary dilatation, if available. Note retinal appearance, lesions, and condition of the disc, vessels, and macula.
- Examine the temples and scalp for tenderness.

A/P: Assessment and Plan

Refer to an HIV-experienced ophthalmologist for dilated retinal or slit-lamp examination and definitive diagnosis. If symptoms raise suspicion of serious or vision-threatening conditions such as herpes ophthalmicus, CMV retinitis, or retinal necrosis, ophthalmologic evaluation should occur within 24-72 hours. Note that patients with HSV or VZV lesions in the V1 distribution (including the forehead, eyelids, or nose) should receive urgent ophthalmologic evaluation.

The differential diagnosis includes the following conditions:

Dry Eye (Keratoconjunctivitis Sicca)

The patient may complain of intermittent eye pain, intermittent blurred vision that clears with blinking, and mild eye irritation. The condition worsens with extended reading or computer use. Keratoconjunctivitis sicca is related to HIV-mediated inflammation with damage to the lacrimal glands. It occurs in 10-20% of HIV-infected patients, most often in those with advanced HIV disease. In patients with a CD4 count of >400 cells/ μ L and no other signs or symptoms, confirm that results of a recent eye examination were normal or refer for same, prescribe artificial tears, and monitor.

Blepharitis

Blepharitis is inflammation of the eyelids, a common condition with dry eyes. The patient may complain of discharge and erythema of the eyes or eyelids. Of the bacterial causes, *Staphylococcus aureus* is the most common. Treatment includes cleaning of the eyelashes with warm water and mild shampoo, and applying antibiotic ointment if indicated.

Infectious Keratitis

The patient may complain of photophobia, eye pain, decreased vision, and irritation. Infectious keratitis may be caused by VZV, HSV, CMV, bacteria, fungi, or *Microsporidia*. VZV and HSV are the most common infectious causes of keratitis in HIV-infected patients. Bacterial and fungal keratitis occur with equal frequency in HIV-infected and HIV-uninfected persons. Fungal infections are caused most often by *Candida* species, especially in intravenous drug users. Keratitis may be more severe and may recur more frequently in HIV-infected patients than in HIV-uninfected persons. Evaluation should include slit-lamp examination by an ophthalmologist.

Refraction Problems

The patient may complain of blurring vision with near or distance vision. Other findings include an abnormal Snellen test or inability to read fine print. The condition may be attributable to presbyopia or other causes. Refer for ophthalmologic examination.

Iridocyclitis/Anterior Uveitis

The patient may complain of redness or watering of the eyes, constriction of the pupil, and blurred vision. Anterior-chamber inflammation is fairly common among patients with HIV infection and is often associated with CMV or HSV retinitis. Ocular bacterial infections, syphilis, toxoplasmosis, and tuberculosis can cause severe symptoms. Fungal retinitis rarely causes iridocyclitis. Other causes include other systemic conditions

(e.g., reactive arthritis, sarcoidosis) and drug toxicity (e.g., rifabutin, cidofovir, ethambutol). Evaluation should include slit-lamp examination by an ophthalmologist.

Treatment should be directed at the causative pathogen or illness. If drug toxicity is suspected, the offending drug should be discontinued or reduced in dosage, if possible. Topical steroids may be indicated as an adjunctive measure. CMV IRIS may present as posterior uveitis; for suspected IRIS, consult an HIV-experienced ophthalmologist.

HIV Retinopathy

The patient typically has no symptoms, but may complain of blurred vision, visual field defects, floaters, or flashing lights. Cotton wool spots on the retina appear as small fluffy white lesions with indistinct borders and without exudates or hemorrhages. Usually, these findings are benign and do not progress. Refer for ophthalmologic examination to rule out other causes.

CMV Retinitis

Patients with retinitis caused by CMV infection may be asymptomatic or may experience blurred vision, floaters, scotomata, or central or peripheral vision loss or distortion. Retinal examination shows creamy to yellowish lesions, white granular areas with perivascular exudates, and hemorrhages (“cottage cheese and ketchup”). The abnormalities initially appear in the periphery, but progress if untreated to involve the macula and optic disc. CMV is a common complication of advanced HIV infection in patients with CD4 counts of <50 cells/ μ L. Vision loss usually is permanent. Urgent ophthalmology consultation and initiation of anti-CMV therapy are required. See chapter *Cytomegalovirus Disease*.

Acute Retinal Necrosis

The patient may complain of eye pain, decreased visual acuity, and floaters. Rapidly progressing peripheral necrosis frequently causes blindness. Retinal necrosis usually is caused by VZV, although HSV and CMV also have been implicated. Treatment should be initiated urgently.

***Toxoplasma* Retinochoroiditis**

Toxoplasma retinochoroiditis may occur in patients with CD4 counts of <100 cells/ μ L and cause blurred vision, visual field defects, floaters, or flashing lights. In HIV-infected patients, ocular manifestations often appear after the infection of the central nervous system with *Toxoplasma* (see chapter *Toxoplasmosis*). Retinal examination may reveal yellow-white infiltrates without hemorrhage and active vitreous inflammation. Evaluation requires consultation with an HIV-experienced ophthalmologist. If toxoplasmosis is confirmed or strongly suspected, treatment should be initiated as quickly as possible.

Neuro-Ophthalmologic Manifestations

Symptoms or signs of papilledema, optic neuritis, cranial nerve palsies, and visual field defects may indicate encephalopathy, increased intracranial pressure, neurosyphilis, toxoplasmosis, progressive multifocal leukoencephalopathy, meningitis, or central nervous system lymphomas. A thorough neurologic examination is required to determine whether additional diagnostic testing, such as imaging studies or cerebrospinal fluid testing, is needed in addition to ophthalmologic evaluation.

Retinal Detachment

The patient may complain of flashes of light, sudden loss of vision, or both. This condition requires immediate referral to an emergency department.

Patient Education

- Patients should report any changes in vision to their health care provider as soon as possible.
- Patients with CD4 counts of <50 cells/ μ L should be examined by an ophthalmologist at baseline and every 6 months thereafter.

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Fatigue

Julie Barroso, PhD, ANP-BC, APRN, FAAN

Background

Fatigue is one of the most common and debilitating complaints of HIV-infected people, with an estimated prevalence of 33-88%. Fatigue is defined by the NIH Patient Reported Outcomes Measurement Information System (PROMIS) initiative as “mild subjective feelings of tiredness to an overwhelming, debilitating, and sustained sense of exhaustion that is likely to decrease one’s ability to carry out daily activities, including the ability to work effectively and to function at one’s usual level in family or social roles. Fatigue is divided conceptually into the experience of fatigue (such as its frequency, duration, and intensity), and the impact of fatigue upon physical, mental and social activities.” The consequences of severe fatigue may include curtailment of work and other activities, need for frequent breaks, limitations in involvement with family and friends, and difficulty completing even the simplest household chores.

In HIV-infected individuals, fatigue may be caused by comorbid conditions or by HIV itself. HIV-related fatigue is a broad term referring to fatigue that begins or significantly worsens after the patient is infected with HIV and that has no other identifiable causes. HIV-infected people with fatigue should be evaluated carefully for reversible causes, such as depression, anemia, hypothyroidism, hypogonadism, poor sleep quality, and medication adverse effects; if these are found, they should be treated aggressively. In some patients, fatigue may be related to advanced immunosuppression (e.g., low CD4 cell counts) or to high levels of circulating HIV virus. Unfortunately, for many patients, a specific cause of fatigue is not identified, and fatigue in many HIV-infected individuals may result from a complex interplay between physiologic and psychosocial variables. Recent research has examined genes that are predictive of low vs. high fatigue; abnormal neuronal circuitry involving striatal-cortical pathways that may play a role in HIV-related fatigue; prior use of didanosine or stavudine; and the presence of clinical lipodystrophy syndrome. From a psychosocial standpoint, stress, with its attendant anxiety and depression, seems to be the most consistent predictor of HIV-related fatigue.

S: Subjective

The patient complains of tiredness, easy fatigability, a lack of energy, a need for frequent rest or naps, or waking in the morning feeling unrefreshed. The patient may report difficulty working, difficulty concentrating, inability to exercise without experiencing profound fatigue, or impairment in social relations because of fatigue.

Consider the following during the history:

- No objective clinical indicators exist for fatigue; thus, making a diagnosis of fatigue rests on subjective data.
- Fatigue assessment tools may help in diagnosing fatigue and estimating its severity. One such tool, the HIV-Related Fatigue Scale, was developed specifically for use with HIV-infected individuals; this assesses the intensity of fatigue (on the day of the assessment and during the previous week), the circumstances surrounding fatigue (including patterns), and the consequences of fatigue.
- Take a thorough history of the fatigue symptoms, including onset, duration, exacerbating and alleviating factors, and associated symptoms. Evaluate

for symptoms of other conditions that cause fatigue (e.g., hypothyroidism, hypogonadism, anemia, heart failure, poor nutrition).

- Depression can cause significant fatigue and is common among HIV-infected patients with fatigue. Screen the patient for depression. A single question – “Are you depressed?” – has been shown to be as valid and reliable as most depression instruments. See chapter *Major Depression and Other Depressive Disorders* for further information.
- Inquire about social history, specifically any life stressors including those related to housing status, work stress, and personal relationships.
- Evaluate the patient’s sleep patterns. HIV infection can interfere with sleep architecture early in the illness.
- Inquire about substance use or abuse.
- Obtain a list of all current medications, including herbal and over-the-counter preparations.
- Conduct a nutritional assessment.

O: Objective

Check vital signs, including orthostatic blood pressure and heart rate measurements, if indicated. Perform a physical examination including evaluation of nutritional status, affect, conjunctivae and skin (for pallor), thyroid, lungs and heart, and deep tendon reflexes.

A: Assessment

The differential diagnosis includes the following:

- Anemia
- Depression
- Hypogonadism
- Hypothyroidism
- Insomnia or poor-quality sleep
- Malnutrition
- Medication adverse effects (e.g., zidovudine, interferon)
- Opportunistic infections, malignancy, chronic hepatitis B or C, mononucleosis, other illnesses
- Pregnancy
- Substance use or abuse

P: Plan

Diagnostic Evaluation

To rule out reversible causes of fatigue, perform laboratory tests, including:

- Hemoglobin and hematocrit
- Thyroid function tests
- Testosterone (in both men and women)
- Pregnancy test, if applicable
- CD4 and HIV viral load (if not done recently), electrolytes, creatinine, and liver function tests

Fatigue assessment tools, as mentioned above, may be used to assess the intensity of fatigue, the circumstances surrounding fatigue, and the consequences of fatigue.

Treatment

If testing reveals a specific cause of fatigue, treat appropriately. For example:

- Treat anemia, hypothyroidism, or hypogonadism, as indicated.
- Treat depression with antidepressant

medication, psychotherapy, or both; see chapter *Major Depression and Other Depressive Disorders*.

- Treat insomnia and review good sleep-hygiene practices with the patient; see chapter *Insomnia*.
- Refer for treatment of substance use or abuse, if possible.
- Provide counseling regarding any current life stressors that may be contributing to fatigue. Involve social work and case management services regarding housing issues or other social needs that may be contributing to fatigue.
- Treat malnutrition, ideally in conjunction with a nutritionist.
- Treat opportunistic infections and other illnesses. (See section *Comorbidities, Coinfections, and Complications*.)
- Control other symptoms that could be causing fatigue (e.g., diarrhea).
- If fatigue seems to be related to antiretroviral medication(s), weigh the benefits of the medication(s) against the possible adverse effects, and discuss these with the patient.

After appropriate evaluation, if the fatigue is thought to be related to HIV infection or if no specific cause is identified, consider the following:

- If HIV infection is inadequately controlled, particularly if the CD4 count is low or the HIV viral load is high, initiate or optimize antiretroviral therapy (ART), if otherwise appropriate.
- Patients taking effective ART may still experience HIV-related fatigue. Prepare patients for the possibility that fatigue may persist despite ART initiation.
- Encourage patients to track their patterns of fatigue with a fatigue diary. Once patients recognize their individual patterns, they can better cope with fatigue by planning their daily activities accordingly (e.g., performing the most strenuous tasks during times of

peak energy or staggering activities to avoid excessive fatigue).

- Ask patients what seems to aggravate their fatigue. This information, too, will help patients determine their patterns of fatigue and identify self-care actions they might take to avoid triggers that will worsen the fatigue.
- Recommend moderate exercise and frequent rest.
- Refer the patient to community-based agencies for assistance with housekeeping.
- Evaluate the need for occupational therapy (e.g., energy conservation techniques) or physical therapy (e.g., reconditioning and strengthening exercises).
- Medications such as stimulants (e.g., modafinil) may be helpful for some patients with severe or debilitating fatigue.

Patient Education

- Fatigue is often unrelated to the CD4 cell count or HIV viral load. Teach patients not to dismiss feelings of fatigue if they have higher CD4 counts and lower viral loads. Encourage them to discuss their symptoms with a health care provider.
- For patients with depression, advise them that appropriate treatment may reduce fatigue.
- Help patients identify how current life circumstances and stressors may contribute to fatigue and encourage them to seek the appropriate social services to help manage appropriately.
- Talk to patients about their sleep habits and recommend changes, as appropriate, to improve their sleep hygiene.
- Prepare patients to accept the fact that their fatigue (in some cases) may be a chronic condition, in which case it can be best managed by maintaining open communication with their providers and remaining engaged in care.

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Fever

Background

Although fever may accompany HIV infection at various stages of disease, fever in a patient with a low CD4 count (<200 cells/ μ L) should prompt the clinician to rule out opportunistic infections.

S: Subjective

The patient complains of persistent fever, or new-onset fever of $>101^{\circ}\text{F}$ (38.3°C).

Assess the following during the history:

- Duration of fever
- Associated symptoms, including chills, sweats, weight loss
- Visual disturbances (see chapter *Eye Problems*)
- Nasal or sinus symptoms
- Asymmetric, tender, or new lymphadenopathy
- Cough or shortness of breath (see chapter *Pulmonary Symptoms*)
- Diarrhea, tenesmus (see chapter *Diarrhea*)
- Rash, lesions, soft-tissue inflammation
- Pain (for headache, see chapter *Headache*)
- Neurologic symptoms (see chapter *Neurologic Symptoms*)
- Vaginal or urethral discharge
- Other localizing symptoms
- Unprotected sexual contacts
- Recent injection drug use
- Intravenous line or venous access device
- Travel within the past 6-12 months
- Medications (as a cause of fever)
- Use of antipyretic agents including aspirin, nonsteroidal antiinflammatory drugs (NSAIDs), and acetaminophen; when was most recent dose taken?

O: Objective

Document fever. Check other vital signs, including orthostatic measurements. Check weight and compare with previous values.

Search for evidence of an infectious focus. Perform a complete physical examination, including evaluation of the eyes (including fundus), sinuses, oropharynx, ears, lymph nodes, lungs and heart, abdomen, joints, genitals, uterus, rectum, skin, and neurologic system.

Review recent CD4 measurements, if available, to determine the patient's risk of opportunistic illnesses as a cause of fever.

A: Assessment

The differential diagnosis varies depending on the CD4 count. Possibilities include the following:

Conditions More Likely with Low CD4 Count

- Aspergillosis
- Cryptococcosis
- Cytomegalovirus (CMV) infection
- Disseminated Mycobacterium avium complex (MAC)
- Disseminated histoplasmosis
- HIV infection itself
- Lymphoma, other neoplasms
- Pneumocystis jiroveci pneumonia (PCP)
- Toxoplasmosis
- Tuberculosis (atypical or extrapulmonary)

Conditions That May Occur with Any CD4 Count

- Abscess, cellulitis
- Acute hepatitis
- Autoimmune process
- Bacteremia or sepsis
- Bacterial pneumonia or bronchitis
- Disseminated herpes simplex virus; chickenpox
- Drug-induced fever (common culprits include abacavir, nevirapine, sulfonamides, dapsone, penicillin, clindamycin, carbamazepine, phenytoin, barbiturates, and bleomycin)
- Endocarditis
- Immune reconstitution syndromes, related to opportunistic infections, are often associated with fever (see chapter *Immune Reconstitution Inflammatory Syndrome*)
- Influenza
- Otitis
- Malaria
- Pelvic inflammatory disease (PID)
- Sexually transmitted diseases
- Sinusitis
- Tuberculosis (pulmonary)
- Urinary tract infection (UTI)

**P: Plan
Diagnostic Evaluation**

Perform laboratory work and other diagnostic studies as suggested by the history, physical examination, and differential diagnosis. These may include the following:

- CD4 count (if not done recently) to help with risk stratification for opportunistic illnesses
- Complete blood count (CBC) with differential
- Blood cultures (bacterial, mycobacterial, fungal)
- Urinalysis, urine culture if UTI symptoms are present
- Liver transaminases, renal panel
- Chest X-ray
- Sinus films if indicated by symptoms and physical examination findings
- If respiratory symptoms and signs are present: sputum evaluation (Gram stain and acid-fast bacilli smear, evaluation for PCP), with culture of sputum for bacterial pathogens, acid-fast bacilli, viruses, and fungi as indicated; consider sputum induction or bronchoscopy if indicated
- Serum cryptococcal antigen, particularly if CD4 count is <100 cells/ μ L and symptoms are consistent with cryptococcosis
- If neurological symptoms and signs are present: computed tomography (CT) or magnetic resonance imaging (MRI) of head, lumbar puncture
- For new lymphadenopathy: aspirate with culture (including acid-fast bacilli and fungal) and cytology
- For cytopenias: bone marrow aspirate and biopsy may be needed; see applicable treatment guidelines

- For fever of unknown origin (FUO), defined as persistent fever $>101^{\circ}\text{F}$ for >3 weeks without findings on initial workup, more intensive workup may be needed, such as lumbar puncture, other scans or biopsies; consult with a specialist in infectious diseases or an HIV expert to determine whether hospitalization or other laboratory tests are needed
- For patients who recently started abacavir or nevirapine, or other medications, rule out hypersensitivity reactions (see chapter *Adverse Reactions to HIV Medications*)

Treatment

Once a diagnosis is made, appropriate treatment should be initiated. In seriously ill patients, presumptive treatment may be started while diagnostic tests are pending. In some cases, the source of fever cannot be identified. Consult with an HIV expert.

Symptomatic treatment may include NSAIDs (e.g., ibuprofen, naproxen), acetaminophen, and analgesics. Monitor for adverse gastrointestinal effects with NSAIDs. Cold compresses also can be used to relieve fever symptoms. Refer to a dietitian to avoid weight loss during the hypermetabolic state. See section *Comorbidities, Coinfections, and Complications* in this manual if an HIV-related cause is identified.

Patient Education

- Patients should report any new fever to their health care provider. They should measure their temperature using a thermometer at home in order to report actual temperatures.
- Patients should know that fever usually is a sign that their bodies are battling an infection. Their health care providers may need to do special tests to find out what could be causing the fever.
- Many over-the-counter remedies are available to treat fevers. Patients should check with their care provider before taking these. Acetaminophen-containing products (e.g., Tylenol) generally are well tolerated. Persons with liver disease should use acetaminophen only as prescribed. NSAIDs (e.g., ibuprofen, naproxen) may be used, but they can cause adverse gastrointestinal effects, especially if taken without food. Patients should let their care provider know if they need to take these medicines for more than 2 or 3 days.

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Headache

Background

Headache in HIV-infected persons may result from many causes, particularly if the CD4 cell count is low. Possible causes include infections (opportunistic and other) and central nervous system malignancies, HIV-related systemic illnesses, and medication toxicity. In addition, headache may be caused by any of the processes that cause headache in HIV-uninfected individuals. New or severe headache should be evaluated carefully.

S: Subjective

The patient complains of a new type of headache.

Determine the following during the history:

- History of headaches or migraines
- Characteristics of the headache (e.g., location, quality of pain, timing, duration)
- Recent head trauma
- Fever
- History of sinusitis
- Allergies
- Visual changes
- Dizziness, vertigo, nausea
- Mental status changes
- Seizures
- Focal or other neurologic symptoms (see chapter *Neurologic Symptoms*)
- New rashes or ulcerations
- Other symptoms
- Caffeine intake; recent changes in intake
- New medications (e.g., zidovudine, dolutegravir)
- Relief of headache by any medication
- Unprotected sex, new sex partner

O: Objective

Perform a physical examination as follows:

- Check vital signs. Look for fever, orthostasis, and hypertension.
- Examine the head and neck for trauma, sinus tenderness, scalp or temple tenderness, and neck mobility; check lymph nodes.
- Check the eyes, including fundoscopic examination, for lesions or papilledema.
- Look for oral lesions, dental abscess, thrush, and pharyngeal drainage.
- Examine the lungs for abnormal sounds.
- Check the skin, including palms and soles, for rashes or lesions.
- Perform a complete neurologic examination, including mental status examination.
- Review recent CD4 measurements, if available, to determine the patient's risk of opportunistic illnesses as a cause of headache.

A: Assessment

A partial differential diagnosis includes the following:

- Anemia
- Caffeine withdrawal
- Central nervous system lymphoma
- Cryptococcal meningitis
- Cytomegalovirus (CMV) meningoencephalitis or retinitis
- Dehydration
- Depression, anxiety disorder
- Fever
- Hypertension
- Medication adverse effect
- Migraine or cluster headache
- Neurosyphilis
- Other encephalitis
- Progressive multifocal leukoencephalopathy (PML)
- Sinusitis
- Stress or tension headache
- Systemic infection
- Temporal arteritis
- Toxoplasmic encephalitis
- Tuberculous meningitis; other meningitis

Other causes of headache unrelated to HIV should be considered.

P: Plan**Diagnostic Evaluation**

Evaluation should include the following:

- CD4 cell count (if not done recently), to help with risk stratification for opportunistic illnesses
- Complete blood count with differential (if fever or suspected anemia); see chapter *Fever*
- Blood chemistries, including liver function tests, electrolytes, creatinine, glucose
- Serum cryptococcal antigen (if fever is present and CD4 count is <100 cells/μL); see chapter *Cryptococcal Disease*
- *Toxoplasma* immunoglobulin G (consider if previously negative and CD4 count is <100 cells/μL; may indicate risk of toxoplasmosis); see chapter *Toxoplasmosis*
- Syphilis testing: rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL) test; see chapter *Syphilis*

When indicated, also consider:

- Computed tomography (CT) scan with contrast or magnetic resonance imaging of the head; see chapter *Neurologic Symptoms*
- Lumbar puncture with cerebrospinal fluid (CSF) studies to include opening pressure, cell count, chemistries, bacterial cultures; fungal and acid-fast bacilli evaluations and cultures; India ink stain; cryptococcal antigen, VDRL, as indicated
- Sinus imaging
- Erythrocyte sedimentation rate, if temporal arteritis is suspected

Treatment

- Once a diagnosis is made, appropriate treatment should be initiated. In seriously ill patients, presumptive treatment may be initiated while diagnostic test results are pending. In some cases, the source of headache cannot be identified. Consult with an HIV expert or a neurologist.
- Refer to disease-specific treatment guidelines or primary care management guidelines as appropriate.
- Treat symptomatically with nonsteroidal antiinflammatory drugs (NSAIDs), acetaminophen, or narcotics, if indicated, to control pain.

Patient Education

- Headache can be a sign of an opportunistic infection, especially in patients with low CD4 cell counts. Patients should notify their health care provider if they develop a new headache.
- Providers should inform patients that they may have to do additional tests to determine the cause of the headache.
- Many over-the-counter remedies are available for headache. Patients should check with their health care provider before taking these. Acetaminophen-containing products (e.g., Tylenol) generally are well tolerated. Persons with liver disease should use acetaminophen only as prescribed. NSAIDs (e.g., ibuprofen, naproxen) may be used, but these agents can cause adverse gastrointestinal effects, especially if taken without food. Patients should inform their care provider if they need to take these medicines for more than 2 or 3 days.

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Lymphadenopathy

Background

Lymphadenopathy is very common among HIV-infected individuals and may occur at any stage of HIV infection. It may be the first indication of a serious local or systemic condition, and it should be evaluated carefully. Rapid enlargement of a previously stable lymph node or a group of nodes requires evaluation to identify the cause and to determine whether treatment is needed. Similarly, nodes that are abnormal in consistency, tender to palpation, fluctuant, asymmetrical, adherent to surrounding tissues, or accompanied by other symptoms should be evaluated promptly.

Lymphadenopathy may be generalized or localized and usually is characterized by lymph nodes that are >1 cm in diameter. A multitude of conditions can cause lymphadenopathy, including HIV itself, opportunistic or other infections, and malignancies. The likely causes of lymphadenopathy, and thus the diagnostic workup, will depend in part on the patient's degree of immunosuppression. The risk of opportunistic and certain malignant conditions increases at lower CD4 cell counts (see chapter *Risk of HIV Progression/Indications for ART*).

Many individuals with primary HIV infection (see chapter *Early HIV Infection*) have generalized lymphadenopathy that may resolve or may persist for months to years. If lymphadenopathy of >2 cm in size occurs in two or more noncontiguous sites and persists for more than 3 months, and if appropriate evaluation reveals no other cause, the patient is diagnosed with persistent generalized lymphadenopathy (PGL). PGL usually is caused by follicular hyperplasia from chronic HIV infection. Antiretroviral therapy (ART) should be initiated or optimized, but as long as enlarged nodes are stable in number, location, and size, persons with PGL require no specific management other than monitoring of nodes at each physical examination. Changes in the character of the lymph nodes should prompt further evaluation. Rapid involution of PGL may occur with advanced HIV disease and is a poor prognostic sign.

S: Subjective

The patient complains of new, worsening, or persistent glandular swellings in the neck, axilla, groin, or elsewhere.

Ascertain the following during the history:

- Symptoms that accompany the lymphadenopathy, particularly constitutional symptoms such as fever, sweats, fatigue, and unintentional weight loss
- Localized symptoms or conditions that involve areas of the body with lymphatic drainage into the area of abnormal lymph nodes (e.g., in the case of axillary lymphadenopathy, ask about breast masses and skin conditions or trauma involving the arm)
- A full review of systems
- HIV-related or other malignancies, opportunistic illnesses
- Recent travel, country or region of origin, disease exposures (e.g., tuberculosis [TB], sexually transmitted diseases [STDs]), and risk behaviors (e.g., injection drug use)
- Recent initiation of ART (may indicate immune reconstitution inflammatory syndrome [IRIS])
- Trauma or injury (including cat scratches)
- Exposure to household pets
- Current medications

O: Objective

- Review recent CD4 cell counts and HIV viral load measurements.
- Check vital signs.
- Perform a complete examination of lymph nodes, including the cervical, submandibular, supraclavicular, axillary, epitrochlear, and inguinal sites. Document the location, size, consistency, mobility, and presence or absence of tenderness of all abnormal nodes. In cases of localized lymphadenopathy, examine the area drained by the node.
- Check for hepatosplenomegaly.
- Perform a focused examination (e.g., lung, breast, skin, genitals) to identify signs of local or systemic illness.

A: Assessment

The differential diagnosis of lymphadenopathy in HIV-infected patients depends in part on the degree of immunosuppression. For further information, see chapter *Risk of HIV Progression/Indications for ART*.

Infectious Causes**Generalized lymphadenopathy**

- HIV infection, including PGL
- Mononucleosis; Epstein-Barr virus
- *Mycobacterium avium* complex
- TB
- Cytomegalovirus
- Secondary syphilis
- Toxoplasmosis

- Histoplasmosis, other fungal diseases
- *Bartonella* infection
- Hepatitis B
- Lyme disease
- Widespread skin infections
- IRIS involving various infections
- Follicular hyperplasia
- Castleman disease

Localized lymphadenopathy

- Any of the above
- Oropharyngeal and dental infections
- Cellulitis or abscesses
- TB (scrofula)
- Chancroid
- Chlamydia (lymphogranuloma venereum [LGV])
- Other STDs

Neoplastic Causes

- Lymphoma
- Acute and chronic lymphocytic leukemias
- Other malignancy; metastatic cancer
- Kaposi sarcoma

Other Causes

- Reactive process (benign)
- Sarcoidosis
- Hypersensitivity reaction to medications
- Serum sickness
- Rheumatoid arthritis

P: Plan**Diagnostic Evaluation**

After the history and physical examination, the cause of lymphadenopathy may be clear and further diagnostic testing may not be necessary. If the cause of the lymphadenopathy is still uncertain, perform diagnostic testing as indicated by the patient's presentation. This may include the following tests:

- CD4 count (with or without HIV viral load), to determine the risk of opportunistic illnesses
- Complete blood count with differential; liver function tests; urinalysis
- Chest X-ray
- TB screening (tuberculin skin test [TST] or interferon-gamma release assay [IGRA])
- Syphilis screening (rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL] test)
- Blood cultures, if patient is febrile (bacterial, mycobacterial, and fungal, as indicated)
- Testing for specific infections if suspected (e.g., *Bartonella*, LGV)

If a node is large, fixed, nontender, or otherwise worrisome, or if the diagnosis is unclear after initial evaluation, fine-needle aspiration (FNA) biopsy may provide a diagnosis. If FNA is nondiagnostic (false-negative results are relatively common), obtain an excisional biopsy for definitive evaluation. Biopsy specimens should be sent for bacterial, mycobacterial, and fungal cultures; acid-fast staining for mycobacteria; and cytologic examination.

If a node is large, inflamed, tender, or fluctuant, and a bacterial infection is suspected, consider initiating empiric

antibiotic treatment and monitoring the patient over the course of 1-2 weeks. If the node does not respond to antibiotic treatment or the patient becomes more symptomatic, arrange for FNA or open biopsy to establish the diagnosis.

Treatment

Treatment will depend on the cause of lymphadenopathy. Refer to section *Comorbidities, Coinfections, and Complications* or to OI management guidelines as appropriate. In the case of HIV-related lymphadenopathy, ART may be effective.

Patient Education

- Lymphadenopathy may come and go throughout the course of HIV infection, but it may be a sign of a serious condition.
- Advise patients to notify their care provider if lymph nodes increase in size or change in character.

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Nausea and Vomiting

Background

Nausea with or without vomiting, and occasionally vomiting without nausea, can occur at any stage of HIV infection. Nausea is a common adverse effect of many antiretroviral (ARV) and other medications, and it often occurs within weeks of starting new medications. In some cases, nausea causes significant discomfort and may interfere with medication adherence. Nausea and vomiting also may be symptoms of a serious complication of ARV therapy, or signs of an opportunistic infection or neoplasm in patients with late-stage AIDS. Clinicians must identify the cause of nausea and vomiting and initiate appropriate treatment.

S: Subjective

The patient experiences nausea with or without vomiting, or vomiting without nausea.

Ascertain the following during the history:

- Duration of symptoms
- Characteristics, timing, and precipitating factors
- Vomiting, including hematemesis
- Diarrhea
- Abdominal pain
- Fever
- Jaundice
- Lightheadedness, dizziness, vertigo, or orthostatic symptoms
- Polyuria
- Polydipsia
- Headache
- Changes in vision
- Neck stiffness
- Pruritus
- Medications, new and ongoing
- Nutritional supplements and non-prescription medications
- Possibility of pregnancy (for women) (e.g., missed menses)

- Alcohol intake, substance use or abuse
- History of:
 - Hepatitis
 - Kidney disease
 - Pancreatitis
 - Cytomegalovirus
 - Central nervous system (CNS) infections, including toxoplasmosis, cryptococcosis, chronic meningitis
 - CNS lymphoma

O: Objective

Check vital signs, including orthostatic blood pressure and heart rate measurements.

Conduct a thorough physical examination, including evaluation of the following:

- Skin turgor
- Eyes and fundi (retinal abnormalities such as papilledema)
- Oropharynx (dryness of oral mucosa, thrush, ulcerations)
- Neck (stiffness or other signs of meningeal irritation)
- Abdomen (tenderness, distention, masses, organomegaly)
- Pelvis (tenderness, masses)

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- Neurologic system (mental status, focal neurologic abnormalities)

Review recent CD4 measurements, if available, to determine the patient's risk of opportunistic illnesses.

A: Assessment

A partial differential diagnosis includes the following conditions:

- Medication effect or reaction
- Foodborne illness
- Viral or other infectious gastroenteritis
- Pancreatitis
- Hepatitis, infectious or drug related (see chapters *Hepatitis B Infection* and *Hepatitis C Infection*)
- Appendicitis
- Esophagitis (see chapter *Esophageal Problems*)
- Lactic acidosis attributable to nucleoside analogues
- Pregnancy
- Adrenal insufficiency
- CNS lymphoma
- Meningitis
- Uremia
- Diabetic ketoacidosis
- Influenza
- Pelvic inflammatory disease (see chapter *Pelvic Inflammatory Disease*)
- Myocardial infarction

P: Plan

Diagnostic Evaluation

Perform laboratory work and other diagnostic studies as suggested by the history, physical examination, and differential diagnosis. Tests may include the following:

- Complete blood count with differential
- Electrolytes, creatinine, blood urea nitrogen
- Glucose
- Amylase and lipase if symptoms of pancreatitis are present
- Liver function tests and hepatitis serologies for possible acute or chronic hepatitis
- Blood cultures and other fever workup as needed (see chapter *Fever*)
- Computed tomography scan of the brain if neurologic symptoms are present (see chapter *Neurologic Symptoms*)
- Cortisol and cosyntropin stimulation test if indicated (e.g., fatigue, weakness, unexplained abdominal pain, weight loss, orthostasis; usually in late-stage AIDS)
- If odynophagia or dysphagia is present, see chapter *Esophageal Problems*
- Lactic acid levels if lactic acidosis is suspected
- Pregnancy test if indicated
- Electrocardiogram if patient has chest pain or suspicious symptoms

Consult with an HIV expert to determine whether hospitalization or other laboratory tests are needed.

Treatment

Once the diagnosis is made, appropriate treatment should be initiated. In seriously ill patients, presumptive treatment may be started while diagnostic test results are pending. See appropriate chapters in section *Comorbidities, Coinfections, and Complications* and relevant guidelines.

In the case of significant adverse effects from ARVs or other medications, substitute a less-emetogenic ARV for the problematic medication, if possible (without compromising the efficacy of the treatment regimen). In the case of serious or life-threatening medication toxicities (e.g., lactic acidosis or abacavir hypersensitivity reaction), discontinue the problematic medication (see chapter *Adverse Reactions to HIV Medications*).

After the workup and exclusion of life-threatening illness, symptomatic treatment can be considered. If nausea and vomiting are attributable to medications that are vital to the patient, and these complications are not life-threatening, antiemetic therapy may be the best treatment. Chronic therapy is not always necessary. Some patients obtain adequate relief by breaking the “nausea cycle” with effective antiemetics for 1-2 days and then establishing meals or snacks with medications. Patients with dehydration may require administration of fluids (PO or IV) to relieve nausea. For patients with chronic nausea resulting in weight loss, refer to a nutritionist for assessment and nutritional support.

Symptomatic treatment

Consider the following strategies for symptomatic treatment:

- For nausea that occurs in relation to an event or action (e.g., after taking ARVs) antiemetics may be given preemptively (e.g., 30 minutes beforehand).
- Ginger capsules have proven effective in clinical trials for the management of pregnancy-related and chemotherapy-related

nausea. Foods and beverages containing ginger (e.g., tea, cookies, ginger ale, candies) may help provide relief.

- Promethazine (Phenergan) may be given as a 12.5-25 mg PO tablet Q4-6H as needed. For patients unable to tolerate the PO formulation, promethazine suppositories (12.5 or 25 mg) may be used.
- Prochlorperazine (Compazine) may be given as a 5 mg or 10 mg PO tablet, or a 25 mg rectal suppository, Q6-8H as needed. Extended-release spansule, 10 mg Q12H or 15 mg QAM, also can be considered.
- Lorazepam (Ativan) may be given as a 0.5 mg PO tablet 30 minutes before taking medications for symptoms of anticipatory nausea. Patients with anticipatory nausea develop significant nausea or vomiting when even thinking about medications or reaching for the medications.
- Dronabinol (Marinol) may relieve nausea, especially when nausea is accompanied by a loss of appetite. This remedy is best tolerated by patients who have tolerated inhaled marijuana. The starting dosage is 2.5 to 5 mg BID or TID.
- 5-Hydroxytryptamine (5-HT₃) receptor antagonists such as dolasetron 50 mg and 100 mg, granisetron 1 mg, and ondansetron 4 mg and 8 mg are highly effective and highly effective in relieving severe nausea and vomiting resulting from chemotherapy and other causes. However, access to these medications is limited by their cost. Their use should be considered a short-term strategy or reserved for cases of nausea/vomiting refractory to other antiemetics.
- Metoclopramide (Reglan) may be used to enhance gastrointestinal motility in patients who experience nausea and vomiting caused by gastroparesis. The typical PO dose is 5-10 mg Q4-6H, or it can be taken TID with meals if the nausea or vomiting is associated with eating.

- H2 antagonists or proton pump inhibitors may be helpful in treating nausea/vomiting related to gastritis or acid reflux (caution: these agents interfere with absorption of atazanavir and rilpivirine; consult dosing recommendations); see chapter *Esophageal Problems* and relevant tables in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (see Appendix).
- Many patients wonder whether they should take their medicines again if they vomit after taking a dose. Generally, the medicines are still in the body unless the pills actually come back up. Patients should call their health care provider if they have any questions.
- Ginger may help to relieve nausea. Ginger can be taken in a variety of ways, including ginger ale, tea, cookies, candies, and ginger capsules. Patients can choose the form of ginger that works best for them.

Patient Education

- Nausea and vomiting can have many different causes. Patients should let their health care provider know if they are having these symptoms so that the most likely cause can be determined.
- Patients should stay nourished and well hydrated even if they are experiencing nausea and vomiting. Eating small, frequent meals may be best tolerated, while avoiding dairy products, spicy or greasy foods, and high-fat meals. Taking medications with food may reduce symptoms of nausea (note that some medications must be taken on an empty stomach).
- Patients should not stop taking any of their medications without first discussing it with their health care provider. Many medications must be continued despite nausea. Nausea and vomiting owing to ARVs may resolve or become tolerable over time.

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Neurologic Symptoms

Background

The nervous system may be a site of complications throughout the course of HIV infection, and neurologic complaints are common among HIV-infected individuals. Neurologic symptoms may be caused by many factors, including infections (opportunistic and other), central nervous system (CNS) malignancies, medication toxicities, comorbid conditions (e.g., diabetes, cerebrovascular disease, chronic hepatitis, mental illness), and nervous system injuries related to HIV itself.

The risk of some conditions, such as CNS infection, malignancy, and dementia, increases with advancing immunosuppression, and the CD4 cell count will help to stratify the patient's risk of opportunistic illnesses (see Table 1 in chapter *Risk of HIV Progression/Indications for ART*). This chapter presents a general approach to neurologic symptoms in HIV-infected patients, with reference to other chapters in this manual for more detailed reading. For information on peripheral neuropathy, see chapter *Pain Syndrome and Peripheral Neuropathy*; for information on neurocognitive disease, see *HIV-Associated Neurocognitive Disorders*.

S: Subjective

The patient, or a friend or family member on his or her behalf, reports new neurologic symptoms such as pain, headache, seizures, altered mental status, or weakness.

Ascertain the following during the history:

- Onset and duration: rapid (hours to days), subacute, chronic
 - Characteristics of the symptoms (e.g., location, quality, timing)
 - Progression or stability of symptoms
 - Constitutional symptoms: fever, night sweats, unintentional weight loss
 - Associated symptoms, including other neurologic, muscular, psychiatric, or behavioral symptoms
 - Recent trauma to the head or other area
 - Visual changes, photophobia
 - Dizziness, vertigo
 - Mental status changes (including changes in behavior, personality, or cognition; short-term memory loss; mental slowing; reading comprehension difficulties; changes in personal appearance and grooming habits)
 - Seizures (description, duration, number)
 - Pain
 - Sensory symptoms
 - Weakness (distinguish weakness from fatigue or pain; determine whether bilateral or focal, proximal or distal)
 - Bowel or bladder changes
 - Rash or ulcerations
 - Medications: current, past, and recently initiated medications, including antiretroviral (ARV) medications
 - Alcohol or drug use; date of last use
 - Exposures (sexual, environmental), travel history
 - Psychiatric history and past psychiatric care
 - Most recent CD4 cell count and HIV viral load, previous AIDS-defining illnesses
 - Functional impact of the symptoms: social functioning, ability to work and perform activities of daily living
- Differentiate delirium and dementia. Delirium presents as acute onset of clouded sensorium, disturbed and fluctuating

level of consciousness, disorientation, cognitive deficits, and reduced attention, sometimes with hallucinations. Delirium often is caused by medication toxicities, infections, hypoxia, hypoglycemia, electrolyte imbalances, or mass lesions, and it frequently is correctable. Dementia emerges more gradually and is characterized by cognitive impairment and behavioral, motor, and affective changes. See chapter *HIV-Associated Neurocognitive Disorders*.

O: Objective

- Check vital signs (temperature, blood pressure, heart rate, respiratory rate, and oxygen saturation) and orthostatic measurements.
- Perform a careful physical examination as guided by the history, with special attention to the following:
 - General appearance: mood, affect, mannerisms
 - Head and neck: signs of trauma, sinus tenderness, lymph node status, neck mobility
 - Eyes, including fundi: lesions, papilledema
 - Lungs, heart: abnormal sounds
 - Extremities: muscle tone and bulk
 - Skin, mucous membranes: rash, lesions
- Conduct a thorough neurologic examination, including cranial nerves, motor function, sensory function, coordination, gait, and deep tendon reflexes.
- Conduct a mental status examination.
- Review recent CD4 measurements, if available, to determine the patient's risk of opportunistic illnesses.

A: Assessment

The differential diagnosis of neurologic abnormalities in patients with HIV infection may be broad, particularly if the CD4 count is low. Both HIV-related and HIV-unrelated causes should be considered; remember that more than one cause of symptoms may be present.

Possible Causes of Neurologic Abnormalities

Causes related to the cerebrum or cranial nerves

- Toxoplasmic encephalitis
- Primary CNS lymphoma
- Cryptococcal meningitis
- Cytomegalovirus (CMV) encephalitis
- Other meningitis (bacterial, tuberculous, fungal, viral)
- Progressive multifocal leukoencephalopathy (PML)
- Neurosyphilis
- CNS coccidioidomycosis, histoplasmosis
- HIV-related dementia
- Cerebrovascular accident; stroke
- Metabolic abnormalities, including hypo- or hyperglycemia, electrolyte abnormalities
- Alcohol or drug intoxication or withdrawal (medications or illicit drugs); chronic alcohol abuse
- Medication adverse effects (e.g., efavirenz, corticosteroids, anticholinergics, many others)
- Depression, mania, anxiety, psychosis

Causes related to the spinal cord, nerve roots, peripheral nerves, and muscle

- Inflammatory demyelinating polyneuropathy (e.g., Guillain-Barré syndrome)
- Polyradiculitis (e.g., CMV, herpes simplex virus)
- Vitamin deficiency
- Myositis
- Myopathy (e.g., owing to zidovudine)
- Myelopathy (e.g., HIV vacuolar myelopathy)
- Epidural abscess or mass
- Mononeuritis multiplex
- Lactic acidosis
- Electrolyte abnormality (e.g., hypokalemia)
- Peripheral neuropathy
- Distal sensory polyneuropathy
- Antiretroviral toxic neuropathy (especially stavudine, didanosine)
- Other neuropathy (e.g., owing to diabetes, alcohol, medications [isoniazid, dapsone, many others])

Note that organic causes of neurologic symptoms must be ruled out before concluding that symptoms are psychiatric in nature.

P: Plan

Diagnostic Evaluation

Unstable or seriously ill patients should be hospitalized for evaluation and treatment. Criteria for hospitalization include acutely altered mental status, fever with focal neurologic findings, and new or unstable seizures.

Perform laboratory work and other diagnostic studies as suggested by the history, physical examination, and differential diagnosis. This may include the following:

- Establish the CD4 count (if not done recently) to help with risk stratification for opportunistic illnesses.

- Determine which laboratory tests are appropriate, depending on the patient's presentation. The initial evaluation often includes a complete blood count with differential and monitoring of electrolyte and glucose levels.
 - In patients with CNS symptoms or signs and low CD4 counts (<100 cells/ μ L), check serum levels of *Toxoplasma* antibody (IgG) if not previously checked. Check serum cryptococcal antigen (CrAg) titer.
 - In patients with symptoms of neuropathy or dementia, check serum levels of vitamin B12 and thyroid-stimulating hormone (TSH).
 - In patients with cranial nerve abnormalities, meningoencephalitis, symptoms of dementia, or any symptoms of neurosyphilis, check syphilis serology by rapid plasma reagin (RPR), Venereal Disease Research Laboratory (VDRL) test, or treponemal enzyme immunoassay (see chapter *Syphilis*).
- When CNS symptoms or signs are present, brain imaging by computed tomography (CT) scan with contrast is usually adequate as the initial test. Magnetic resonance imaging (MRI) is the modality of choice if the neurologic examination is nonfocal or if physical examination suggests a lesion in the posterior fossa.
- For patients with fever and CNS findings, perform lumbar puncture (LP) with cerebrospinal fluid (CSF) sampling. CT or MRI should be performed before the LP, if possible, to rule out a mass lesion that could cause herniation.
- Record the opening pressure, and send CSF for cell count and differential with protein and glucose measurements. Depending on the clinical suspicion, the fluid also should be sent for bacterial culture, India ink stain for fungal organisms (75-85% sensitive), acid-fast bacilli smear and culture, VDRL test, and CrAg titer (95% sensitive).

- If CMV is suspected, perform polymerase chain reaction (PCR) for CMV DNA in the CSF.
- For suspected drug or alcohol use, perform urine or serum toxicology screen. (Note that alcohol usually has been metabolized by the time withdrawal symptoms set in, typically 7-48 hours after the last alcohol intake.)
- For new-onset seizures, perform an electroencephalogram (EEG).
- Consult with neurology specialists if the workup or the diagnosis is in question.
- Advise patients who have seizures that driving and other potentially dangerous activities will be prohibited until the condition is stable.
- Counsel patients to avoid substances that impair the nervous system, such as alcohol and recreational drugs.
- If a patient is forgetful, educate other members of the household about the medication regimen and help devise a plan for adherence to medications and appointments.

Treatment

- Specific treatment will depend on the cause of neurologic symptoms. Consult relevant chapters in this manual. For complex cases, consult with an HIV-experienced neurologist.

Patient Education

- Inform patients that keeping the CD4 count >200 cells/ μ L (and preferably higher) with ART is the best way to prevent most HIV-associated neurologic diseases.
- Advise patients to take prophylaxis, as appropriate, to prevent opportunistic infections.
- When an antibiotic treatment is prescribed, advise patients to complete the entire regimen to prevent relapse of symptoms. Long-term treatment (secondary prophylaxis) will be needed to prevent recurrence of certain infections.

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Pulmonary Symptoms

Background

Shortness of breath and cough are manifestations of common acute or chronic respiratory diseases, but also may be symptoms of HIV-related opportunistic infections. Further, these symptoms may indicate nonpulmonary conditions such as anemia, cardiovascular disease, and sinusitis, or adverse effects of medications such as angiotensin-converting enzyme inhibitors (ACEIs).

The onset and duration of symptoms, and the presence or absence of other factors such as sputum production, fever, and weight loss, will guide the evaluation. In addition, the patient's CD4 cell count will establish a context for the evaluation, because it will help to stratify the risk of opportunistic infections.

S: Subjective

The patient complains of dyspnea or cough.

Determine the following factors relating to the patient's history:

Recent History

- Onset and duration of symptoms: rapid (hours to days), subacute, chronic
- Progression or stability of symptoms
- Dyspnea at rest or with exertion
- Cough: productive (character of sputum), hemoptysis
- Associated symptoms (e.g., chest pain, pleuritic pain)
- Constitutional symptoms: fever, night sweats, unintentional weight loss
- Sinus congestion, facial tenderness, postnasal discharge, sore throat
- Orthopnea, paroxysmal nocturnal dyspnea (PND), peripheral edema
- Wheezing

Past History

- CD4 nadir, current CD4 count
- If the CD4 count is <200 cells/ μ L, ask whether the patient is taking *Pneumocystis jiroveci* pneumonia (PCP) prophylaxis (primary or secondary); if taking PCP prophylaxis and adhering to the regimen, the diagnosis of PCP is less likely
- Tuberculosis (TB): date and result of tuberculin skin test (TST) or interferon-gamma release assay (IGRA), risk factors for *Mycobacterium tuberculosis* infection
- PCP, bacterial or other pneumonia, bronchitis
- Smoking (and secondhand smoke exposure), pack-years, related symptoms
- Cardiovascular diseases, including congestive heart failure, coronary heart disease, arrhythmia, pulmonary hypertension
- Asthma, emphysema
- Pollen, dander, or dust allergies
- Drug allergies, specifically to penicillins and sulfa drugs
- Medications (e.g., ACEIs)
- Travel history (exposure to regions endemic for particular infections, such as coccidioidomycosis or histoplasmosis)
- Use of inhaled stimulants, injection drugs

- Prolonged exposure (via inhalation) to chemicals or other harmful pulmonary irritants (e.g., asbestos)

O: Objective

Check vital signs, oxygen saturation (resting and after exercise), and weight.

Conduct a thorough physical examination that includes evaluation of the following:

- Ears, nose, oropharynx
- Neck
- Lungs
- Heart
- Extremities

Note: If patients are coughing, strongly consider having them wear a surgical mask in the clinic or office until TB or other transmissible infection is ruled out. Covering both the nose and the mouth should prevent the discharge of infectious particles into the environment.

A: Assessment

The differential diagnosis of pulmonary symptoms is broad (see Table 1). Both HIV-related and HIV-unrelated causes should be considered; the patient's risk of HIV-related causes is strongly influenced by the CD4 count. More than one cause of symptoms may be present.

Table 1. Partial Differential Diagnosis of Pulmonary Symptoms

CD4 Cell Count	Possible Cause
Any Count	• Upper respiratory tract illness • Upper respiratory tract infection (URI) • Sinusitis • Pharyngitis • Acute or chronic bronchitis • Bacterial pneumonia • TB • Influenza • Chronic obstructive pulmonary disease • Reactive airway disease, asthma • Pulmonary embolus • Congestive heart failure • Pulmonary hypertension • Pneumothorax • Bronchogenic carcinoma • Non-Hodgkin lymphoma • Anemia • Gastroesophageal reflux (may cause cough) • Lactic acidosis • Medication adverse effect
≤500 cells/μL	• Bacterial pneumonia (recurrent) • Pulmonary <i>Mycobacterium</i> pneumonia (nontuberculous)
≤200 cells/μL	• PCP • <i>Cryptococcus neoformans</i> pneumonia or pneumonitis • Bacterial pneumonia (associated with bacteremia or sepsis) • Disseminated or extrapulmonary TB
≤100 cells/μL	• Pulmonary Kaposi sarcoma • Bacterial pneumonia (risk of gram-negative bacilli and <i>Staphylococcus aureus</i> is increased) • <i>Toxoplasma</i> pneumonitis
≤50 cells/μL	• Disseminated histoplasmosis • Disseminated coccidioidomycosis • Cytomegalovirus pneumonitis • Disseminated <i>Mycobacterium avium</i> complex • Disseminated <i>Mycobacterium</i> (nontuberculous) • <i>Aspergillus</i> pneumonia • <i>Candida</i> pneumonia

Adapted from: Huang L. *Pulmonary Manifestations of HIV* (Table 4). In: Coffey S, Volberding PA, eds. *HIV InSite Knowledge Base* [textbook online]; San Francisco: UCSF Center for HIV Information; January 2009. Available at hivinsite.ucsf.edu/InSite?page=kb-00&doc=kb-04-01-05. Accessed December 1, 2013.

P: Plan**Diagnostic Evaluation**

Perform laboratory work and other diagnostic studies as suggested by the history, physical examination, and differential diagnosis. This may include the following:

- Chest X-ray, especially if the patient has abnormal findings on chest examination, fever, or weight loss, or if the CD4 count is <200 cells/ μ L. Consider further imaging such as chest computed tomography (CT) scan or high-resolution chest CT (HRCT) if chest X-ray result is unremarkable in a setting of suspected PCP or persistent symptoms, or if there is question of pulmonary nodules or suspected empyema.
- Arterial blood gas (ABG) on room air, particularly if PCP is suspected, or if the oxygen saturation is low.
- Complete blood count and white blood cell (WBC) count with differential, metabolic panel, and lactate dehydrogenase (LDH).
- If fever is present (especially temperature $>38.5^{\circ}\text{C}$), obtain routine blood cultures (two specimens) for bacteria. If the CD4 count is <50 cells/ μ L, obtain blood culture for acid-fast bacilli (AFB); if <100 cells/ μ L, check the serum level cryptococcal antigen (CrAg) and consider checking urine *Histoplasma* antigen.
- Induced sputum (outside, or in a negative-pressure room or area that is safely vented to the outside, to prevent TB aerosolization) for AFB smear and cultures (three specimens), Gram stain and bacterial cultures, PCP stains, fungal stains and cultures, and cytology, as indicated.
- CD4 count and HIV viral load, if recent values are not known.
- Bronchoscopy with bronchoalveolar lavage (BAL) or biopsy if sputum studies are negative, if the diagnosis is unclear after initial evaluation or if the patient is not responsive to empiric therapy.
- Pulmonary function tests if no infectious or HIV-related pulmonary diagnosis is suspected and symptoms persist.
- Lactate level if lactic acidosis is suspected (e.g., nausea, tachypnea, abdominal pain, fatigue, in the setting of long-term nucleoside analogue therapy).
- Toxicology screen if symptoms are suspected to be related to recent drug use (e.g., crack cocaine pneumonitis).

Treatment

Once the diagnosis is made, appropriate treatment should be initiated. In seriously ill patients, presumptive treatment may be started while diagnostic test results are pending. See the appropriate chapter in section *Comorbidities, Coinfections, and Complications* or relevant guidelines. In some cases, the source of dyspnea or cough cannot be identified. In these cases, consult with an HIV expert or a pulmonologist.

Patient Education

- Shortness of breath and cough can be signs of an opportunistic illness, especially in patients with low CD4 counts. Patients should notify their health care provider if they develop new or worsening symptoms.
- Patients taking antibiotics should be instructed to take their medications exactly as directed and to call their health care provider if they experience worsening fevers, shortness of breath, inability to take the prescribed medications, or other problems.
- Counsel smokers about the importance of smoking cessation; refer to tobacco cessation programs and prescribe cessation supports, as indicated; see chapter *Smoking Cessation*.
- Counsel drug users (particularly those who smoke or inject drugs) regarding the impact of illicit drugs on their overall health and especially their lungs; refer to appropriate cessation programs or rehabilitation programs.

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Vaginitis/Vaginosis

Background

Vaginitis is defined as inflammation of the vagina, usually characterized by a vaginal discharge containing many white blood cells (WBCs); it may be accompanied by vulvar itching and irritation. Vaginosis presents with increased vaginal discharge without inflammation. Vaginitis usually is caused by an infection, but may be caused by other factors, such as chemicals or irritants. Vaginal infections are common among HIV-infected women. The presence of vaginal infections or inflammation, in the case of bacterial vaginosis in particular, may facilitate acquisition of HIV and other sexually transmitted diseases (STDs), and trichomoniasis may facilitate HIV transmission to HIV-uninfected partners. This chapter focuses on two of the most common types of vaginal infections: trichomoniasis and bacterial vaginosis (BV). For information on the topic of vulvovaginal candidiasis, see chapter *Candidiasis, Vulvovaginal*.

S: Subjective

The patient complains of vaginal discharge with or without odor, itching, burning, pelvic pain, vulvar pain, or pain during intercourse.

Take a focused history, including the following:

- Duration of symptoms
- Sexual history, especially recent new partners, unprotected sex
- Relationship of symptoms to sexual contacts
- Contraceptive use, especially:
 - Vaginal contraceptive film
 - Other products containing nonoxynol-9 (N-9)
 - Condoms; type of condoms
- Use of feminine hygiene products (e.g., sprays, deodorants)
- Douching
- Use of perfumed toiletries (e.g., bath salts, scented toilet tissue, or sanitary napkins)
- Use of any vaginal creams
- Postcoital bleeding
- Vulvar pain
- Pain or burning during urination

- Pain with intercourse
- Recent antibiotic use
- History of STDs, pelvic inflammatory disease (PID)
- Medications, including supplements

O: Objective

Perform a focused physical examination of the external genitalia, including perineum and anal area, for the following:

- Inflammation
- Edema
- Excoriation
- Lesions

Perform speculum examination for:

- Discharge (note color, quality; note that the character of the discharge is not diagnostic)
- Erythema, edema, erosions, lesions
- Cervical friability
- Foreign body

Perform a bimanual examination for masses or tenderness, if indicated.

A: Assessment

A partial differential diagnosis includes the following:

- BV
- Candidiasis
- Trichomoniasis
- PID
- Latex or condom allergy
- Urinary tract infection (UTI)
- Condyloma
- Herpes simplex virus (HSV)
- Contact dermatitis (e.g., from irritants, perfumes)
- Chlamydia
- Gonorrhea
- Normal vaginal discharge

P: Plan**Diagnostic Evaluation**

- Obtain a cervical sample for STD testing, if indicated.
- Obtain samples (swabs) from the vaginal wall for wet mounts and pH testing.
- Wet mounts: Perform microscopic examination of saline and potassium hydroxide (KOH) preparations for the following:
 - WBCs, clue cells, motile trichomonads (saline slide)
 - Yeast forms (KOH)
- Perform a whiff test of KOH preparation; if positive, check pH (if >4.5, likely BV or trichomoniasis).

Treatment depends on the specific diagnosis, and in general is the same as for HIV-uninfected women.

Trichomoniasis

Trichomoniasis is caused by the protozoan *Trichomonas vaginalis*. Many infected women have a diffuse, malodorous, yellow-green discharge. Most men who are infected with *T. vaginalis* have no symptoms; others have symptoms of nongonococcal urethritis. The diagnosis usually is made by visualization of motile trichomonads on microscopic examination of wet mounts. Antigen or nucleic acid assays have greater specificity and sensitivity than wet mount preparations, and may be used if microscopy is negative. Culture of vaginal secretions is the most sensitive and specific diagnostic test for *T. vaginalis*, and also may help to rule out other infections.

Treatment: Recommended regimen

- Metronidazole 2 g PO in a single dose
- Tinidazole 2 g PO in a single dose

Treatment: Alternative regimen

- Metronidazole 500 mg PO BID for 7 days

Treatment during pregnancy

- Metronidazole, as in nonpregnant women (see above); the 7-day regimen may be better tolerated.
- Counsel patients about the potential risks and benefits of therapy. In pregnant women with asymptomatic trichomoniasis, deferring therapy until after 37 weeks' gestation may be considered; consult with a specialist.

Treatment notes:

- Single-dose metronidazole is associated with more side effects than the other treatment regimens.
- Sex partners should be treated. Patients should refrain from unprotected intercourse until both partners have resolution of symptoms and have completed treatment; this should be at least 7 days after single-dose therapy.

- Patients must avoid alcohol while taking metronidazole or tinidazole, and for at least 1 day after discontinuing metronidazole and 3 days after discontinuing tinidazole. The combination of alcohol and these drugs may cause a disulfiram-like reaction. Patients taking ritonavir capsules or tipranavir also may experience symptoms because of the small amount of alcohol in the capsules.

Treatment failure

Certain strains of *T. vaginalis* have diminished susceptibility to metronidazole and must be treated with higher dosages. If treatment failure occurs on metronidazole, consider tinidazole as above, or if single-dose metronidazole was used initially, consider metronidazole 500 mg PO BID for 7 days. If this is not effective, consult with a specialist.

Bacterial Vaginosis

BV is a clinical syndrome resulting from loss of the normal vaginal flora, particularly *Lactobacillus*, and replacement with anaerobic and other bacteria such as *Gardnerella vaginalis* and *Mycoplasma hominis*. The diagnosis is made on clinical and laboratory criteria. Usually, three of the following four characteristics should be present (note: only the clue cells are specific to BV):

- Homogeneous, gray-white, noninflammatory discharge on the vaginal walls
- Clue cells on the wet-mount slide
- Vaginal fluid pH level of >4.5
- Fishy odor to the vaginal discharge before or after the addition of KOH (whiff test)

Vaginal culture does not help establish the diagnosis. Rapid diagnostic test cards are available in some settings.

Many studies have documented an association between BV and infections such as endometritis, PID, and vaginal cuff cellulitis after gynecologic procedures. Therefore, the U.S. Centers for Disease Control and

Prevention (CDC) recommends screening for and treating BV before invasive gynecologic procedures.

The sex partners of women with BV do not need to be treated.

Treatment: Recommended regimens

- Metronidazole 500 mg PO BID for 7 days
- Metronidazole gel 0.75%, 1 full applicator (5 g) intravaginally QHS for 5 days
- Clindamycin cream 2%, 1 full applicator (5 g) intravaginally QHS for 7 days

Treatment: Alternative regimens

- Tinidazole 2 g PO QD for 2 days
- Tinidazole 1 g PO QD for 5 days
- Clindamycin 300 mg PO BID for 7 days
- Clindamycin ovules 100 g intravaginally QHS for 3 days

Treatment during pregnancy

- Symptomatic pregnant women should be treated with oral metronidazole (500 mg BID or 250 mg TID) or oral clindamycin 300 mg BID for 7 days.

Treatment notes:

- Patients must avoid alcohol while taking metronidazole or tinidazole, and for at least 1 day after discontinuing metronidazole and 3 days after discontinuing tinidazole. The combination of alcohol and these drugs may cause a disulfiram-like reaction. Patients taking ritonavir capsules or tipranavir also may experience symptoms because of the small amount of alcohol in the capsules.

Treatment failure

Consider re-treatment for 7 days with metronidazole or clindamycin. Consider the possibility of an alternative or second cause of the patient's symptoms, as multiple conditions or pathogens may present concurrently. Perform testing for other conditions as

suggested by symptoms, or if symptoms do not resolve with initial treatment:

- Perform herpes culture if indicated by lesions; see chapter *Herpes Simplex, Mucocutaneous*.
- Test for chlamydia and gonorrhea if indicated; see chapter *Gonorrhea and Chlamydia*.
- Perform urinalysis (with or without culture and sensitivities) if urinary symptoms are prominent.
- If an irritant or allergen is suspected, including N-9, discontinue use.
- If symptoms are related to the use of latex condoms, switch to polyurethane male or female condoms.
- For tenderness on cervical motion or other symptoms of PID, see chapter *Pelvic Inflammatory Disease*.
- Perform workup or obtain referral as needed for other abnormalities found on bimanual examination.

For information on other STDs or related conditions, see the CDC treatment guidelines at www.cdc.gov/std/treatment.

Patient Education

- Advise patients to avoid any form of alcohol while taking metronidazole or tinidazole and for 24 hours after taking the last dose (72 hours after the last tinidazole dose). Alcohol and metronidazole together can cause severe nausea, vomiting, and other immobilizing symptoms.
- Patients taking ritonavir capsules may experience these symptoms because of the small amount of alcohol in the capsules and should be told to contact their health care provider if nausea and vomiting occur.
- Advise patients that clindamycin cream and ovules are oil based and will weaken latex condoms, diaphragms, and cervical caps. Patients should use alternative methods to prevent pregnancy and HIV transmission.
- Recurrence of BV is common. Patients should contact their health care provider and return for repeat treatment if symptoms recur.
- Instruct patients to avoid douching.
- To avoid being reinfectd by *Trichomonas*, patients should bring their sex partners to the clinic for evaluation and treatment.

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Abnormalities of Body-Fat Distribution

Background

Abnormalities of body-fat distribution are a recognized complication of HIV infection and of antiretroviral therapy (ART), and they are a common concern of patients. They include central fat accumulation (lipohypertrophy) and subcutaneous fat wasting (lipoatrophy). These morphologic changes are often referred to as lipodystrophy, though that term fails to distinguish between the two phenomena. Abnormalities in fat distribution and body shape have been noted in up to 40-50% of patients treated with older antiretroviral (ARV) medications, but the incidence may be much lower with the use of newer, less lipotoxic ARVs and with earlier initiation of ART. Lipohypertrophy and lipoatrophy are associated with other metabolic abnormalities, such as dyslipidemia and insulin resistance, and visceral fat accumulation (at least in HIV-uninfected persons) is a risk factor for cardiovascular disease.

Research on fat maldistribution has yielded varying results, in part because there are no standard clinical case definitions of lipodystrophy, lipoatrophy, or lipohypertrophy. The pathogenesis of fat abnormalities in HIV-infected individuals is not well understood, but research to date suggests that it is multifactorial and is associated with HIV-related immune depletion and immune recovery, ARV medications, dysregulation of fatty acid metabolism, hormonal influences, individual genetic predispositions, and factors that are not related to HIV such as diet and obesity. Lipodystrophy has been associated with lower nadir CD4 count as well as with gender (central lipohypertrophy may be more common in women) and age (more common in older patients), and longer exposure to ART. Lipohypertrophy has not been definitively proven to be related to specific ARVs or to specific ARV classes, but has been variably associated with protease inhibitors (PIs) and with nucleoside reverse transcriptase inhibitors (NRTIs). However, morphologic changes occasionally develop in ARV-naïve individuals. Lipoatrophy is most commonly associated with NRTIs, notably stavudine, as well as didanosine and zidovudine.

The most common morphologic changes seen in lipohypertrophy are a firm enlarged abdomen caused by central or visceral fat accumulation, breast enlargement (gynecomastia) in both men and women, development of a dorsocervical fat pad (“buffalo hump”), and neck enlargement. Lipoatrophy most commonly appears as the loss of subcutaneous fat in the face, arms, legs, and buttocks. Lipoatrophy differs from the generalized wasting seen in advanced AIDS, because lean cell mass generally is preserved. When lipohypertrophy and lipoatrophy occur together, the affected individuals show a mixed picture of abdominal obesity with thinning in the face, arms, and legs.

Severe lipoaccumulation can cause discomfort and, in some cases, impairment of breathing or other bodily functions. It may be associated with other metabolic abnormalities, including dyslipidemia, insulin resistance, and the metabolic syndrome. Both lipoaccumulation and lipoatrophy can be disfiguring, can damage self-image and quality of life, and can negatively influence ARV adherence.

S: Subjective

The patient may report any of the following: abdominal fat accumulation with change in waist size, increased neck size, “buffalo hump,” enlarged breasts, and reduced range of motion.

Alternatively (or in addition), the patient may report sunken cheeks, decreased arm or leg circumference, prominence of veins in the arms or legs, or buttock flattening.

Determine CD4 cell count nadir, ARV medication history with particular attention to past use of thymidine analogues and PIs, and duration of and response to each regimen. Ask about past medical and family history, specifically regarding hyperlipidemia, diabetes or insulin resistance, other metabolic disorders, and cardiovascular disease. Evaluate the effect of body-shape changes on the patient’s self-esteem, medication adherence, and interpersonal relationships.

O: Objective

Compare past and current weights. Calculate body mass index (BMI); see chapter *Initial Physical Examination* for information on BMI.

Measure and document waist and hip circumferences. A waist circumference of >102 cm (39 inches) in men and >88 cm (35 inches) in women is the clinical definition of abdominal obesity and is associated with the metabolic syndrome. Waist-to-hip ratios of >0.95 in men and >0.85 in women have been associated with an increased risk of coronary heart disease.

Examine the head, neck, back, breasts, and abdomen for fat accumulation, especially looking for dorsocervical fat pad and facial, neck, or breast enlargement. Examine the face and extremities for subcutaneous fat loss (e.g., in the cheeks, temples, limbs, and buttocks).

Review laboratory history (glucose, lipid panel) to identify other metabolic disorders. (See chapters *Dyslipidemia* and *Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy*.)

A: Assessment

No uniform standard criteria are available for defining or grading lipohypertrophy or lipoatrophy in clinical practice. Clinicians must base their assessment on patient self-report, physical examination (for characteristic body-shape changes), associated symptoms, and psychological consequences.

In research settings, modalities such as dual-energy X-ray absorptiometry (DEXA), computed tomography (CT), and magnetic resonance imaging (MRI) have been used to characterize and quantify lipoaccumulation and lipoatrophy. Anthropometric measurements may be made in the clinic by trained personnel (e.g., nutritionists), but do not measure visceral fat directly. Although measurements such as waist circumference cannot be used to assess lipohypertrophy, they have been validated (in HIV-uninfected individuals) as an assessment of cardiovascular risk (see chapters *Dyslipidemia* and *Coronary Heart Disease Risk*). Bioelectrical impedance analysis (BIA) does not measure regional body composition and thus is not used to measure abnormal body-fat changes.

Differential diagnosis of lipohypertrophy includes obesity or excess weight gain, ascites, and Cushing syndrome.

Differential diagnosis of lipoatrophy includes weight loss and wasting.

P: Plan**Diagnostic Evaluation****Laboratory**

Check for other metabolic abnormalities associated with the use of ARVs, such as dyslipidemia and impaired glucose metabolism (check fasting lipids and random or fasting glucose). See chapters *Dyslipidemia* and *Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy* for further information about workup and treatment.

Treatment

Treatments for lipohypertrophy and lipoatrophy have not reliably reversed body shape changes once these changes have occurred. In general, treatment interventions have shown poor results in patients with marked or severe fat maldistribution and inconsistent or limited responses in those with milder conditions. The best approaches to managing lipodystrophy are prevention and early intervention.

Clinicians can help to prevent body fat abnormalities by avoiding, whenever possible, ARV agents known to confer a greater risk of this disorder (particularly stavudine, didanosine, and zidovudine, which are most closely associated with lipoatrophy). All patients who take ARVs should be monitored carefully for the development of fat maldistribution. If abnormalities are noticed, the suspect ARV should be discontinued and a more benign ARV started in its place, if possible.

The optimal management strategy for established lipoaccumulation or lipoatrophy is not known, although the following approaches can be considered (see below). Also consider referring the patient to clinical studies of lipodystrophy treatment, and for psychological or adherence support and counseling, if indicated. If the patient is distressed enough to consider discontinuing or interrupting ART, review with the patient any gains he or she has made on ART and discuss treatment options (see below). In some cases the patient may insist on discontinuing ARV medications; in this situation, carefully review the risks of treatment interruption as well as the alternatives to discontinuing treatment.

ARV Substitutions

Avoiding thymidine analogue NRTIs, particularly stavudine, and avoiding the NRTI combination stavudine + didanosine have been shown to reduce the risk of lipoatrophy.

In patients with lipoatrophy, modest slow improvement in limb fat has been demonstrated after switching from thymidine analogues (stavudine, zidovudine) to nonthymidine NRTIs (such as abacavir or tenofovir) or to NRTI-sparing regimens. In patients with lipohypertrophy, similar NRTI switch strategies have had little effect on visceral or trunk fat. Studies in which PIs were eliminated from the ART regimen generally have not shown significant effects on body fat measures.

Before switching therapies, carefully assess the potential risk to the patient's long-term HIV management.

Nonpharmacologic Measures

Diet

The effects of diet on lipohypertrophy have not been evaluated thoroughly. If overall weight reduction is needed, recommend dietary changes and exercise. Avoid rapid weight loss plans, as lean body mass often is lost disproportionately. Refer to a dietitian to help the patient decrease intake of saturated fat, simple sugars, and alcohol.

Exercise

Regular, vigorous cardiovascular exercise may help control central fat accumulation, whereas resistance exercises (strength training) will improve the ratio of muscle to fat. Some studies of exercise (done alone or in combination with diet) have shown a reduction in visceral fat accumulation with minimal or no changes in peripheral lipotrophy. Moderate aerobic exercise should be encouraged for all patients.

Pharmacologic Measures

Insulin-sensitizing agents

In diabetic and non-HIV lipodystrophy, treatment with thiazolidinediones may decrease visceral fat, increase peripheral fat, and improve glycemic control. In HIV-infected patients with lipotrophy, studies of thiazolidinediones, specifically rosiglitazone and pioglitazone, have shown mixed results. Some patients have reported improvement in limb fat, particularly those with insulin resistance; however, a larger, 48-week randomized trial of rosiglitazone found no significant increase in limb-fat mass. In patients with visceral fat accumulation, thiazolidinediones have not been found to be effective.

In clinical studies, metformin has been modestly effective in treating visceral adiposity in patients with insulin resistance, but may cause worsening of lipotrophy. Metformin should be used with caution in patients with chronic liver or renal disease.

Growth hormone-releasing factor

Tesamorelin, a synthetic growth hormone-releasing factor analogue, is approved by the U.S. Food and Drug Administration (FDA) for treatment of excess abdominal fat in HIV-infected persons with lipodystrophy. It has been shown to reduce central fat accumulation by about 18% over the course of 12 months, without adverse effects on glucose or lipid parameters. Unfortunately, patients rapidly regain visceral fat when tesamorelin is discontinued. That, along with its expense, has limited the use of tesamorelin. No long-term safety data are available.

Recombinant human growth hormone

Treatment with recombinant human growth hormone (rHGH), 3-6 mg/day for 12 weeks followed by maintenance therapy with lower doses of 1-2 mg/day, has been shown to reduce visceral fat in many patients with minimal impact on peripheral fat wasting; other studies suggest efficacy (and improved tolerability) of lower dosages of rHGH. However, the high cost of rHGH, the high rate of adverse effects (including insulin resistance), and the frequent recurrence of visceral fat accumulation once rHGH is discontinued have resulted in a limited role for this treatment.

Plastic and reconstructive surgery

Various techniques have been investigated, but generally have limited applicability and efficacy. Poly-L-lactic acid (Sculptra, New-Fill) and a calcium hydroxylapatite preparation (Radiesse) are approved by the FDA as treatments for facial lipotrophy. These injectable materials have shown good cosmetic results and often significantly improve patients' satisfaction with their appearance. Treatment effects of both agents typically wane with time and the procedures often must be repeated. Other facial fillers, as well as cheek implants and autologous fat transfer, have been used successfully in some cases. For lipoaccumulation, treatments such as liposuction for focal areas of fat deposition

(e.g., dorsocervical) and breast reduction may be effective in the short term, though fat often reaccumulates.

These interventions may be covered by private- and public-payer sources, but still often are deemed to be the financial responsibility of the patient. In some cases, they may be only a temporary solution, because abnormalities may reappear after treatment.

Patient Education

- Instruct patients who are receiving ARV medications to inform their health care provider if they notice changes in the shape or appearance of their bodies.
- Review the importance and benefits of ART and assess adherence to the regimen.
- For patients with lipohypertrophy, recommend aerobic and resistance exercise to reduce fat and build muscle. Assess local resources for safe muscle-strengthening.
- If weight reduction is needed, refer to a dietitian for consultation. Remind the patient that quick weight-loss diets may result in excessive muscle loss.
- For patients with severe facial lipodystrophy, consider referral to an experienced dermatologist or plastic surgeon for restorative treatment.

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Dyslipidemia

Susa Coffey, MD

Background

HIV-infected individuals, both those on antiretroviral therapy (ART) and those who are untreated, appear to have higher rates of coronary heart disease (CHD) than HIV-uninfected individuals and higher rates of various risk factors for CHD, including dyslipidemia. As the average lifespan of patients on effective ART lengthens, and as people living with HIV become older, morbidity and mortality from CHD are likely to continue to increase. Thus, identification and reduction of modifiable risk factors for CHD are important aspects of primary care for HIV-infected patients.

Dyslipidemia is a well-described independent risk factor for CHD, and it occurs in a high proportion of persons with HIV infection. Current research suggests that this dyslipidemia is caused by a combination of factors related to HIV disease, ART regimens, and individual patient characteristics. HIV itself causes lipid perturbations, particularly in persons with more advanced immunosuppression; HIV-infected individuals who are not on antiretroviral (ARV) medications often have elevations in triglyceride (TG) levels and decreases in high-density lipoprotein (HDL) as well as in low-density lipoprotein (LDL) cholesterol and total cholesterol (TC). Lipid abnormalities also may be caused by or compounded by ARVs (see chapter *Coronary Heart Disease Risk*). They may appear or worsen within a few weeks to months after starting ART. With some patients, this may, at least in part, represent a return to pre-illness lipid levels, whereas the ARVs cause the abnormality in other cases.

Not all ART-treated patients experience lipid abnormalities to the same degree. Patients with a personal or family history of dyslipidemia, glucose intolerance, diabetes, obesity, or a combination of these health problems may be genetically predisposed to lipid abnormalities that become evident once ART is initiated.

The use of potent combination ART, particularly the use of protease inhibitors (PIs), has increased the prevalence of abnormally high TG, TC, and LDL levels among HIV-infected patients. In fact, dyslipidemia has been associated not only with certain PIs but also with certain nonnucleoside reverse transcriptase inhibitors (NNRTIs) and nucleoside reverse transcriptase inhibitors (NRTIs). In the PI class, ritonavir-boosted PIs (though unusually with atazanavir or darunavir) are particularly likely to cause marked elevations of TG and LDL levels. Although NNRTIs also may contribute to increases in TC, LDL, and TG levels the effects, particularly with efavirenz, are more variable (and efavirenz may increase HDL). Of the NRTIs, stavudine, zidovudine, and perhaps abacavir may increase TC and TG levels. To date, available agents from the integrase inhibitor and CCR5 antagonist classes do not appear to have significant adverse impacts on lipid levels.

The largest prospective study of CHD events related to ARVs (the D:A:D study) showed a small but significant increase in the risk of myocardial infarction among HIV-infected patients treated with ARVs; moreover, the effect increased with cumulative years of ARV exposure. This effect was largely but not entirely associated with increases in LDL cholesterol (see chapter *Coronary Heart Disease Risk*).

HRSA HAB Performance Measures

Percentage of patients, regardless of age, with a diagnosis of HIV who were prescribed HIV antiretroviral therapy and who had a **fasting lipid panel** during the measurement year

(All-Age measure)

Identification and management of dyslipidemia in HIV-infected patients is an important part of HIV primary care. For patients with CHD or CHD risk equivalents (see below), ART regimens should, if possible, be selected to minimize the risk of hyperlipidemia.

Guidelines for the evaluation and management of dyslipidemia have been developed by the National Cholesterol Education Program (NCEP). These recommendations are based on studies of HIV-uninfected persons and may not be entirely applicable to HIV-infected persons, in whom HIV itself may increase risk of CHD events. Despite this limitation, expert panels generally recommend similar treatment goals when evaluating and managing dyslipidemia in patients with HIV infection. (For recommendations on screening, see chapter *Initial and Interim Laboratory and Other Tests*.)

Note: The American College of Cardiology and the American Heart Association released new guidelines on treatment of hyperlipidemia late in 2013. These take a different approach to many aspects of lipid management, including the evaluation of patients for lipid-lowering therapy, the use and monitoring of lipid lowering agents, and the use of treatment targets. These guidelines have generated controversy. As their appropriateness to the management of HIV-infected individuals is not clear at this time, this chapter will discuss the approach presented in the NCEP guidelines.

S: Subjective

The history should focus on factors that suggest CHD, risk equivalents, or risk factors for CHD. Both CHD risks and CHD equivalents should be the focus of lifestyle modification strategies and lipid-normalizing treatment.

- **CHD** includes the following:
 - A history of myocardial infarction
 - Angina
 - CHD procedures
 - Evidence of clinically significant myocardial ischemia
- **CHD risk equivalents** are considered to be equal in terms of risk level to known CHD. These include the following:
 - Diabetes mellitus
 - Peripheral vascular disease
 - Symptomatic carotid artery disease
 - Abdominal aortic aneurysm
 - Transient ischemic attacks
 - Two or more CHD risk factors with a 10-year risk of CHD >20% (see “Calculations to Estimate the 10-Year Risk of Cardiac Events for Men and Women,” below, or the online risk calculator at cvdrisk.nhlbi.nih.gov/calculator.asp).
- **CHD risk factors** are conditions associated with a greater risk of serious cardiac events. These are as follows:
 - Male sex
 - Age (≥45 in men; ≥55 in women)
 - Hypertension
 - Cigarette smoking
 - Low HDL (<40 mg/dL); if >60 mg/dL, subtract one risk factor
 - Family history of premature CHD (first-degree relative aged <55 [men] or <65 [women])
- Assess for causes of secondary dyslipidemias, including insulin resistance, diabetes, hypothyroidism, obstructive liver diseases, chronic renal failure, and medications such as corticosteroids and progestins.
- Screen for other factors that contribute to hyperlipidemia, including obesity, chronic liver diseases, alcohol abuse, high-fat or high-carbohydrate diet, and prothrombotic or proinflammatory states.
- Screen for health behaviors that increase CHD risk, including smoking, high-fat diet, sedentary lifestyle, and use of recreational drugs such as cocaine and methamphetamine.

- Review the patient's family history for premature CHD (as discussed above), obesity (body mass index [BMI] ≥ 30), diabetes, and lipid abnormalities.
- Review the patient's medications, with special attention to ARVs known to increase LDL or TG levels (particularly ritonavir and ritonavir-boosted PIs).

O: Objective

Check vital signs with special attention to blood pressure and weight. Calculate BMI (see chapter *Initial Physical Examination* for information on BMI).

Perform a focused physical examination with particular attention to signs of hyperlipidemia, such as xanthelasma and xanthoma, and to the cardiovascular system.

A: Assessment

Determine whether a specific intervention is appropriate based on the patient's lipid values and identified CHD risks, as indicated in Tables 1 and 2.

LDL is the main indicator for treatment, and the main target for lipid-lowering therapy. Hypertriglyceridemia is associated with CHD risk, but thresholds of risk have not been defined precisely, and targets for intervention are not entirely clear (for persons with triglyceride levels of ≥ 500 mg/dL, the triglycerides usually are treated first; see "Treatment," below). Severe hypertriglyceridemia (e.g., TG $>1,000$ mg/dL) also increases the risk of pancreatitis.

For patients who do not have diabetes or preexisting CHD and who have two or more CHD risk factors, calculate the "10-year risk of cardiovascular events" by using the Risk Assessment Tool for estimating the 10-year risk of a major CHD event. Use the risk-estimate tool at the end of this chapter or the online risk calculator at the National Institutes of Health website (cvdrisk.nhlbi.nih.gov/calculator.asp).

Table 1. Low-Density Lipoprotein Cholesterol Goals and Thresholds for Treatment*

Risk Category	LDL Goal*	Initiate Therapeutic Lifestyle Changes	Consider Drug Therapy
Lower risk: No CHD or CHD risk equivalents and <0 -1 risk factor	<160 mg/dL (<4.1 mmol/L)	LDL ≥ 160 mg/dL (≥ 4.1 mmol/L)	≥ 190 mg/dL (≥ 4.9 mmol/L); at 160-189 mg/dL, LDL drug therapy is optional
Moderate risk: No CHD or CHD risk equivalents and ≥ 2 risk factors, with 10-year estimated risk $<10\%$	<130 mg/dL (<3.4 mmol/L)	LDL ≥ 130 mg/dL (≥ 3.4 mmol/L)	≥ 160 mg/dL (≥ 4.1 mmol/L)
Moderately high risk: No CHD or CHD risk equivalents and ≥ 2 risk factors and 10-year estimated risk 10-20%	<130 mg/dL (<3.4 mmol/L) (optional goal of <100 mg/dL)	LDL ≥ 130 mg/dL (≥ 3.4 mmol/L)	≥ 130 mg/dL (≥ 3.4 mmol/L)
High risk: CHD or CHD risk equivalent (see above)	<100 mg/dL (<2.6 mmol/L) (optional goal of <70 mg/dL#)	LDL ≥ 100 mg/dL (≥ 2.6 mmol/L)	≥ 100 mg/dL (≥ 2.6 mmol/L)

This goal (LDL <70 mg/dL) is preferred by many cardiologists for persons with CHD or risk equivalents.

Adapted from Adult Treatment Panel III, National Cholesterol Education Program. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults*. September 2002; NIH publication 02-5215. Available at www.nhlbi.nih.gov/guidelines/cholesterol/index.htm. Accessed December 1, 2013.

Table 2. Classification of Triglyceride Levels

Risk Category	Triglyceride Measurement	Initiate therapy
Normal triglycerides	<150 mg/dL	
Borderline-high triglycerides	150-199 mg/dL	
High triglycerides	200-499 mg/dL	Start therapeutic lifestyle changes; consider medication if CHD, CHD equivalents, or high risk
Very high triglycerides	≥500 mg/dL	Start therapeutic lifestyle changes; consider medication

Adapted from Adult Treatment Panel III, National Cholesterol Education Program. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults*. September 2002; NIH publication 02-5215. Available at www.nhlbi.nih.gov/guidelines/cholesterol/index.htm. Accessed December 1, 2013.

P: Plan

Diagnostic Evaluation

The fasting serum lipid panel should be performed at least 8 hours, but ideally 12 hours, after last food and beverage intake. It measures TC, HDL, TG, non-HDL cholesterol with calculated LDL, and TC/HDL cholesterol ratio.

A fasting lipid panel should be checked at baseline, before patients start ART.

Repeat the fasting lipid panel within 3-6 months after ARVs are started, and sooner for patients who have abnormal values at baseline.

Patients with normal lipid values should be rechecked annually (sooner if ARVs are changed). Those with dyslipidemia may need more intensive monitoring (e.g., every 4-6 weeks) until the LDL goal is met, after which monitoring every 4-6 months is adequate.

Treatment

Treatment of dyslipidemia usually involves a multimodal approach, including diet and exercise in all cases, lipid-modifying medication, and consideration of changes in ARV medication. The primary goal of lipid-lowering therapy is to reduce LDL to target levels. For persons with CHD and CHD risk equivalents, the type and intensity of LDL lowering therapies are adjusted according to LDL baseline levels. Note that other interventions to reduce CHD risk also should be undertaken (e.g., smoking cessation if appropriate).

For patients with serum TG level of >400 mg/dL, the LDL cholesterol calculation is unreliable. In this situation, non-HDL cholesterol (TC minus HDL) can be used as a surrogate target of therapy; the non-HDL goal is 30 mg/dL higher than the LDL goal. For these individuals, dietary intervention is warranted, and drug therapy to decrease LDL (or non-HDL) can be considered if TC is >240 mg/dL or HDL cholesterol is <35 mg/dL. For those with TG levels of 200-500 mg/dL, achieving the LDL cholesterol target is the primary goal, and lowering non-HDL cholesterol levels is a secondary goal (see Table 1 for LDL intervention levels).

The NCEP guidelines recommend that very high TG levels (≥500 mg/dL) be reduced before LDL is treated directly (see “Treatment of hypertriglyceridemia,” below).

The LDL levels at which either therapeutic lifestyle change (TLC) or drug therapy should be initiated are shown in Table 1, along with the target goals for LDL cholesterol. The response to therapy should be monitored and therapeutic interventions should be intensified or augmented until lipid targets are met.

Therapeutic lifestyle change

TLC, consisting of diet modification and exercise, is fundamental to the management of dyslipidemia for HIV-infected patients.

Target goals for lipid abnormalities are difficult to achieve without prioritizing these behavioral change efforts. Although TLC is hard to maintain, it can yield significant results in reducing CHD risk and improving quality of life. Effective TLC is best achieved with a multidisciplinary team approach. HIV primary care providers should be instrumental in identifying TLC as a treatment priority and providing referrals to nutritionists for dietary counseling, to mental health professionals for assessment of treatable mood disorders, and to social workers, peer counselors, or clinical nurse specialists for assistance with health-behavior changes, self-care strategies, and identification of resources in the community for smoking cessation support and exercise programs. Specific recommendations for TLC goals and behavior change strategies are contained in the Adult Treatment Panel guidelines, which are available at www.nhlbi.nih.gov/guidelines/cholesterol/index.htm.

Pharmacologic treatment for hypercholesterolemia

All patients with elevated lipid levels should initiate TLC. If pharmacologic intervention is indicated, statins (hydroxymethylglutaryl coenzyme A [HMG-CoA] reductase inhibitors) are the first-line treatment for most patients. These agents can be effective in reducing TC, LDL, and non-HDL cholesterol levels

in HIV-infected patients (see Table 3). More importantly, they have been shown to reduce the risk of cardiovascular events in persons with or at risk of CHD.

Recommended starting dosages of statins for patients taking PIs are as follows (Note: see “Potential ARV Interactions,” below):

- Pravastatin: 20 mg PO QD
- Atorvastatin: 10 mg PO QD

Fibrates may be considered as an alternative or adjunct to statins (see “Treatment of hypertriglyceridemia,” below, for further information). When given concomitantly, statins and fibrates increase the risk of rhabdomyolysis and must be used cautiously and with careful monitoring). Niacin may be effective as adjunctive therapy, but it has not been shown to decrease CHD events. It may worsen insulin resistance and may cause hepatotoxicity. It also causes uncomfortable flushing in some patients; the sustained-release formulations are better tolerated. Ezetimibe (Zetia) appears to be effective in combination with statins for patients whose cholesterol is not controlled adequately with a statin alone, but it also has not been shown to decrease CHD events. Bile acid sequestrants generally should be avoided because they may interfere with the absorption of other drugs and may increase TG levels.

Table 3. Drug Treatments for Lipid Abnormalities

Lipid Abnormality	First Choice	Second Choice	Comments
Isolated high LDL, non-HDL cholesterol	Statin	Fibrate	Start with pravastatin* or atorvastatin* (available as generics). Use low statin dosages and titrate upward; patients taking PIs have increased risk of myopathy.
Isolated high TG	Fibrate	Statin, N-3 (omega-3) fatty acids	Start with gemfibrozil or fenofibrate. Combined statin and fibrate may increase myopathy risk.
High LDL and TG (TG level 200-500 mg/dL)	Statin	Fibrate	Start with pravastatin or atorvastatin* (available as generics). Use fluvastatin,* rosuvastatin,* pitavastatin,* gemfibrozil, or fenofibrate as alternatives. Combined statin and fibrate may increase myopathy risk.
High LDL and TG (TG level >500 mg/dL)	Fibrate	N-3 (omega-3) fatty acids, niacin, statin	Start with gemfibrozil or fenofibrate. Niacin is associated with insulin resistance. May need to add statin if cholesterol is not controlled adequately.

* May have significant interactions with certain ARVs; see Table 4.

Potential ARV Interactions

Clinicians should note that there are clinically significant drug interactions between most statins and PIs, NNRTIs, and the pharmacokinetic enhancer cobicistat (see Table 4). PIs and cobicistat can increase serum levels of most statins significantly, thus increasing the risk of severe statin adverse events such as rhabdomyolysis. Of the statin drugs, pravastatin is the least affected by most PIs (darunavir is an exception) and is the recommended statin for most patients with hypercholesterolemia without hypertriglyceridemia. Atorvastatin, if used, should be initiated at low dosage (10 mg) and titrated slowly upward to achieve target lipid levels (note that atorvastatin may lower TG, TC, and LDL levels). Lovastatin and simvastatin are contraindicated for use by patients taking PIs or cobicistat. These can result in severe statin-related adverse events if prescribed. Other available statins include rosuvastatin, pitavastatin, and fluvastatin. These have not been as well studied but may be used with most PIs (there are exceptions; see table on the following page). When statins are given concurrently with interacting PIs, the statins should be started at low dosage and increased incrementally, if indicated; in general, maximum dosages should not be used.

NNRTIs decrease levels of most statins (however, etravirine increases fluvastatin levels); higher dosages of statins may be needed to overcome this interaction. Be aware that various formulations and combination products contain these statins; check the generic name of components in new or unfamiliar cardiac prescriptions to determine whether they contain lipid-lowering agents.

The integrase inhibitors dolutegravir and raltegravir, and other classes of ARV drugs (NRTI, fusion inhibitor, CCR5 antagonist), do not have recognized interactions with statins. Other types of lipid-lowering medications generally are not metabolized by hepatic cytochrome P450 and are not affected by ARVs (an exception to this is gemfibrozil, whose levels are decreased by lopinavir/ritonavir, by an unknown mechanism).

Table 4. Interactions Between Statin Agents and Antiretroviral Medications

	Atorvastatin	Fluvastatin	Lovastatin	Pitavastatin	Pravastatin	Rosuvastatin*	Simvastatin
Protease Inhibitors							
Atazanavir	!	No data	☒	✓(unboosted) ! (ritonavir boosted)	!	! Rosuvastatin AUC ↑ 213%; C _{max} ↑ 600%	☒
Darunavir/ritonavir	!	No data	☒	✓	! Pravastatin AUC ↑ 81% to 500%	!	☒
Fosamprenavir	!	No data	☒	No data	✓ May need to ↑ pravastatin dosage	✓	☒
Indinavir	!	No data	☒	☒	!	!	☒
Lopinavir/ritonavir	! Atorvastatin AUC ↑ 488%	No data	☒	✓	✓ pravastatin AUC ↑ 33%	! Rosuvastatin AUC ↑ 108%; C _{max} ↑ 466%	☒
Nelfinavir	!	No data	☒	No data	!	No data	☒
Ritonavir	!	No data	☒	No data	!	No data	☒
Saquinavir	!	No data	☒	No data	✓ saquinavir + ritonavir: May need to ↑ pravastatin dosage	No data	☒
Tipranavir	☒ Atorvastatin AUC ↑ 836%	No data	☒	No data	!	✓ Rosuvast AUC ↑ 26%	☒
Nonnucleoside Reverse Transcriptase Inhibitors							
Efavirenz ^Δ	✓ May need to ↑ atorvastatin dosage	No data	✓ May need to ↑ lovastatin dosage	No data	✓ May need to ↑ pravastatin dosage	No data	✓ May need to ↑ simvastatin dosage
Etravirine	✓ May need to ↑ atorvastatin dosage	No data; May ↑ fluvastatin levels	✓ May need to ↑ lovastatin dosage	No data	✓	No data	✓ May need to ↑ simvastatin dosage
Rilpivirine	✓	No data	No data	No data	No data	No data	No data
Integrase Inhibitor/Cobicistat Combination							
Elvitegravir/cobicistat	!	No data	☒	No data	No data	✓ Rosuvast AUC ↑ 38%	☒

Code:
 ✓ Generally safe to begin treatment with usual starting dosage
 ! Caution; start with low dosage, monitor effects

☒ Coadministration is contraindicated

^Δ Nevirapine in combination with statins has not been well studied; its interactions would be expected to be similar to those of efavirenz. Delavirdine's interactions would be expected to be similar to those of PIs.

* Other risk factors for elevated rosuvastatin levels include Asian or Pacific Islander heritage, renal insufficiency, and concurrent treatment with gemfibrozil; use with extra caution.

Adapted from: Coffey S. *Interactions between ARVs and Statin Medications: Recommendations for Coadministration of PIs and NNRTIs with Statins*. San Francisco: HIV InSite; Up-

dated October 2012. Available at hivinsite.ucsf.edu/InSite?page=md-rr-30. Accessed December 1, 2013.

Treatment of hypertriglyceridemia

Patients with TG levels of 200-500 mg/dL should begin non-drug interventions such as diet modification, reduction in alcohol consumption, aerobic exercise, and smoking cessation. When the TG level is ≥ 500 mg/dL, a low-fat diet ($<15\%$ of caloric intake) is recommended to help prevent pancreatitis, and pharmacologic therapy probably will be required. Patients with CHD or CHD equivalents, those at high risk of CHD, and those with TG levels >200 mg/dL may need pharmacologic therapy.

Fibrates are the first-line drug option for isolated hypertriglyceridemia and are an alternative treatment for combined hypertriglyceridemia and hypercholesterolemia. Fenofibrate or gemfibrozil reduce TG levels effectively in patients on ARVs. Because they are not metabolized by the cytochrome P450 hepatic enzyme system, they do not have significant drug interactions with most ARVs (an exception may be gemfibrozil with dolutegravir: dolutegravir levels may be increased). Fibrates are contraindicated for use by patients with renal failure. Recommended dosages of these agents are as follows:

- Fenofibrate: 40-200 mg PO QD
- Gemfibrozil: 600 mg PO BID, 30 minutes before meals

If a fibrate alone is inadequate in reducing TG levels, several options are possible. A statin (e.g., atorvastatin, which acts on TGs as well as cholesterol) could be added cautiously, although there is an increased risk of skeletal muscle toxicity with concomitant use of a fibrate and a statin. N-3 (omega-3) fatty acid supplements (e.g., fish oils), administered at 1-2 g BID or TID, have decreased TG levels in patients taking ART. Extended-release niacin at 1,500-2,000 mg/day also decreases both TG and TC levels, although its clinical utility is restricted because of associated insulin resistance and flushing.

Switching antiretroviral therapy

For patients with CHD or CHD equivalents, ARV medications should, if possible, be selected to minimize the risk of hyperlipidemia. In patients with dyslipidemia caused by ARV agents, data suggest that it may be beneficial to discontinue ARVs known to increase lipids if reasonable alternatives exist. Substituting atazanavir or an integrase inhibitor in place of a lipogenic PI or replacing stavudine with tenofovir may improve the lipid profile. Before making ARV substitutions, however, consider carefully the possible effect of the substitution on HIV virologic control and the potential adverse effects of new ARVs. In some cases, antihyperlipidemic agents may be necessary even after ARV substitution.

Appendix:

Calculations to Estimate the 10-Year Risk of Cardiac Events for Men and Women — Framingham Calculator

To calculate the 10-year risk of cardiac events, add up points from the following five tables pertaining to age, HDL, systolic blood pressure, TC, and smoking status (Tables 5.1-5.5). Note that in Tables 5.3-5.5, women's points are in parentheses. After adding points from all of the tables, consult Table 5.6. (Alternatively, an online calculator is available at cvdrisk.nhlbi.nih.gov/calculator.asp.)

(The Framingham Heart Study risk calculator has not been validated for HIV-infected individuals and may underestimate the risk in this population.)

Table 5.1. Estimate of 10-Year Risk of Cardiac Events: Age

Age (Year)	Points (Men)	Points (Women)
20-34	-9	-7
35-39	-4	-3
40-44	0	0
45-49	3	3
50-54	6	6
55-59	8	8
60-64	10	10
65-69	11	12
70-74	12	14
75-79	13	16

Table 5.2. Estimate of 10-Year Risk of Cardiac Events: High-Density Lipoprotein Cholesterol

HDL (mg/dL)	Points (Men)	Points (Women)
≥60	-1	-1
50-59	0	0
40-49	1	1
<40	2	2

Table 5.3. Estimate of 10-Year Risk of Cardiac Events: Systolic Blood Pressure

Systolic Blood Pressure	Points if Untreated — Men (Women)	Points if Treated — Men (Women)
<120	0 (0)	0 (0)
120-129	0 (1)	1 (3)
130-139	1 (2)	2 (4)
140-159	1 (3)	2 (5)
≥160	2 (4)	3 (6)

Table 5.4. Estimate of 10-Year Risk of Cardiac Events: Total Cholesterol

Total Cholesterol (mg/dL)	Points for Men (Women)				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
<160	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
160-199	4 (4)	3 (3)	2 (2)	1 (1)	0 (1)
200-239	7 (8)	5 (6)	3 (4)	1 (2)	0 (1)
240-279	9 (11)	6 (8)	4 (5)	2 (3)	1 (2)
≥280	11 (13)	8 (10)	5 (7)	3 (4)	1 (2)

Table 5.5. Estimate of 10-Year Risk of Cardiac Events: Smoking Status

Smoking Status	Points for Men (Women)				
	Age 20-39	Age 40-49	Age 50-59	Age 60-69	Age 70-79
Nonsmoker	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Smoker	8 (9)	5 (7)	3 (4)	1 (2)	1 (1)

Table 5.6. Estimate of 10-Year Risk of Cardiac Events: Calculating Risk

Men		Women	
Point Total	10-Year Risk (%)	Point Total	10-Year Risk (%)
<0	<1	<9	<1
0	1	9	1
1	1	10	1
2	1	11	1
3	1	12	1
4	1	13	2
5	2	14	2
6	2	15	3
7	3	16	4
8	4	17	5
9	5	18	6
10	6	19	8
11	8	20	11
12	10	21	14
13	12	22	17
14	16	23	22
15	20	24	27
16	25	≥25	≥30
≥17	≥30		

Patient Education

- Review the importance of reducing cardiovascular risk factors. This is of increasing importance for all patients with HIV infection, particularly as they age.
- Educate patients about the benefits of diet and exercise in improving lipid levels and reducing cardiovascular risk.
- If lipid-lowering medications are prescribed, advise patients on possible adverse effects, and advise them to contact their health care provider if these develop.
- Advise patients to talk with their health care provider before starting any new medications so they can be evaluated for possible drug-drug interactions.

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Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy

Background

Diabetes is a substantial risk factor for coronary artery disease, stroke, and peripheral vascular disease, as well as for a number of other conditions including retinopathy and kidney disease. Patients taking antiretroviral (ARV) medications, especially certain protease inhibitors (PIs) and nucleoside reverse transcriptase inhibitors (NRTIs), appear to have an increased risk of hyperglycemia and diabetes mellitus. In particular, the ARVs indinavir and stavudine (now seldom used in the United States) have been shown to induce insulin resistance in short-term studies of healthy HIV-uninfected volunteers, but other ARVs also perturb glucose homeostasis.

Disorders of glucose metabolism may present as the following:

- **Insulin resistance:** a state in which higher concentrations of insulin are required to exert normal effects; blood glucose levels may be normal but fasting insulin levels may be high because of compensatory insulin secretion by the pancreas
- **Impaired glucose tolerance:** glucose 140-199 mg/dL 2 hours after a 75 g oral glucose load
- **Impaired fasting glucose:** glucose 100-125 mg/dL after an 8-hour fast
- **Diabetes mellitus:** any of the following four criteria may be used (results must be confirmed by retesting on a subsequent occasion):
 - Fasting glucose ≥ 126 mg/dL
 - Glycosylated hemoglobin (HbA1c) level $\geq 6.5\%$ (note that HbA1c testing has not been validated in HIV-infected persons; see “Diagnostic Evaluation,” below)
 - 2-hour glucose level ≥ 200 mg/dL during glucose tolerance testing
 - Random glucose values ≥ 200 mg/dL in the presence of symptoms of hyperglycemia

The incidence of new-onset hyperglycemia among HIV-infected patients on ARV therapy (ART) has been reported as about 5%, on average. Even if fasting glucose levels remain normal in patients taking ARVs, up to 40% of those on a PI-containing regimen will show impaired glucose tolerance. The etiology of insulin resistance and hyperglycemia in HIV-infected patients probably is multifactorial, with varying contributions from traditional risk factors (e.g., obesity, family history), comorbid conditions (e.g., hepatitis C virus infection), and ARV-related factors (e.g., direct effects of PIs, cumulative exposure to NRTIs, hepatic steatosis, and fat redistribution).

Patients who have preexisting diabetes should be monitored closely when starting ART; some experts would consider avoiding PIs for these patients, if other options are feasible. Alternatively, PIs with favorable metabolic profiles (e.g., atazanavir) may be preferred for such patients. Patients with no history of diabetes should be advised about the warning signs of hyperglycemia (polydipsia, polyuria, and polyphagia) and the need to use diet and exercise to maintain an ideal body weight.

S: Subjective

Clinicians should consider the potential for abnormal glucose metabolism in the following types of patients:

- Those who are about to begin ART
- Those on an ARV regimen that includes a PI
- Those with extensive exposure to NRTIs
- Those who are obese or overweight
- Those with central fat accumulation or lipoatrophy

Although most patients with hyperglycemia are asymptomatic, some (rarely) may report polydipsia, polyuria, polyphagia, or blurred vision.

When recording the patient's history, ask about the following:

- **Risk factors:**
 - Family history of diabetes
 - Obesity
 - Habitual physical inactivity
 - Racial or ethnic heritages (higher risk: African-American, Hispanic, Native American, Asian/Pacific Islander)
 - Gestational diabetes or delivery of an infant weighing >9 lb (4.1 kg)
 - Current pregnancy
 - Hepatitis C virus coinfection
 - Polycystic ovary syndrome
 - Medications, including PIs, NRTIs, niacin, corticosteroids, antipsychotics
- **Comorbidities:**
 - Hypertension
 - Low level of high-density lipoprotein (HDL)
 - Elevated triglycerides
 - Coronary artery disease
 - Fat redistribution on ARVs (see chapter *Abnormalities of Body-Fat Distribution*)
 - Smoking

O: Objective

Perform a physical examination that includes the following:

- Blood pressure, weight, body mass index (BMI) (see chapter *Dyslipidemia*)
- Heart and lung examination
- Peripheral pulses
- Examination of neck, dorsocervical area, breasts, and abdomen for fat accumulation; measurement of waist circumference
- For patients with hyperglycemia or diabetes:
 - Retinal examination (refer to ophthalmologist for dilated examination)
 - Visual inspection of feet (for ulcers)
 - Sensory examination of feet (for neuropathy)

**A/P: Assessment and Plan
Diagnostic Evaluation**

Determine whether the patient has normal blood glucose, impaired fasting glucose, or diabetes.

Most experts recommend routine checks of fasting blood glucose levels at baseline and within 3-6 months after starting or changing ART, if baseline results are normal. For patients with normal glucose levels, recheck every 6-12 months. Monitoring should be more frequent if abnormalities are detected or if any additional risk factors exist. Patients with risk factors for diabetes must be counseled about prevention of hyperglycemia before starting ART.

The role of 2-hour postprandial glucose measurements or the 75 g oral glucose tolerance test for diabetes is uncertain but these screenings may be appropriate for patients with multiple risk factors. The use of HbA1c testing to screen for diabetes has yet to be validated for the HIV-infected population. Of note, HbA1c values may underestimate glycemia in HIV-infected patients, especially

in the setting of elevated red blood cell mean corpuscular volume (MCV) (e.g., owing to zidovudine) or anemia.

For patients with diabetes, monitor the following:

- HbA1c, every 3 months for patients who have elevated HbA1c or whose therapy has changed, every 3-6 months for patients with stable and adequate glucose control
- Fasting lipid panel
- Electrolytes, creatinine, estimated glomerular filtration rate (eGFR) (see chapter *Renal Disease*)
- Urine albumin/creatinine ratio (microalbuminuria: 30-299 mg/g)

Treatment

Patients with insulin resistance

For patients with insulin resistance who have normal blood glucose levels, current evidence is inadequate to recommend drug treatment. However, it may be possible to prevent the development of diabetes, and lifestyle modifications can be recommended, including exercise, avoidance of obesity, weight loss if indicated, and diet changes. Weight loss is strongly recommended if the patient is overweight. Refer the patient to a dietitian, if possible. Studies of insulin resistance in HIV-infected individuals are under way, and patients with access to clinical trials may be referred to these studies.

Patients with insulin resistance and hyperglycemia require treatment. A trial of lifestyle modifications may be attempted, including weight loss (if indicated), diet changes, and exercise.

For patients with diabetes and those whose lifestyle changes are not adequate to control blood glucose, specific treatment should be started.

Patients with diabetes

- Treatment should be instituted to control blood sugar and to modify other cardiovascular risk factors, with the aim of preventing heart disease and other end-organ disease.
- Control glucose: maintain the HbA1c level at <7%, while avoiding hypoglycemia.
- For hyperglycemia that is associated with the use of PIs, switching to an alternative agent (e.g., a nonnucleoside reverse transcriptase inhibitor, an integrase inhibitor, or a different PI) may be effective if the HIV treatment history and resistance profile permit.
- Metformin usually is the initial drug of choice for overweight patients; other options include sulfonylureas and thiazolidinediones.
- Metformin can worsen lipoatrophy and should be avoided in the presence of significant lipoatrophy. Metformin increases risk of lactic acidosis; it should not be used for patients with elevated serum creatinine (>1.5 mg/dL in men or >1.4 mg/dL in women), hepatic impairment, or metabolic acidosis.
- Sulfonylureas may cause hypoglycemia. In starting therapy, shorter-acting agents (e.g., glipizide) may be preferable to longer-acting agents (e.g., glyburide). Some agents should not be used for patients with renal impairment (CrCl <50 mL/min).
- Thiazolidinediones should be avoided in patients with significant liver disease. Rosiglitazone may increase the risk of myocardial infarction and death (study results conflict); both rosiglitazone and pioglitazone have been associated with congestive heart failure and are contraindicated for use by patients with this condition.

- In some cases, insulin may be the safest drug therapy for patients with symptomatic hyperglycemia, although episodes of hypoglycemia are much more common with insulin than with most oral agents.
- Treat dyslipidemia: maintain low-density lipoprotein (LDL) at <100 mg/dL and maintain triglycerides at <150 mg/dL. (Note that diabetes is considered a coronary heart disease equivalent state when evaluating goals for lipid management; see chapter *Dyslipidemia*.)
- Treat hypertension: Maintain systolic blood pressure at <130 mm Hg and diastolic blood pressure at <80 mm Hg.
- Reduce cardiovascular risks through lifestyle modifications such as smoking cessation, exercise, weight loss, nutritional counseling, and moderation of alcohol intake.
- Decrease the risk of end-organ complications:
 - Measure urine microalbumin and creatinine; if the urine albumin/creatinine ratio is >30 mg/g, treat with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) to slow the progression of nephropathy.
 - Schedule annual retinal examination by an ophthalmologist.
 - Perform an annual foot examination.
- Start aspirin therapy (75-162 mg daily) if the patient has evidence of macrovascular disease or a history of vascular events. Consider daily aspirin for those with increased coronary heart disease risk (e.g., men >50 years and women >60 years of age with ≥1 coronary heart disease risk factor, such as a family history of coronary artery disease or a history of smoking) (see chapter *Coronary Heart Disease Risk*).

For further information, see the American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, available at care.diabetesjournals.org.

Patient Education

- ART can increase the risk of diabetes in some individuals. Patients should report any difficulty with excessive hunger and thirst and increased urination. Health care providers will monitor blood glucose when doing laboratory work, but it is important for the patient to report the presence of any symptoms.
- Review the patient's eating habits and explain the need to work with a dietitian to keep blood glucose (and triglycerides) within normal limits. Eating a proper diet can reduce the risk of permanent damage to the blood vessels of the eye, the kidney, and the brain, and it can reduce the risk of a heart attack.
- Emphasize other lifestyle modifications, such as weight loss (if appropriate).
- Encourage patients to get regular cardiovascular exercise; work with them to identify activities that might be realistic and acceptable for them.
- Provide medication-specific education, especially if the patient will be taking diabetes medications.
- Consider referral to a diabetes clinic for specialty needs.

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Coronary Heart Disease Risk

Marshall Glesby, MD, PhD

Background

Epidemiologic studies suggest that the incidence of myocardial infarction or hospitalization for coronary heart disease (CHD) is increased up to twofold in HIV-infected individuals compared with age-matched controls without HIV infection. This increased risk of ischemic events likely is attributable to a higher prevalence of certain CHD risk factors that are independent of HIV status, such as smoking, as well as to both HIV infection and antiretroviral (ARV) medications. These various factors may interact in ways that are complex and incompletely understood.

Among the traditional CHD risk factors, dyslipidemia is common among persons with HIV infection, and can be caused both by HIV itself (e.g., resulting in low high-density lipoprotein [HDL] cholesterol) and by ARV therapy (ART); see chapter *Dyslipidemia*. Insulin resistance and diabetes also appear to be more prevalent in HIV-infected patients. (See chapter *Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy*.) Visceral fat accumulation, a poorly understood complication of HIV or ART, also may contribute to CHD risk in certain patients (see chapter *Abnormalities of Body-Fat Distribution*).

Several studies have suggested that low CD4 cell counts are associated with myocardial infarction and stroke. Additionally, a number of studies suggest that inflammation and immune activation owing to uncontrolled HIV infection also likely contribute to atherosclerosis. For example, in the Strategic Management of Antiretroviral Therapy (SMART) study, CHD events were more common in patients on intermittent ART than in those on continuous ART, possibly because of adverse effects of intermittent HIV viremia on inflammation, coagulation, and lipid parameters. There is even preliminary evidence that so-called elite controllers – patients with undetectable HIV viremia and preserved CD4 counts in the absence of ART – have increased carotid intima-medial thickness (a marker of atherosclerotic burden) compared with HIV-uninfected subjects, after adjusting for other CHD risk factors. Limited data also suggest that initiation of ART leads to improvement of endothelial dysfunction (an early marker of atherosclerosis that is predictive of future CHD events) and to improvement in markers of inflammation and immune activation. Taken together, these observations suggest that earlier initiation of ART could reduce CHD risk.

On the other hand, even patients with virologic suppression on ART appear to have higher levels of various physiologic markers of cardiovascular risk than the HIV-uninfected persons, perhaps owing to persistent immune activation. Additionally, exposure to ARVs has been linked to risk of myocardial infarction in large cohort studies such as the D:A:D study. In particular, the risk has been associated with use of ARV regimens that are based on protease inhibitors (PIs) rather than nonnucleoside reverse transcriptase inhibitors (NNRTIs). The risk is attributable in part to adverse changes in lipid profiles, but there appears to be additional risk associated with PIs that is not accounted for by changes in lipids; this remains poorly understood. Among the nucleoside reverse transcriptase inhibitors (NRTIs), abacavir and didanosine have been associated with increased risk of myocardial infarction in some but not all studies. The mechanism of this potentially increased risk has not been determined.

S: Subjective

Clinicians should ask all patients about CHD, CHD risk equivalents, and CHD risk factors. Assess the following during the history:

- Age (>45 for men, >55 for women)
- History of angina, myocardial infarction, or other heart disease
- Family history of premature CHD in first-degree relatives (men aged <55, women aged <65) and diabetes mellitus
- Smoking history
- Glucose intolerance or diabetes mellitus
- Hypertension
- Dyslipidemia
- CHD risk-equivalent states:
 - Diabetes mellitus
 - Peripheral vascular disease
 - Cerebrovascular disease
 - Abdominal aortic aneurysm
- Use of cocaine or amphetamines
- Physical inactivity

O: Objective

Perform a physical examination to include the following:

- Vital signs, including blood pressure, pulse, weight, and body mass index (BMI); see chapter *Dyslipidemia*
- Jugular venous distention
- Heart and lung examination
- Auscultation for carotid or femoral bruits
- Peripheral pulses and evaluation of extremities for peripheral edema
- Abdominal examination for fat accumulation, ideally with measurement of waist circumference

A: Assessment

- Determine whether the patient has established CHD or a CHD risk-equivalent state (see above).
- Stratify risk based on the number of CHD risk factors and the Framingham risk calculator if two or more major CHD risk factors are present. The risk calculator is available at cvdrisk.nhlbi.nih.gov/calculator.asp.
- Check fasting lipids and glucose annually; more frequently if abnormal.
- Patients with established or suspected CHD should undergo standard evaluations such as electrocardiography and exercise stress testing; refer to a cardiologist as appropriate.

P: Plan

- Work closely with patients to reduce their risks of CHD events.
- For patients who smoke, smoking cessation is the single most important intervention to reduce risk of CHD events (see chapter *Smoking Cessation*).
- Manage dyslipidemia according to established guidelines (see chapter *Dyslipidemia*).
- Manage hypertension by lifestyle intervention (e.g., sodium restriction, exercise, weight loss) and pharmacologic therapy as indicated.
- Optimize glycemic control in patients with diabetes mellitus (see chapter *Insulin Resistance, Hyperglycemia, and Diabetes on Antiretroviral Therapy*).
- Encourage weight loss in overweight and obese patients, with referral to a dietitian as appropriate.
- Encourage exercise, ideally 30 minutes at moderate intensity 5-6 times per week.
- Encourage a healthy diet that is low in saturated fats.

- Consider aspirin 81 mg QD for primary prevention of CHD in patients at moderate to high risk who do not have contraindications to aspirin use.
- For patients who use cocaine or amphetamines, encourage cessation.

Patient Education

- Both HIV infection and ARV medications may contribute to the risk of CHD, and the available data suggest that the risk of CHD is increased in HIV-infected patients relative to the general population.
- Review the benefits of smoking cessation.
- Review exercise possibilities to determine which activities might be realistic and acceptable for the patient.
- Review the patient's eating habits and explain the need to work with a dietitian to optimize lipid levels and keep blood glucose within normal ranges.
- Emphasize the importance of other lifestyle modifications, such as weight loss (if appropriate).
- Educate patients about any pharmacologic therapy that is indicated.

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Renal Disease

Alfredo Tiu, DO

Background

The prevalence of renal complications among patients with HIV infection has increased as more patients with HIV are living longer as a result of effective antiretroviral therapy (ART) and opportunistic infection prophylaxis. More widespread access to and earlier initiation of ART has decreased the incidence of HIV-associated nephropathy (HIVAN), but other causes of renal disease persist, and in some cases are increasing in prevalence. These may be infections and other conditions related to HIV infection, other comorbidities (e.g., hypertension, diabetes), or medication adverse effects, including those caused by some antiretroviral (ARV) medications (see “Kidney disease associated with HIV infection” and Table 2, below).

Risk factors for renal disease in HIV-infected patients include the following:

- CD4 count <200 cells/ μ L
- HIV viremia, particularly RNA levels >4,000 copies/mL
- African-American race
- Family history of kidney disease
- Use of nephrotoxins (including medications; see Table 2, below)
- Comorbidities
 - Diabetes mellitus
 - Hypertension
 - Hepatitis C

Renal disease in HIV-infected individuals can occur as a primary disease, as a secondary disease in the setting of other systemic illness, or as an adverse effect of medications. In the United States, the most common causes of end-stage renal disease in the general population are diabetes mellitus and hypertension. HIV-infected patients are at a fourfold higher risk of developing diabetes mellitus and a threefold higher risk of developing hypertension compared with seronegative individuals. Chronic hepatitis C, seen in 30–40% of HIV-infected individuals in the United States, is associated with several types of chronic kidney disease, including progressive secondary glomerulonephropathy, membranoproliferative glomerulonephropathy, and mixed cryoglobulinemia.

Note that ART should be given to HIV-infected individuals with renal disease, according to usual criteria for ART initiation; however, some ARVs must be avoided and some should be given at modified dosages according to the degree of renal dysfunction (see Table 3). Additionally, for patients with HIVAN, ART is the primary treatment.

Screening

Screening for kidney disease in HIV-infected persons is an important aspect of primary care, as patients typically have no symptoms until very late. High-risk patients (see list of risk factors, above) should be identified and monitored. Early identification of patients with renal dysfunction allows early intervention targeted at reversing the process of renal injury or slowing its progression. Current guidelines of the U.S. Department of Health and Human Services (HHS) and the Infectious Diseases Society of America recommend screening at entry to care, with subsequent screening as indicated by the patient's risk factors.

Screening consists of three tests:

- **Serum creatinine (Cr) and calculated estimate of renal function (eGFR);** the eGFR usually is provided by the laboratory but may be calculated as follows:

- *eGFR by the Modification of Diet in Renal Disease (MDRD) equation:*

$$\text{GFR (mL/min/1.73 m}^2\text{)} = 186 \times [\text{serum Cr (mg/dL)}]^{-1.154} \times [\text{age (years)}]^{-0.203} \times [0.742 \text{ if female}] \times [1.212 \text{ if African-American}]$$

Normal GFR: $\geq 90 \text{ mL/min/1.73 m}^2$

Chronic kidney disease (CKD): $\text{GFR} < 60 \text{ mL/min/1.73 m}^2$

An online eGFR calculator is available at www.nkdep.nih.gov/lab-evaluation/gfr-calculators.shtml.

- The creatinine clearance (CrCl) can be used as a surrogate for eGFR but is considered to be less accurate. Note that CrCl is used in determining medication dosages.

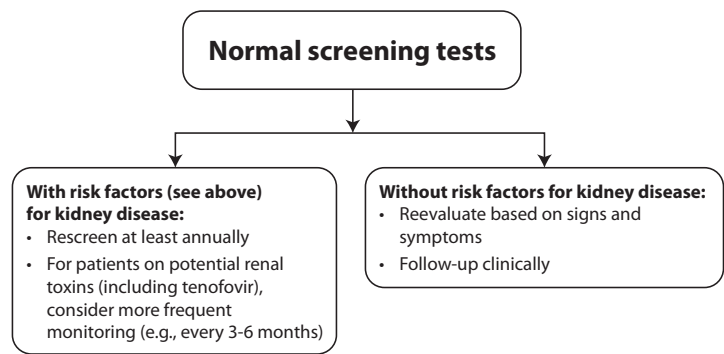
CrCl (Cockcroft-Gault equation):

$$\frac{(140 - \text{age}) \times (\text{weight in kilograms})}{72 \times \text{serum Cr (mg/dL)}}$$
 multiply by 0.85 for females

- **Urinalysis, for proteinuria, hematuria**
- **Quantitative test for proteinuria** (if eGFR $< 60 \text{ mL/min/1.73m}^2$ or $\geq 1+$ protein on dipstick):
 - Random urinary protein to urinary Cr ratio (U Pr/U Cr)
 - This estimates 24-hour protein excretion and correlates well with grams per day of proteinuria; for example, a random U Pr/U Cr of 1.0 correlates with 1 g/day of proteinuria (normal is ≤ 0.2)

Suggested follow-up for patients with normal screening test results is shown in Figure 1; suggested follow-up of abnormal screening test results is shown in “Diagnostic Evaluation.”

Figure 1. Follow-Up for Patients with Normal Screening Test Results



S: Subjective

As noted above, patients usually have no symptoms until late in the course of kidney disease and are diagnosed on the basis of laboratory abnormalities.

In symptomatic patients, presenting signs or symptoms are nonspecific. Patients with renal failure may present with fatigue, weakness, anorexia, nausea, pruritus, vomiting, edema, diminished urine output, discolored urine, altered mental status, and seizures. Those with renal disease associated with systemic illnesses may present with fever, arthralgias, respiratory symptoms, flank pain, abdominal pain, and diarrhea.

For patients with renal disease suspected on the basis of laboratory abnormalities (e.g., elevated serum Cr [azotemia], electrolyte disturbances, acid-base disorders, proteinuria, hematuria, and anemia), and for symptomatic patients with known kidney disease, ask about the risk factors and symptoms described above, and about the following:

- Systemic illness
 - Night sweats, fever, weight loss
 - Shortness of breath, cough, hemoptysis, nasal congestion, rhinorrhea
 - Diarrhea, hematochezia, melena
 - Dysuria, frequency, urgency, polyuria, decreased urine output, discoloration of urine
 - Skin rash or skin lesions
 - Edema, arthralgias, painful swollen joints, myalgias
- Family history of kidney disease, hypertension, diabetes mellitus
- Recent radiographic imaging with IV contrasts (including those containing gadolinium or iodinated agents)

Review the patient’s medication list (see Table 1).

- Include over-the-counter medications, nonsteroidal antiinflammatory drugs, phosphate-containing enemas

O: Objective

Check blood pressure, temperature, and weight. Compare these with values from previous readings. Perform a physical examination, including evaluations of the following:

- Volume status (blood pressure, pulse, skin turgor, mucous membrane moistness, edema)
- Optic fundi (signs of retinopathy)
- Cardiovascular system (peripheral pulses, bruits), to assess for peripheral vascular disease
- Abdomen (auscultate for unilateral bruit [renal artery stenosis], distention, mass, organomegaly, tenderness)
- Musculoskeletal system (bruises, muscle pain, muscle weakness, swollen joints)
- Skin (rash to help evaluate for drug reaction, vasculitis)
- Rectum (enlarged prostate, if obstruction is suspected)

Review previous laboratory values (e.g., serum Cr, blood urea nitrogen [BUN], electrolytes, urinalysis) to determine whether the kidney disease is acute or chronic.

- Acute kidney injury (AKI) is assumed if there are no previous serum Cr values.

The presence of an abnormal GFR (≤ 60 mL/min for at least 3 months) suggests chronic kidney disease (CKD).

Review the CD4 cell count and HIV viral load.

A: Assessment

Once the duration of the elevated serum Cr is assessed, a differential diagnosis can be made.

The causes of renal failure are classified traditionally based on the area of the renal anatomy where the injury occurred: prerenal, renal, and postrenal (obstructive uropathy). Acute tubular necrosis (ATN) is the most common cause of acute kidney injury.

Table 1. Causes of Renal Failure

Prerenal	Renal	Postrenal
Laboratory Data		
• Urine sodium (Na) <30 mEq/L • Fractional excretion of Na (FeNa) $<1\%$ (see below) • Fractional excretion of urea $<35\%$ • Serum BUN: serum Cr ratio ≥ 20	• Urine Na >30 mEq/L • FeNa $>1\%$ (see below) • Fractional excretion of urea >50 • Serum BUN: serum Cr ratio ≥ 10	Hematuria Imaging showing obstruction

Prerenal	Renal	Postrenal
Partial Differential Diagnosis		
Decreased renal perfusion • Volume depletion • Effective volume depletion • Heart failure • Cirrhosis • Shock Vascular disease • Renal artery stenosis Medication induced • Prostaglandin inhibition (NSAID) • ACE inhibitors and angiotensin receptor blockers	Acute Tubular Necrosis Ischemia leading to ATN • Prolonged hypotension attributable to any cause • Sepsis syndrome • Volume depletion (gastrointestinal bleeding) • Atheroembolism and thromboembolism • Systemic vasculitis • Thrombotic microangiopathy (TTP, HUS) Endogenous toxins • Myoglobin (rhabdomyolysis) • Uric acid and calcium-phosphate complexes (tumor lysis syndrome) Exogenous-induced ATN • Aminoglycosides • Amphotericin B • Foscarnet • Ganciclovir • Intravenous pentamidine • Tenofovir • Chemotherapeutic agents (methotrexate, cisplatin) Glomerulonephropathy • Many specific types; some associated with HIV (including HIVAN) or associated infections and other conditions Other intrarenal lesions • Acute interstitial nephritis (AIN) • Drug induced • Infections associated with AIN • Bacterial (<i>Streptococcus</i>, <i>Mycobacteria</i>, <i>Legionella</i>, <i>Pneumococcus</i>) • Viral (Epstein-Barr, herpes simplex type 1, cytomegalovirus, BK virus) • Fungal (histoplasmosis, candidiasis) • Other infections (toxoplasmosis, syphilis, schistosomiasis, malaria, leptospirosis) • Infectious • Granulomatous (mycobacterial disease, coccidioidomycosis, histoplasmosis) • Tumors • Multiple myeloma • Lymphoma • Nephrolithiasis • Intratubular obstruction • Drug-induced crystalluria ▶ Antiviral (acyclovir, indinavir, atazanavir) ▶ Antibiotic (trimethoprim/sulfamethoxazole)	Prostate hypertrophy Tumors Stones or crystal deposition

Abbreviations: ACE = angiotensin-converting enzyme; HUS = hemolytic uremic syndrome; NSAID = nonsteroidal antiinflammatory drug; TTP = thrombotic thrombocytopenic purpura

Kidney Disease Associated with HIV Infection

A discussion of glomerulonephropathy is beyond the scope of this chapter, but HIV and associated comorbidities (e.g., infections such as hepatitis C, hepatitis B, and cytomegalovirus, along with malignancies, heroin use, nephrotoxic medications, diabetes mellitus, and hypertension) are among the many causes of glomerulonephropathy. The condition most closely associated with HIV is HIVAN. This is a collapsing focal segmental glomerulosclerosis (FSGS) that usually occurs in persons of African heritage, and particularly those with a low CD4 count or high HIV RNA level. The clinical presentation includes the following:

- Nephrotic syndrome or nonnephrotic proteinuria
- Normal blood pressure
- Elevated Cr, often with rapid progression to end-stage renal disease (<6 months)
- Renal ultrasound usually reveals normal size or slightly enlarged echogenic kidneys
- Renal biopsy shows a collapsing FSGS

In addition, several conditions may be caused by ARV medications. Tenofovir may cause, though rarely, AKI with type 2 renal tubular acidosis (RTA) and Fanconi syndrome.

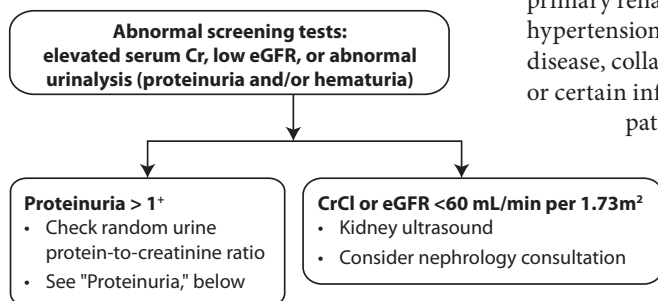
Alternatively, it more commonly causes a gradual increase in serum Cr over a period of months or years; this appears to occur more frequently in persons concomitantly taking ritonavir-boosted PIs and perhaps also in those taking cobicistat. Patients who take tenofovir should have renal function monitored every 3-6 months. Indinavir can cause crystalluria, nephrolithiasis, and acute interstitial nephritis, and atazanavir can cause nephrolithiasis.

Some other medications commonly used in the treatment of patients with HIV infection and associated conditions may cause acute or chronic kidney injury. See Table 1, above, and Table 2, below.

It should be noted that several ARVs (including the NNRTI rilpivirine and the integrase inhibitor dolutegravir) as well as the pharmacokinetic inhibitor cobicistat (in the coformulation elvitegravir/cobicistat/tenofovir/emtricitabine, Stribild) may inhibit renal tubular secretion of creatinine and thus cause modest increases in serum Cr (in the range of 0.1-0.2 mg/dL) and modest decreases in eGFR. This does not result from kidney injury, and actual GFR remains stable. These creatinine increases occur in the initial weeks of treatment with one of these agents and remain stable afterward (if increases in Cr exceed what is expected for these drugs, it is important to conduct an evaluation for other causes).

Table 2. Selective Drugs Causing Acute or Chronic Kidney Injury in HIV-Infected Patients

Drugs	Acute Tubular Necrosis	Acute Interstitial Nephritis	Other Associated Abnormalities
Antiretroviral Medications			
Abacavir		+/-	
Atazanavir		+	Nephrolithiasis
Indinavir		+	Crystalluria
Tenofovir	+		Fanconi syndrome (hypokalemia, non-gap metabolic acidosis, hypophosphatemia, glycosuria) May cause a slow increase in Cr
Other Medications			
TMP-SMX (Bactrim, Septra)		+++	Hyperkalemia, crystalluria
Beta-lactams		++	
Sulfonamides		++	
Fluoroquinolones		+	
Aminoglycosides (e.g., streptomycin, gentamycin, amikacin)	+++		
Rifampin	+	+	
Isoniazid		+	Overdose leads to high anion gap metabolic acidosis
Dapsone	+/-		Papillary necrosis
Amphotericin B	+++		Hypokalemia, hypernatremia (nephrogenic diabetes insipidus)
Pentamidine	+++		Crystalluria
Foscarnet	+++		
Ganciclovir	+		
Acyclovir	+		Crystalluria
NSAIDs		+	Proteinuria, secondary minimal change disease, papillary necrosis

P: Plan**Diagnostic Evaluation****Figure 2. Workup of Abnormal Screening Test Results**

Determine whether the renal disease is acute or chronic, as above (see “O: Objective”).

Perform a targeted laboratory evaluation, depending on results of initial tests, history, and physical examination.

- Urinalysis with microscopy and examination of urine sediment (e.g., hematuria, pyuria, casts) can help in identifying etiologies such as nephritic syndrome, ATN, or infection.
- Quantify the proteinuria by obtaining a random urine protein-to-urine creatinine ratio (U Pr/U Cr), if not done already; this correlates well with grams per day of proteinuria, as discussed above.
- Fractional excretion of sodium (FeNa) may be helpful in distinguishing causes of acute kidney injury.
 - $$\text{FeNa} = \frac{\text{Urine sodium} \div \text{Serum sodium}}{\text{Urine Cr} \div \text{Serum Cr}}$$
 - FeNa <1 is highly suggestive of prerenal state
 - FeNa >1 is suggestive of intrinsic renal injury
- Urine culture, if urinary tract infection is suspected

Further workup will depend on the findings and the suspected cause.

Proteinuria

Proteinuria can be present in patients with primary renal disease, and also in those with hypertension, diabetes mellitus, vascular disease, collagen vascular disease, malignancy, or certain infections. Proteinuria is not always pathologic and may be caused by

transient conditions such as pregnancy, strenuous exercise, fever, seizure, or congestive heart failure; in some cases, it may be benign. However, proteinuria should be evaluated if it persists. If

present with hematuria, proteinuria is highly suspicious for a glomerular disease.

The major classifications of persons with proteinuria are as follows:

Nephrotic syndrome:

- >3.5 g/day proteinuria
- “Bland” sediment, with no or few red or white blood cells
- Edema
- Hyperlipidemia
- Hypoalbuminemia
- Check serum complements (C3 and C4):
 - Low complements: glomerulonephritis associated with subacute bacterial endocarditis, infection (postinfectious), lupus, membranoproliferative glomerulonephritis, and mixed cryoglobulinemia

Glomerulonephritis:

- Proteinuria
- “Active” sediment, with white and red blood cells; may see red blood cell casts
- Further categorized into those with normal renal function and those with abnormal renal function

Hematuria

For asymptomatic isolated microscopic hematuria, obtain a follow-up urinalysis. If hematuria is persistent, obtain a renal and bladder ultrasound. If the result is normal, the eGFR is normal, and there are no other urine abnormalities, conduct routine follow-up with urinalysis and serum Cr testing. Refer patients aged ≥ 40 with persistent hematuria to a urologist for formal evaluation. Consider checking urine cytology, though that test is not sensitive enough to rule out genitourinary malignancy.

Red blood cell casts

Red blood cell casts strongly suggest glomerulonephritis, which can progress rapidly.

ATN

ATN is the most common cause of AKI. A history of certain medication exposures, recent IV contrast, and concurrent illness may provide important clues to ATN. Laboratory findings that are consistent with ATN include increasing serum Cr and a characteristic urine sediment that shows “muddy brown” casts, which are casts that contain densely packed tubular cells.

AIN

During AIN, the classic triad of AKI, fever, and rash is not always present. Laboratory findings suggestive of AIN in the setting of AKI include sterile pyuria and eosinophiluria.

Sterile pyuria

Sterile pyuria also may occur in malignancy (e.g., renal, bladder), and in genitourinary tuberculosis. If tuberculosis is suspected, further testing usually requires three first-void urine specimens sent for acid-fast bacilli culture.

Crystalluria and nephrolithiasis

Usual causes of nephrolithiasis should be considered in patients with hematuria, particularly if symptoms consistent with nephrolithiasis are present. Other causes in

persons with HIV infection include some medications, including the ARVs indinavir and (rarely) atazanavir; see Table 2 above.

Obtain radiographic imaging (see below) as part of the initial evaluation, and send the passed renal stone, if available, for analysis in order to provide more specific recommendations for management. If there is suspicion that the condition is caused by a medication, order specific chemical analysis (e.g., for atazanavir).

In patients with multiple renal stones, active renal stone formation, and recurrent kidney stones, a metabolic evaluation should be done. This includes a serum intact parathyroid hormone measurement and 24-hour urine collection for Cr, sodium, calcium, oxalate, uric acid, and citrate.

Imaging

Radiographic imaging of the kidneys is important in the evaluation of renal disease. The size and echogenicity of the kidneys may help differentiate acute and chronic kidney disease. Small and echogenic kidneys are consistent with CKD, though HIV, diabetes, and some other chronic conditions are associated with normal size or large kidneys. Imaging also helps identify obstruction (though the absence of hydronephrosis does not completely rule that out), malignancy, and other conditions.

Both spiral computed tomography (CT) scan and renal ultrasound are acceptable radiographic imaging studies for nephrolithiasis. The advantage of spiral CT scan is its ability to localize stones and assess their size without the use of contrast. Gallium renal scan may be helpful in AIN.

Renal biopsy

Biopsy is not always indicated for patients with renal disease, but it can be very helpful in establishing some diagnoses and determining treatment options.

Treatment

Patients with proteinuria will benefit from angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs). Follow the serum potassium and Cr during treatment with an ACEI or ARB (check 1 week after initiation, then periodically). Follow the JNC VII (Joint National Committee on Prevention, Detection, Evaluation and Treatment of Blood Pressure) guidelines for blood pressure control. For patients with hypertension and proteinuria, the target blood pressure is <125/80 mm Hg.

The cornerstone of HIVAN management is fully suppressive ART, and this should be quickly initiated or optimized in all patients, if possible. An ACEI or ARB also should be used to treat proteinuria. A trial of corticosteroids can be considered for patients with deteriorating kidney function while on effective ART plus an ACEI or ARB; consult with a specialist.

For ATN and AIN, discontinue the offending medications and provide supportive care, which may include gentle volume repletion, replacement of bicarbonate deficit, and management of electrolyte abnormalities (e.g., hyperkalemia); consult with a renal specialist.

Other modalities of treatment such as steroids or immunomodulators may be needed, depending on the specific glomerular disease diagnosed by renal biopsy.

Uncomplicated nephrolithiasis can be managed with hydration and pain control. Oral fluid intake should be titrated to produce ≥ 2 liters of urine output per day. Recommendations for dietary modifications should be based on the 24-hour urine metabolic evaluation. A low-calcium diet usually is not helpful for patients with normal serum calcium and may be detrimental to patients with oxalate renal stones. If the crystalluria is caused by medications, discontinue the offending medications, if possible (in the case of ARVs, make substitutions to maintain optimal virologic suppression).

Patients with complicated nephrolithiasis or pyelonephritis require urgent urologic evaluation.

Follow-Up

- Acute kidney injury
 - Monitor serum electrolytes, BUN and Cr
 - After these normalize, perform routine follow-up
- Acute interstitial nephritis
 - Avoid offending medications
- Chronic kidney disease
 - Follow blood pressure closely
 - If hypertensive, consider an ACEI or ARB as first-line medication, as above
 - Target blood pressure is <130/80 mm Hg
 - If evidence of nephropathy, target blood pressure is <125/75 mm Hg
- For patients with diabetes, optimize blood glucose control
- Address other risk factors for cardiovascular disease (see chapter *Coronary Heart Disease Risk*)
 - Dyslipidemia
 - Cigarette smoking
 - Obesity
 - Physical inactivity
- Monitor serum electrolytes, BUN, Cr, and hemoglobin
- Risk of secondary hyperparathyroidism:
 - Serum calcium <9.5 mg/dL
 - Parathyroid hormone level >35 pg/mL
 - Management:
 - Low-phosphate diet
 - Phosphate binders with meals
 - Vitamin D supplement

- Anemia
 - Consider recombinant human erythropoietin and iron supplement (consult with a nephrologist)
 - Target hemoglobin 11-12 g/dL
- Avoid nephrotoxins, if possible
- Adjust medication dosages based on renal function (eGFR); see below

Patients with severe or chronic renal disease should be referred to Nephrology for further evaluation and assistance with the following:

- Management
- Education
- Evaluation for renal replacement therapy
 - Peritoneal dialysis
 - Hemodialysis
- Kidney transplant evaluation

Medication Dosage Adjustment

Dosages of many medications, including most nucleoside analogues (NRTIs), must be adjusted for patients with CKD, and for those on hemodialysis; see Table 3, below.

Table 3. Dosing of Antiretroviral Drugs in Adults with Chronic Kidney Disease and Hemodialysis

Drug	Standard Dosage	Dosing in Chronic Kidney Disease and Hemodialysis		
Abacavir	300 mg PO BID	Dosage adjustment for CKD does not appear necessary		
Didanosine (enteric-coated capsules)	250 mg to 400 mg PO QD, depending on weight	CrCl (mL/min)	Weight ≥60 kg	Weight <60 kg
		≥60	400 mg QD	250 mg QD
		30-59	200 mg QD	125 mg QD
		10-29	125 mg QD	125 mg QD
		<10	125 mg QD	Formulation not suitable
		HD	125 mg QD	Formulation not suitable
Emtricitabine	200 mg PO QD	CrCl (mL/min)		
		≥50	200 mg QD	
		30-49	200 mg Q48H	
		15-29	200 mg Q72H	
		<15	200 mg Q96H	
		HD	200 mg Q96H, take after dialysis	
Lamivudine 150 mg PO BID or 300 mg PO QD	150 mg PO BID or 300 mg PO QD	CrCl (mL/min)		
		≥50	150 mg BID or 300 mg QD	
		30-49	150 mg QD	
		15-29	150 mg first dose, then 100 mg QD	
		5-14	150 mg first dose, then 50 mg QD	
		<5	50 mg first dose, then 25 mg QD	
		HD	50 mg first dose, then 25 mg QD, take after dialysis	
Stavudine	20 mg to 40 mg PO BID, depending on weight	CrCl (mL/min)	Weight ≥60 kg	Weight <60 kg
		>50	40 mg BID	30 mg BID
		26-50	20 mg BID	15 mg BID
		10-25	20 mg QD	15 mg QD
		HD	20 mg QD, take after dialysis	15 mg QD, take after dialysis

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Drug	Standard Dosage	Dosing in Chronic Kidney Disease and Hemodialysis	
Tenofovir	300 mg PO QD	Experience in patients with CrCl <60 mL/min is limited.	
		CrCl (mL/min)	
		≥50	300 mg QD
		30-49	300 mg Q48H
		10-29	300 mg BIW (i.e., Q 3-4 days)
		<10	Not recommended
Zidovudine	300 mg PO BID	HD	300 mg once weekly, after dialysis
		CrCl (mL/min)	
		<15	100 mg TID (or 300 mg QD)
		HD	100 mg TID (or 300 mg QD); take after dialysis

Fixed-Dose Combinations

Drug	Standard Dosage	Dosing in Chronic Kidney Disease and Hemodialysis	
Atripla (efavirenz/tenofovir/emtricitabine)	1 tab PO QHS	Substitute component drugs, adjusting dosage of each drug for CrCl	
Combivir (zidovudine/lamivudine)	1 tab PO BID	Substitute component drugs, adjusting dosage of each drug for CrCl	
Complera (rilpivirine/tenofovir/emtricitabine)	1 tab PO QD	Substitute component drugs, adjusting dosage of each drug for CrCl	
Epzicom or Kivexa (abacavir/lamivudine)	1 tab PO QD	Substitute component drugs, adjusting dosage of each drug for CrCl	
Trizivir (zidovudine/abacavir/lamivudine)	1 tab PO BID	Substitute component drugs, adjusting dosage of each drug for CrCl	
Stribild (elvitegravir/cobicistat/tenofovir/emtricitabine)	1 tab PO QD	Do not initiate if CrCl <70 mg/mL; discontinue if CrCl <50 mg/mL	
Truvada (emtricitabine/tenofovir)	1 tab PO QD	CrCl (mL/min)	
		≥50	1 tablet QD
		30-49	1 tablet Q48H
		<30	Substitute component drugs, adjusting dosage of each drug for CrCl

Abbreviations: CrCl = creatinine clearance; HD = hemodialysis

Adapted from McNicholl I, Rodriguez R. *Dosing of Antiretroviral Drugs in Adults with Chronic Kidney Disease and Hemodialysis*. In: HIV InSite, Coffey S, Volberding P, eds. San Francisco: UCSF Center for HIV Information. Available at hivinsite.ucsf.edu/InSite?page=md-rr-18. Accessed December 1, 2013.

Protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs) do not appear to require dosage adjustment in persons with CKD. Some PIs and NNRTIs, however, do require changes in dosing strategy for patients on hemodialysis. (It should be noted that most PIs have not been studied in the setting of hemodialysis.) The CCR5 antagonist maraviroc should not be used for certain patients with CKD. Available recommendations for hemodialysis patients include the following:

Atazanavir

- Unboosted atazanavir should not be used.
- Treatment-naïve patients: atazanavir must be boosted by ritonavir.
- Treatment-experienced patients: atazanavir (boosted or unboosted) is not recommended.

Lopinavir/ritonavir

- QD dosing should not be used.
- In patients with PI resistance, lopinavir/ritonavir levels may be subtherapeutic.

Maraviroc

- CrCl <30 mL/min or on HD: not recommended with potent CYP3A inhibitors or inducers. Without potent CYP3A inhibitors or inducers: 300 mg BID (150 mg BID if postural hypotension occurs).

Nevirapine

- An additional dose (200 mg) should be given after each dialysis session.

Patient Education

- Early diagnosis of kidney disease is important. Acute kidney injury usually is reversible but may take time and may require temporary hemodialysis support.
- Advise patients to report all the medications they take, including over-the-counter medications and herbs or supplements.
- Risk factors for kidney disease are uncontrolled HIV infection (viral load above 4,000 copies/mL and CD4 count <200 cells/ μ L), coexisting conditions (diabetes mellitus, hypertension, hepatitis C), and ethnicity (African-Americans, Hispanic Americans, Asians, Pacific Islanders, and American Indians). Advise patients that it is important to reduce any modifiable risks, including optimizing HIV control and diabetes mellitus or hypertension management.
- Advise patients that control of blood pressure is important in slowing the progression of renal disease. Hypertension control can be maximized by both lifestyle modifications (e.g., weight lost, exercise, avoiding excessive alcohol intake) and antihypertensive medications. ACEIs or ARBs are the drugs of choice for patients with hypertension and kidney disease. Target blood pressure is <125/75 mm Hg for patients with proteinuric kidney disease.
- Educate patients that management of chronic kidney disease helps avoid or control complications such as high blood pressure, weak bones (osteodystrophy), anemia, and nerve damage (neuropathy).
- When the kidney disease progresses to end-stage renal disease, several options can be explored. These are dialysis, kidney transplant, or palliative care. There are two modes of dialysis, hemodialysis and peritoneal dialysis. A nephrologist and the patient can decide which option is best. HIV control (suppressed viral load, optimal CD4) is required if kidney transplant is to be considered.

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Immune Reconstitution Inflammatory Syndrome

Background

For most patients, initiating antiretroviral therapy (ART) improves immune responses to a wide range of opportunistic pathogens. The process of ART-induced immune reconstitution typically is uneventful. However, a small percentage of patients develop inflammatory disease in response to specific opportunistic pathogens within a few weeks or months after initiating therapy. This exuberant inflammatory response has been called the immune reconstitution inflammatory syndrome (IRIS), also known as immune reconstitution syndrome (IRS) or immune reconstitution disease (IRD).

The term IRIS is used to describe two distinct entities:

- An exacerbation of a partially or successfully treated opportunistic infection (OI), referred to as paradoxical IRIS
- An inflammatory response to a previously undiagnosed (subclinical) OI, often more pronounced than the typical presentation of this OI, referred to as unmasking IRIS

IRIS may occur in response to many pathogens. IRIS commonly occurs in association with *Mycobacterium tuberculosis*, *Mycobacterium avium* complex (MAC), cytomegalovirus (CMV), and *Cryptococcus*, and it may occur with *Pneumocystis*, *Toxoplasma*, hepatitis B and C, human herpes virus 8 (HHV-8, which causes Kaposi sarcoma), and JC virus (which causes progressive multifocal leukoencephalopathy, PML).

Risk factors for development of paradoxical IRIS include low CD4 cell count (particularly <50 cells/ μ L) at time of ART initiation and high baseline HIV RNA. Starting ART in close proximity to initiation of treatment for a recognized OI also increases the risk of IRIS, though data also show that earlier ART initiation tends to reduce mortality and AIDS progression, particularly in persons with advanced immunosuppression (see “Timing of ART initiation,” below).

Paradoxical IRIS also can occur in the absence of ART, as has been reported during tuberculosis (TB) treatment. The specific mechanisms involved in the pathogenesis of IRIS are not well understood and may vary from one infection to another. However, experts believe that IRIS is caused by an enhanced and dysregulated immune response to disease-specific antigens, which leads to an overproduction of inflammatory mediators.

IRIS may be difficult to identify in clinical practice because the clinical presentation is nonspecific and, currently, there are no laboratory markers to identify the syndrome. To make the diagnosis of IRIS, the following must be excluded:

- Presence of a new OI or concomitant illness
- Failure of treatment for a known OI (e.g., owing to drug resistance, inadequate treatment, or poor adherence)
- Failure of treatment for HIV infection (e.g., owing to poor adherence or drug resistance)

The severity of IRIS varies widely, from mild to life-threatening. Treatment varies according to the specific pathogen and clinical situation, but typically includes continuing ART if possible, treating the OI as indicated, and adding antiinflammatory therapy (including corticosteroids) as needed.

Clinical Presentation

IRIS is largely a clinical diagnosis, and other conditions must be excluded, as indicated above. To consider IRIS in the differential diagnosis, clinicians must recognize the clinical findings (typical or atypical) of a specific OI and the temporal association with treatment (usually after ART initiation, but IRIS may occur with treatment of the OI alone). For example, for a patient with TB who has recently initiated ART after responding to treatment of TB, the “red flags” for a diagnosis of IRIS (rather than progression of the TB) would include new or worsening fever, new effusions, and new or worsening lymphadenopathy, in the absence of poor adherence to TB treatment or drug-resistant TB.

The clinical manifestations of IRIS associated with some common OIs are described below. (This is not an exhaustive list, but it includes most of the important IRIS manifestations seen in patients with HIV infection.)

Tuberculosis

The signs and symptoms of TB IRIS may include various clinical or radiologic features (e.g., new or worsening enlarged lymph nodes, fevers, weight loss, pulmonary symptoms, and radiographic features of TB such as infiltrates and pleural effusions). Nonpulmonary presentations may include expanding central nervous system (CNS) deficits or lesions, lymphadenopathy (mediastinal or peripheral), ascites, pericardial effusions, skin or visceral abscesses, bone lesions, and hypercalcemia. In a patient who is receiving therapy for active TB, the onset of TB IRIS typically occurs within weeks to several months after the patient begins ART and is more common among patients with low CD4 cell counts at the time of ART initiation (see chapter *Mycobacterium tuberculosis*).

Mycobacterium avium Complex

Lymphadenitis and fever are the characteristic symptoms of MAC IRIS, but pulmonary symptoms, abdominal pain, bone and hepatic involvement, and CNS manifestations may develop. Signs and symptoms of MAC IRIS may be clinically indistinguishable from active MAC. In contrast to disseminated MAC, MAC IRIS is associated with a rapid and striking increase in CD4 count (usually from <50 cells/ μ L to ≥ 100 cells/ μ L), and MAC bacteremia usually is absent. MAC IRIS can be mild and localized or it can be severe, requiring systemic antiinflammatory therapy (sometimes for long periods), in addition to anti-MAC therapy.

Cytomegalovirus

CMV IRIS is usually localized to the eye, as described below. However, CMV IRIS will rarely present with extraocular disease such as colitis, pancreatitis, or pneumonitis.

CMV retinitis

CMV retinitis may occur in patients with a history of CMV retinitis or in patients with no previous evidence of retinitis. In those with a previous diagnosis of CMV retinitis, a new opacified retinal lesion develops, frequently at the site of an earlier lesion. CMV retinitis IRIS is identical to active CMV retinitis on ophthalmologic examination. Clinical information, therefore, will guide the diagnosis, and patients should be monitored closely. As with other IRIS reactions, symptoms often are associated temporally with initiation of ART.

In order to initiate appropriate treatment, and to avoid IRIS, an ophthalmic examination to assess for the presence of CMV retinal infection should be performed for all patients with CD4 cell counts of <50 cells/ μ L), preferably prior to the initiation of ART. This is particularly important for patients who report visual symptoms such as floaters or abnormal vision.

For patients who experience IRIS after being adequately treated for CMV retinitis, serial ophthalmologic examinations will reveal that the lesions clear without a new or different therapy for CMV. This clinical picture differs from that of retinal lesions caused by active CMV infection and uncontrolled CMV replication, in which lesions will increase in size or new lesions will appear, if appropriate CMV therapy has not been introduced (see chapter *Cytomegalovirus Disease*).

CMV vitreitis and CMV uveitis

CMV vitreitis and CMV uveitis are seen exclusively in patients with previous CMV retinitis infection who responded to ART.

CMV vitreitis

CMV vitreitis IRIS is an alarming syndrome, but a benign one. Patients who are receiving anti-CMV therapy typically present with acute onset of blurred vision and “floaters” caused by posterior segment inflammation. Ophthalmologic examination reveals numerous inflammatory cells in the vitreous humor. Symptoms usually resolve in 1 month without specific treatment and without any lasting visual effects.

CMV uveitis

In patients with a history of CMV retinitis, CMV uveitis IRIS may occur within months of ART initiation, but typically is a late complication, occurring about 3 years after patients begin ART. Uveitis is painless and primarily involves inflammation in the iris, the ciliary body, and the choroid layers. However, CMV uveitis may have serious sequelae. It often results in macular edema, epiretinal membrane formation, or cataracts, which can lead to permanent vision loss. Because of the risk of vision loss, clinicians should have a high index of suspicion for CMV uveitis.

Cryptococcal Meningitis

In patients with or without previously diagnosed cryptococcal meningitis, presentation of cryptococcal IRIS typically includes fever, headache, eye pain, and photophobia, and may include meningeal signs. In cryptococcal IRIS, analysis of cerebrospinal fluid (CSF) is characterized by high opening pressure and, unlike initial presentation of cryptococcal meningitis, an elevated white blood cell count and sterile fungal cultures. Onset has been reported between 1 week and 11 months after initiation of ART. Lymphadenitis, pulmonary disease, and cutaneous involvement also have been reported (see chapter *Cryptococcal Disease*).

Pneumocystis jiroveci Pneumonia

Pneumocystis jiroveci pneumonia (PCP) IRIS may occur in patients with current or recent PCP who are starting ART in the early weeks after initiation of PCP treatment. IRIS may present as worsening pulmonary symptoms (typically after corticosteroids given for the initial PCP treatment have been tapered or discontinued) and high fever in patients who had been improving on PCP therapy or in patients with recent successful treatment of PCP. Chest X-rays may show worsening lung involvement, and oxygen saturation or arterial blood gas measurements may show worsening hypoxia or alveolar-arterial oxygen gradient. PCP IRIS sometimes causes severe acute respiratory failure (see chapter *Pneumocystis Pneumonia*).

S: Subjective

Symptoms of IRIS will vary according to the specific illness.

Include the following in the history:

- Specific symptoms and time course of symptoms
- History of OIs, including recently diagnosed OIs
- Treatment of OIs, including date of initiation, medication adherence, duration of therapy, and clinical response
- ART initiation date, specific antiretroviral regimen, medication adherence, and previous history of ART
- CD4 cell count and HIV viral load before ART initiation
- Current CD4 cell count and HIV viral load, if known
- Other medications, especially new medications, including over-the-counter and herbal preparations

O: Objective

Obtain vital signs, including temperature, heart rate, blood pressure, respiratory rate, and oxygen saturation.

Perform a thorough physical examination based on symptoms and suspicion of systems involved.

A: Assessment

In the appropriate clinical setting (especially in patients with advanced AIDS who recently initiated ART), IRIS should be considered in the differential diagnosis of patients who present with new or worsening symptoms. In these patients, the differential is broad, and causes other than IRIS should be considered carefully, including:

- Worsening or progression of a known OI despite treatment (e.g., owing to drug resistance or inadequate therapy)
- A new infection or illness
- Drug toxicity (e.g., hypersensitivity reaction)
- Failure of ART; progression of AIDS

Perform the appropriate diagnostic tests to exclude other etiologies. Consider consulting with an HIV specialist if the diagnosis is in question.

P: Plan**Diagnostic Evaluation**

It is important to rule out new, incompletely treated, or untreated infections; malignancy; and other illnesses before concluding the patient has IRIS.

The workup of the patient with possible IRIS will depend on the specific clinical presentation. Perform laboratory tests, blood cultures, and other diagnostic tests as appropriate for the individual patient. These may include the following:

- Complete blood count (CBC) with differential, electrolytes and creatinine, liver function tests
- CD4 cell count and HIV viral load
- Blood cultures for bacteria, acid-fast bacteria (MAC), fungi
- Chest X-ray; other radiographic studies
- Sputum stain and culture

- Biopsy or culture of skin or other lesions
- Lumbar puncture and cerebrospinal fluid studies, if a CNS process is suspected
- Ophthalmologic examination
- Drug resistance testing for the OI being treated, if indicated

Treatment

Prevention and treatment recommendations from randomized prospective trials are lacking for most IRIS syndromes. However, the majority of cases of IRIS reported in the medical literature are not life-threatening and appear to have resolved within a matter of weeks to months with the following:

- Continuing the current ART regimen (unless the clinical presentation is life-threatening)
- Treating any newly identified, untreated OI
- If indicated, administering antiinflammatory medications to suppress the inflammatory process (prednisone was shown in one study to decrease hospital days and improve symptoms in TB IRIS in sub-Saharan Africa; anecdotal data support the use of nonsteroidal antiinflammatory drugs in mild-to-moderate IRIS)

For patients with recent OIs that resolved with a full course of appropriate therapy, it is not always necessary to resume antimicrobial therapy or to change maintenance therapy. For example, if a patient with TB IRIS has finished a full course of treatment for TB, repeat treatment is not indicated, once recurrent TB infection has been ruled out. If a patient with previously treated cryptococcal meningitis is receiving maintenance therapy and IRIS develops, the therapy does not need to be altered. However, if IRIS reveals a new, untreated OI, that infection should be treated appropriately. For instance, if new cryptococcal meningitis presents as IRIS, the cryptococcus should be treated as indicated. If treatment is in question, consult with an HIV specialist.

Timing of ART initiation

The risk of IRIS is highest for patients who start ART with low CD4 counts (<50-100 cells/ μ L) and those for whom ART is initiated soon after OI treatment is begun. The optimal time for ART initiation in the setting of some OIs is not known, but increasing evidence, including from randomized controlled trials, suggests a mortality benefit to early ART initiation in patients with a variety of newly diagnosed OIs. For patients with TB and HIV infection, for example, data from three randomized studies show reductions in mortality and/or AIDS progression with early initiation of ART, though the urgency of ART varied with CD4 count: for those with CD4 counts of <50 cells/ μ L, benefit was seen if ART was initiated within 2 weeks of TB treatment start (compared with delaying until week 8-12 of TB treatment). For those with CD4 counts of 50-200 cells/ μ L, data support ART initiation between 2 weeks and 2 months after the start of TB treatment. ART should not be deferred until after TB treatment for any patient, regardless of the CD4 cell count. In TB meningitis, however, the optimal ART start time is not clear; in one study, immediate ART increased the risk severe adverse effects and death. In cryptococcal meningitis, data about timing of ART initiation are conflicting; many experts advise delaying ART until 2-10 weeks after the start of cryptococcus treatment.

Decisions about the timing of ART initiation may depend on a number of variables, including the specific pathogen, the severity of the OI, whether the CNS is involved (IRIS in the CNS may be life-threatening), the medication burden, and the potential for drug toxicity or drug interactions. In most cases, ART initiation should be considered within 1-2 weeks after initiation of OI therapy, particularly in patients with TB and CD4 counts of <50 cells/ μ L. For patients with TB meningitis, cryptococcal meningitis, or other CNS or ocular infections, many specialists

would recommend delaying ART until they have received appropriate OI treatment for at least 2 weeks. For decisions about initiating ART in patients with active OIs, consult with an HIV specialist.

IRIS in resource-limited settings

As access to ART improves in resource-limited countries, IRIS increasingly is being recognized in patients receiving ART. Clinicians should include IRIS in the differential diagnosis when evaluating patients who recently have begun ART and present with new or worsening symptoms of an OI. However, limited diagnostic testing resources may make it difficult to establish IRIS and other diagnoses.

Given that coinfection with HIV and TB is epidemic in many countries, and because IRIS is not uncommon in patients with TB, clinicians should be particularly vigilant about symptoms that may signal IRIS. As in resource-sufficient countries, consultation with a clinician trained in caring for patients with HIV is recommended if diagnosis or treatment is in question.

Patient Education

- Patients starting ART who have CD4 counts of <100 cells/ μ L or known concomitant OIs should be counseled about the likelihood of IRIS.
- All patients starting ART should be advised to contact the clinic promptly if they experience new or worsening symptoms.
- Advise patients to take their medications for HIV and for the treatment or prevention of OIs exactly as prescribed.

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Anal Dysplasia

Background

Anal cancer is a squamous cell cancer associated with human papillomavirus (HPV), the same virus that is associated with cervical cancer (see chapter *Cervical Dysplasia*). The anal canal and cervical canal share a common embryologic origin: both have a squamocolumnar transition zone and are prone to infection with HPV, a sexually transmitted virus. HPV infection, in combination with cofactors, may stimulate dysplastic changes in the cervix or anus that may develop through precursor stages into squamous cell cancer. In the United States, the incidence of anal cancer in the general population is approximately 1:100,000 per year. In HIV-infected men and women, the incidence of anal cancer and the prevalence of its precursors are significantly higher than in the general population. Advanced immunosuppression, as demonstrated by lower CD4 cell counts, appears to increase the risk of anal intraepithelial neoplasia (AIN), a precursor to cancer, and anal cancer.

Rates of anal cancer also are higher among men who have sex with men (MSM), whether HIV infected or uninfected, compared with the general population. Current rates in an HIV-infected MSM population have been estimated to be as high as 70-144 per 100,000. Although most studies have examined anal dysplasia and cancer in MSM, its prevalence also is high among HIV-infected women and heterosexual men. Some studies of HIV-infected individuals have shown that anal HPV infection is present in 93% of MSM and 76% of women, and that anal dysplasia (any grade) is present in 56% of MSM and 26% of women. In some studies of HIV-infected women, anal dysplasia has been seen more frequently than cervical dysplasia, and it has not been exclusive to those with behavioral risk factors (e.g., history of receptive anal intercourse). HIV-infected heterosexual men with no history of receptive anal intercourse also have elevated risks of anal HPV infection. Thus, although receptive anal intercourse may increase the likelihood of anal HPV infection, it is not a prerequisite for anal HPV or dysplasia.

Screening strategies for anal dysplasia and cancer and the optimal management of abnormal test results are areas in which questions remain unanswered. The rationale for screening for anal cancer and its precursors is based on the success of cervical Papanicolaou (Pap) screening in reducing cervical cancer incidence and mortality. Because of the similarities between cervical and anal dysplasia, many experts postulate that many of the paradigms of managing cervical cytologic abnormalities may be translated to management of anal dysplasia. However, there are no randomized clinical trials that document the value of screening for anal precancers.

Current guidelines from the HIV Medicine Association of the Infectious Diseases Society of America recommend anal pap tests for MSM, women with a history of abnormal cervical Pap tests or a history of anal receptive sex, and all HIV-infected persons with genital warts, though they do not specify screening intervals. The New York State Department of Health AIDS Institute recommends that an anal Pap test be done at baseline and annually thereafter for MSM, patients with a history of anogenital warts, and women with abnormal cervical or vulvar histology, and many HIV clinics elsewhere do routine screening. Further investigations are ongoing to define appropriate screening intervals, diagnostic approaches, indications for therapy, and modalities of treatment.

ART and subsequent immune reconstitution does not appear to alter the prevalence or distribution of anal cancers and anorectal disease nor does it appear to reduce the progression of AIN and other cancer precursors.

For information on prevention of HPV infection, see “Prevention,” below.

S: Subjective

Patients with anal dysplasia usually are asymptomatic, and the condition cannot be identified without screening tests. Exophytic anal condylomata may cause itching, discomfort, or bleeding, but are usually associated with low-risk phenotypes of HPV and low-grade dysplasia (note, however, that oncogenic HPV types also may be present). Anal cancer may cause nonspecific symptoms such as pain (with defecation or after intercourse), itching, bleeding, or sensation of a rectal mass.

Risk factors for anal dysplasia and cancers include the following:

- HIV infection
- CD4 count of <200 cells/μL
- RAI
- HPV infection
- Genital warts (or history of genital warts)
- Immunosuppression
- High-grade cervical or vulvar dysplasia
- Cigarette smoking
- Multiple sex partners

Ask patients about these risk factors, about previous history of anal dysplasia or cancer, and about previous screening.

O: Objective

Examine the genital and perianal region, and perform a digital anorectal examination. Look and feel for masses, condylomata, and other abnormalities such as hypo- or hyperpigmented plaques or lesions, and lesions that bleed. Note that simple visual examination may not reveal abnormalities. In women, also examine the vulva, vagina, and cervix. Examine the inguinal lymph nodes.

If the digital examination is performed in conjunction with an anal Pap test, the Pap specimen should be obtained before the

introduction of lubrication.

Anoscopic examination with the naked eye may not reveal any abnormality because dysplastic tissue tends to be flat and difficult to differentiate from normal anal tissue; application of 3% acetic acid is required (see below for a description of how high-resolution anoscopy [HRA] is performed).

A: Assessment

HIV-infected individuals with anal dysplasia have an increased risk of progression to anal cancer. If the history or physical examination reveals abnormalities suggestive of anal dysplasia or anal cancer, an appropriate evaluation should be undertaken. Because most patients with anal dysplasia have no symptoms, anal cancer screening using a Pap test can be considered if follow-up evaluation of an abnormal cytologic result (ASCUS or higher, see Bethesda 2001 grading system, below) by high-resolution anoscopy is available either on-site or by referral.

P: Plan Screening

As mentioned above, some organizations and many experts recommend that anal Pap tests and digital anal examination be part of the initial evaluation of both male and female HIV-infected patients. The intervals for screening have not been established, but (based on recommendations for cervical cancer screening) if the first test result is normal, the anal Pap usually is repeated in approximately 6 months. If both results are normal, then anal Pap tests can be performed annually. Some clinicians would consider more frequent screening in patients with genital warts, cervical dysplasia, or a history of treatment for anal dysplasia. Any patients with positive results should be referred for further evaluation; see below.

An anal Pap test is done using a standard Pap

kit. The swab or cytobrush should be inserted into the anal canal, past the anorectal junction, and withdrawn while rotating it against the anal walls to collect cells. The sample should then be handled according to the kit manufacturer's instructions. (See "References," below, for information about a video on how to conduct an anal Pap screen that is available from the Johns Hopkins University Local Performance Site of the Pennsylvania/MidAtlantic AIDS Education and Training Center.)

As with cervical cytology, anal cytology is graded using the Bethesda 2001 system, which categorizes disease in increasing order of severity as follows:

- Negative for intraepithelial lesion or malignancy
- Atypical squamous cells of undetermined significance (ASCUS)
- Atypical squamous cells – cannot exclude HSIL (ASC-H)
- Low-grade squamous intraepithelial lesion (LSIL)
- High-grade squamous intraepithelial lesion (HSIL)
- Squamous cell carcinoma (SCC)

Other abnormalities, such as atypical glandular cells (AGC), may be noted.

All individuals with abnormal anal cytology, defined as ASCUS or higher, should be referred for HRA and biopsy to grade the lesion. HRA typically is performed at specialty anal cancer practices or clinics, colorectal surgery and gastrointestinal specialty facilities, and some academic medical centers.

There currently are no recommendations concerning HPV testing of anal specimens.

Evaluation of Cytologic Abnormalities

HRA of the anal canal should be performed using a colposcope for magnification (16x) and the application of 3% acetic acid with or without Lugol iodine solution to aid in visualization of dysplastic lesions. Abnormal

areas should be examined by biopsy. Anoscopic features of high-grade disease are similar to those seen in the cervix; these include coarse punctation, mosaicism, and the presence of ring glands.

Treatment

The goal of treatment is to prevent progression to anal cancer. Treatment of HSIL to prevent anal cancer is biologically plausible, following the model of cervical dysplasia treatment. However, the indications for treatment of anal dysplasia, the efficacy of treatment, and the most effective treatments have not been optimally defined.

The focus of treatment is on high-grade, premalignant AIN. Patients should be referred to an anal dysplasia specialist specialty clinic, if possible. Specific treatment may vary depending on the size, location, extent of the lesions, and histological grade. Therapies include topical 5-fluorouracil, cryotherapy, infrared coagulation, laser therapy, and surgical excision. Infrared coagulation, an in-office procedure, has been shown to be effective in treating HIV-infected patients with high-grade dysplasia. With some therapies, treatment-associated pain and other complications may occur, and recurrence of dysplastic lesions is common.

LSIL is not considered premalignant, but it frequently progresses to high-grade dysplasia. Some specialists do not treat LSIL but monitor regularly instead with HRA, whereas others choose to treat LSIL to prevent progression.

Prevention

Prevention of HPV infection can be challenging. Latex or plastic barriers may block transmission of HPV in areas covered by these barriers and their use is recommended to prevent transmission or acquisition of HPV (as well as HIV and other sexually transmitted diseases). However, infection may occur through bodily contact outside the area covered by the barriers.

A quadrivalent HPV vaccine against certain oncogenic (types 16 and 18) and wart-causing (types 6 and 11) types of HPV is FDA approved for prevention of anal dysplasia and anal cancer caused by the covered types in males and females 9-26 years of age, and for prevention of genital warts, its use is recommended. (The quadrivalent vaccine also is approved for prevention of cervical cancer and cervical, vaginal, and vulvar dysplasia). A second vaccine against HPV types 16 and 18 has been approved for females (see chapter *Cervical Dysplasia*).

The vaccine is not effective against HPV types other than those covered by the vaccine, and it may not be protective against a covered type to which a patient has been exposed previously. For optimal protection, the vaccine should be given before the individual is exposed to HPV through sexual activity. It is likely to be less effective in older adolescents and adults who may already have been infected with one or more of the covered HPV types. There are few data on the use of the vaccines in persons older than 26 years, and they are not approved for this group. Importantly, vaccination does not offer perfect protection from all oncogenic HPV viruses, so consideration should be given to screening individuals who have been vaccinated in the same way as unvaccinated individuals, as described above.

Patient Education

- All HIV-infected men and women should be encouraged to use condoms during vaginal, anal, and oral sex to prevent the spread of HPV. However, condoms do not offer complete protection from HPV.
- All patients should be counseled on how to reduce or avoid unprotected anal receptive intercourse.
- Both women and men who are HIV infected have an increased risk of developing anal dysplasia and cancer. MSM are at higher risk than other men of developing anal dysplasia.
- Emphasize the importance of keeping follow-up appointments to allow for early detection of precancerous lesions, further grading of abnormalities by HRA, and appropriate monitoring and treatment of abnormalities.
- Patients who have anal dysplasia should be informed about anal cancer symptoms, such as new-onset anal pain, bleeding, or the development of a mass. Patients should call their health care provider if these symptoms develop.
- If an anal Pap test is to be performed, advise patients to avoid having anal sex, douching, or using enemas before the test.

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- A video titled *Anal Pap Smear: A Simple, Fast and Easy Procedure* is available on CD-ROM at-cost to health care professionals (\$12.00 for 1-4 copies) by calling the Johns Hopkins University Local Performance Site of the Pennsylvania Mid/Atlantic AIDS Education and Training Center to order: 888-333-2855 (toll free) or by downloading the order form on the AETC NRC website. Available at aidsctc.org/aetc?page=etres-display&resource=etres-229. Accessed December 1, 2013.

Candidiasis, Oral and Esophageal

Background

Oropharyngeal candidiasis (“thrush”), a fungal disease of the oral mucosa and tongue, is the most common intraoral lesion among persons infected with HIV. In the absence of other known causes of immunosuppression, oral thrush in an adult is highly suggestive of HIV infection. Although thrush in the absence of esophageal disease is not an AIDS-defining condition, it usually occurs with CD4 counts of <200 cells/ μL . Three clinical presentations of thrush are common in people with HIV: pseudomembranous, erythematous, and angular cheilitis. *Candida* also may infect the esophagus in the form of esophageal candidiasis, which causes dysphagia (difficulty with swallowing) or odynophagia (pain with swallowing). Esophageal candidiasis is an AIDS-defining condition, generally occurring in individuals with CD4 counts of <200 cells/ μL . It is the most common cause of esophageal infection in persons with AIDS.

Oropharyngeal and esophageal candidiasis are caused most commonly by *Candida albicans*, although non-*albicans* species increasingly may cause disease and may be resistant to first-line therapies.

S: Subjective

Oropharyngeal Candidiasis

The patient may complain of painless white patches on the tongue and oral mucosa, smooth red areas on the dorsal tongue, burning or painful areas in the mouth, a bad or unusual taste, sensitivity to spicy foods, or decreased appetite.

Esophageal Candidiasis

The patient complains of difficulty or pain with swallowing, or the sensation that food is “sticking” in the retrosternal chest. Weight loss is common, and nausea and vomiting may occur. Fever is not common with candidal esophagitis and suggests another cause. The patient may note symptoms of oral candidiasis (as above).

O: Objective

Perform a thorough oropharyngeal examination. Patients presenting with oral candidiasis may be totally asymptomatic, so it is important to inspect the oral cavity thoroughly. Patients with esophageal

candidiasis usually have oral thrush and often experience weight loss.

Lesions can occur anywhere on the hard and soft palates, under the tongue, on the buccal mucosa or gums, or in the posterior pharynx.

Pseudomembranous oral candidiasis appears as creamy white, curdlike plaques on the buccal mucosa, tongue, and other mucosal surfaces. Typically, the plaques can be wiped away, leaving a red or bleeding underlying surface. Lesions may be as small as 1-2 mm, or they may form extensive plaques that cover the entire hard palate.

Erythematous oral candidiasis presents as one or more flat, red, subtle lesions on the dorsal surface of the tongue or the hard or soft palate. The dorsum of the tongue may show loss of filiform papillae.

Angular cheilitis causes fissuring and redness at one or both corners of the mouth and may appear alone or in conjunction with another form of oral *Candida* infection.

A: Assessment

A partial differential diagnosis for the two conditions is as follows:

Oropharyngeal Candidiasis

- Oral hairy leukoplakia
- Abrasion of the mucosa or a topical burn
- Bacterial gingivitis
- Periodontitis

Esophageal Candidiasis

- GERD
- Cytomegalovirus (CMV)
- Herpes simplex virus (HSV)
- Aphthous ulceration

P: Plan**Diagnostic Evaluation****Oropharyngeal candidiasis**

Clinical examination alone usually is diagnostic. If the diagnosis is unclear, organisms may be detected on smear or culture if necessary.

- On a potassium hydroxide (KOH) preparation of a smear collected by gentle scraping of the affected area with a wooden tongue depressor, visible hyphae or blastospheres on KOH mount indicate *Candida* infection.
- Culture is diagnostic and may detect non-*albicans* species in cases resistant to first-line therapies. Sensitivities also may be needed in such cases to diagnose azole-resistant infections.

Esophageal candidiasis

A presumptive diagnosis usually can be made with a recent onset of typical symptoms, especially in the presence of thrush, and empiric antifungal therapy may be started as a diagnostic trial. If the patient fails to improve clinically after 3-7 days of therapy, endoscopy should be performed for a definitive diagnosis.

Treatment**Treatment of oropharyngeal candidiasis**

- Oral therapy is convenient and very effective as first-line treatment. Note that azole antifungal drugs are not recommended for use during pregnancy. Topical therapy is less expensive, safe for use during pregnancy, and effective for mild to moderate disease. All therapies should be given for 7-14 days.
- Preferred oral therapy: Fluconazole 100 mg PO QD
- Preferred topical therapy:
 - Clotrimazole troches 10 mg dissolved in the mouth 5 times daily
 - Miconazole mucoadhesive tablet 50 mg PO QD
- Alternative oral therapy:
 - Itraconazole oral solution 200 mg PO QD
 - Posaconazole oral solution 400 mg PO BID for 1 day, then 400 mg PO QD (Note: These agents may present a greater risk of drug interactions (see “Potential ARV Interactions,” below) and hepatotoxicity than do fluconazole or topical treatments)
- Alternative topical therapy: Nystatin oral suspension 4-6 mL “swish and swallow” QID or 1-2 pastilles 4-5 times daily

Treatment of esophageal candidiasis

- Duration of therapy: 14-21 days
- Preferred therapy:
 - Fluconazole 100 mg PO (up to 400 mg) QD; IV therapy can be given if the patient is unable to swallow pills.
 - Itraconazole oral solution 200 mg PO QD
- Alternative therapy:
 - Voriconazole 200 mg PO or IV BID
 - Posaconazole 400 mg PO BID
 - IV therapy with an echinocandin

(caspofungin, micafungin, anidulafungin), or amphotericin, if the patient is unable to tolerate PO therapy (Note: Treatment with echinocandins is associated with a higher rate of relapse; see “Potential ARV Interactions,” below, regarding potential drug-drug interactions between voriconazole or posaconazole and ARVs)

Treatment of refractory candidiasis

Oral or esophageal candidiasis that does not improve after at least 7-14 days of appropriate antifungal therapy can be considered refractory to treatment. The primary risk factors for development of refractory candidiasis are CD4 counts of <50 cells/ μ L and prolonged, chronic antifungal therapy (especially with azoles). In such cases, it is important to confirm the diagnosis of candidiasis. As noted, other infections such as HSV, CMV, and aphthous ulcerations can cause similar symptoms. Once refractory candidiasis is confirmed, several treatment options are available, including the following:

- Posaconazole 400 mg PO BID
- Itraconazole oral solution ≥ 200 mg PO QD
- Voriconazole 200 mg PO or IV BID (see “Potential ARV Interactions,” below)
- Therapy with an echinocandin (caspofungin 50 mg QD; micafungin 150 mg QD; anidulafungin 100 mg for 1 dose, then 50 mg QD), or amphotericin B deoxycholate or lipid preparation
(Note: Treatment with echinocandins is associated with a higher rate of relapse. See “Potential ARV Interactions,” below, for information on potential drug interactions.)

The choice of treatment depends upon anticipated drug-drug interactions, the patient’s preferences and tolerability, availability of medications, and the provider’s experience. Consult with an HIV or infectious disease expert for advice about treatment regimens.

Maintenance therapy

Use caution when considering chronic maintenance therapy, because it has been associated with refractory and azole-resistant candidiasis, as noted above. Fluconazole 100 mg PO QD or TIW can be effective for patients who have had multiple or severe recurrences of oral disease (azole sensitive). Fluconazole 100-200 mg PO QD or posaconazole 400 mg PO BID (see “Potential ARV Interactions,” below) can be considered for patients who have had frequent or severe recurrent esophageal candidiasis.

There are no data to guide this decision; it is reasonable to discontinue maintenance therapy in patients who achieve immunologic responses on fully suppressive ART (i.e., with an increase in CD4 count to ≥ 200 cells/ μ L). Patients with fluconazole-refractory oropharyngeal or esophageal disease who respond to IV echinocandins are recommended to take posaconazole or voriconazole suppression until they achieve immune reconstitution on ART, because of high relapse rates.

Potential ARV Interactions

There may be significant drug-drug interactions between certain systemic antifungals (particularly itraconazole, voriconazole, and posaconazole) and ritonavir-boosted protease inhibitors (PIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), elvitegravir/cobicistat, or maraviroc. Some combinations are contraindicated and others require dosage adjustment of the ARV, the antifungal, or both. Check for adverse drug interactions before prescribing. For example, voriconazole use is not recommended for patients taking ritonavir-boosted PIs, and dosage adjustment of both voriconazole and NNRTIs may be required when voriconazole is used concurrently with NNRTIs. See relevant tables in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, or consult with an expert.

Patient Education

- Patients should maintain good oral hygiene by brushing teeth after each meal.
- A soft toothbrush should be used to avoid mouth trauma.
- Advise patients to rinse the mouth of all food before using lozenges or liquid medications.
- Tell patients to avoid foods or liquids that are very hot in temperature or very spicy.
- Patients who have candidiasis under a denture or partial denture should remove the prosthesis before using topical agents such as clotrimazole or nystatin. When not in use, the prosthesis should be stored in a chlorhexidine solution.
- Pregnant women and women who may become pregnant should avoid azole drugs (e.g., fluconazole, itraconazole, voriconazole) during pregnancy because they can cause skeletal and craniofacial abnormalities in infants.
- Patients should be informed of proper storage of oral solutions (e.g., refrigeration requirements).

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Candidiasis, Vulvovaginal

Background

Vulvovaginal candidiasis is a yeast infection caused by several types of *Candida*, typically *Candida albicans*. This disease is common in all women, but may occur more frequently and more severely in immunocompromised women.

Although refractory vaginal *Candida* infections by themselves should not be considered indicators of HIV infection, they may be the first clinical manifestation of HIV infection and can occur early in the course of disease (at CD4 counts of >500 cells/ μ L). The frequency of vaginal candidiasis tends to increase as CD4 counts decrease; however, this may be attributable in part to increased use of antibiotics among women with advanced HIV infection.

Risk factors for candidiasis include diabetes mellitus and the use of oral contraceptives, corticosteroids, or antibiotics.

S: Subjective

The patient may complain of itching, burning, or swelling of the labia and vulva; a thick white or yellowish vaginal discharge; painful intercourse; and pain and burning on urination.

The most important elements in the history include the following:

- Type and duration of symptoms
- Previous vaginal yeast infection
- Oral contraceptive use
- Recent or ongoing broad-spectrum antibiotic therapy
- Recent corticosteroid therapy
- Sexual exposures (to evaluate for sexually transmitted diseases)
- Diabetes history
- Cushing syndrome
- Obesity
- Hypothyroidism
- Pregnancy
- Use of douches, vaginal deodorants, or bath additives

O: Objective

Perform a focused physical examination of the external genitalia, vagina, and cervix. This may reveal inflammation of the vulva with evidence of discharge on the labial folds and vaginal opening. Speculum examination usually reveals a thick, white discharge with plaques adhering to the vaginal walls and cervix. Bimanual examination should not elicit pain or tenderness and otherwise should be normal.

A: Assessment

Rule out other causes of vaginal discharge and pruritus:

- Bacterial vaginosis
- Atrophic vaginitis
- Chemical or mechanical causes
- Trichomoniasis
- Gonorrhea, chlamydia, and other sexually transmitted diseases
- Scabies
- Pediculosis

P: Plan**Diagnostic Evaluation**

A presumptive diagnosis is made on the basis of the clinical presentation and potassium hydroxide (KOH) preparation:

- Perform microscopic examination of a KOH preparation of vaginal secretions. This usually reveals pseudohyphae and *Candida* spores (presumptive diagnosis).
- Definitive diagnosis rarely is needed, but may be made by analysis of a culture of vaginal secretions; this may be useful if azole-resistant or non-*albicans* species are suspected.
- In the presence of urinary tract symptoms (beyond external vulvar burning), perform urinalysis, culture, or both on a clean-catch urine specimen.
- Consider testing for gonorrhea and chlamydia in patients with a history of possible sexual exposure.

Treatment**Uncomplicated infections****Topical medications**

- Prescribe topical vaginal antifungal agents in the form of cream or suppositories, including the following: butoconazole, clotrimazole, miconazole, nystatin, terconazole, and tioconazole. Treat for 3-7 days and offer refills depending on the time to the next scheduled clinic visit. The creams also may be used on the vulva for treatment of pruritus.

Note that the mineral-oil base in topical vaginal antifungal preparations may erode the latex in condoms, diaphragms, and dental dams. Advise the patient to use alternative methods to prevent HIV transmission or conception, or to discontinue intercourse while using these medications. Nonlatex condoms (plastic and polyethylene only) or “female” condoms (polyurethane) can be used.

Oral medications**Preferred**

- Fluconazole 150 mg PO, single dose (see “Treatment notes,” below)

Alternative

- Itraconazole oral solution 200 mg PO QD for 3-7 days (see “Treatment notes,” below)

Complicated infections**Severe or recurrent candidiasis**

Severe or recurrent candidiasis is defined as four or more episodes within 1 year. Consider the following treatments:

- Fluconazole 100-200 mg PO QD for ≥ 7 days (see Treatment notes,” below)
- Topical therapy as described above, for ≥ 7 days

For severe cases that recur repeatedly, secondary prophylaxis can be considered (e.g., fluconazole 150 mg PO once weekly).

Treatment notes

- Systemic azole drugs should not be used during pregnancy, and women taking azoles should use effective contraception. Topical azoles are recommended for the treatment of pregnant women.
- Resistance to azole medications may develop, especially with prolonged use of oral agents.
- Avoid ketoconazole: Case reports have associated ketoconazole with a risk of fulminant hepatitis (1 in 12,000 courses of treatment with oral ketoconazole). Experts agree that the risks may outweigh the benefits for women with vulvovaginal candidiasis. Ketoconazole interacts with many other drugs, including some antiretroviral drugs.

Potential ARV Interactions

There may be significant drug-drug interactions between certain systemic antifungals (particularly itraconazole, voriconazole, and posaconazole) and ritonavir-boosted protease inhibitors (PIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), elvitegravir/cobicistat, or maraviroc. Some combinations are contraindicated and others require dosage adjustment of the ARV, the antifungal, or both. Check for adverse drug interactions before prescribing. For example, voriconazole use is not recommended for patients taking ritonavir-boosted PIs, and dosage adjustment of both voriconazole and NNRTIs may be required when voriconazole is used concurrently with NNRTIs. See relevant tables in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, or consult with an expert.

Patient Education

- Advise patients to wash external genitals daily with a fresh washcloth or water-soaked cotton balls and to wipe the vulva and perirectal area from front to back after toileting. Women should not use baby wipes on inflamed vulval tissue because they may increase irritation.
- Women should avoid the use of perfumed soaps, bubble baths, feminine hygiene or vaginal deodorant products, and bath powders.
- Advise women not to douche.
- Women should wear cotton underwear and avoid tight, constrictive clothing, particularly pantyhose.
- If patients are prescribed medication for vaginal candidiasis, they should take the medication exactly as prescribed and finish the medicine even during a menstrual period.
- Women who continue to have symptoms can purchase miconazole (e.g., Monistat) or clotrimazole (e.g., Gyne-Lotrimin) vaginal cream over the counter. Advise patients to start using these as soon as symptoms return and to contact the clinic if symptoms worsen while they are taking these medicines.
- Women taking oral fluconazole, ketoconazole, or other azoles must avoid pregnancy. Some birth defects have been reported.
- The mineral-oil base in topical vaginal antifungal preparations may erode the latex in condoms, diaphragms, and dental dams. Advise patients to use alternative methods to prevent HIV transmission or conception or to discontinue intercourse while using these medications. Nonlatex condoms (plastic and polyethylene only) or “female” condoms (polyurethane) can be used.
- Sex toys, douche nozzles, diaphragms, cervical caps, and other items can reinfect patients if not properly cleaned and thoroughly dried after use.
- Some studies have suggested that eating yogurt with live cultures (check labels) can reduce the occurrence of vaginal yeast infections.

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Cervical Dysplasia

Background

Precancerous lesions and cancer of the cervix are associated with human papillomavirus (HPV), a sexually transmitted virus. Carcinogenic strains of HPV, in conjunction with other factors, may cause dysplasia and cancer not only of the cervix, but also of the vulva, vagina, anus, and oropharynx. HIV-infected women have a higher prevalence of HPV infection than do HIV-uninfected women, and a higher prevalence of oncogenic HPV types. They are about 10 times more likely to develop cervical dysplasia, or intraepithelial neoplasia (CIN), precursors to cervical cancer. Unfortunately, they also have a higher risk of invasive cervical cancer and tend to have more aggressive forms of cervical cancer and poorer responses to treatment. Invasive cervical cancer is an AIDS-defining illness.

The risk of high-grade cervical lesions and cervical cancer appears to be higher for women with advanced immunodeficiency than for women with preserved CD4 cell counts. Other risk factors for dysplasia and cervical cancer include African-American ethnicity, a history of smoking, younger age at onset of sexual intercourse, and multiple sex partners. Effective antiretroviral therapy (ART) with immune reconstitution has not been shown to prevent the progression of CIN.

Screening for cervical cancer and appropriate intervention in women with high-grade CIN (CIN 3) are effective in preventing cervical cancer. Frequent monitoring and careful follow-up in women with low-grade lesions are essential for preventing progression to invasive disease. For all HIV-infected women (if they have had sex partners), including adolescents and young women, Papanicolaou (Pap) testing should be performed routinely. An initial test should be done at the time of HIV diagnosis, repeated 6 months after the first test, then performed annually thereafter if the results are normal. (See chapter *Initial and Interim Laboratory and Other Tests*.)

Because the risk of anal dysplasia also is increased among HIV-infected women (in some studies, rates of anal dysplasia were higher than rates of cervical dysplasia), many experts and some guidelines recommend concurrent screening for anal dysplasia. For further information, see chapter *Anal Dysplasia*.

For information on prevention of HPV infection, see “Prevention,” below.

HRSA HAB Performance Measures

Percentage of female patients with a diagnosis of HIV who have a **Pap screening** in the measurement year

(Adult and Adolescent measure)

S: Subjective

Patients with CIN or early cervical cancer usually are asymptomatic, and disease will not be diagnosed unless screening is performed. Genital condylomata (warts) indicate infection with HPV and typically are associated with low-risk types of HPV; however, a mixture of HPV types may be present, and women with genital warts may have concurrent dysplasia.

The classic symptom of early invasive cervical neoplasia is intermittent, painless bleeding between menstrual periods, which may present initially as postcoital spotting. Late symptoms of invasive cervical carcinoma include flank and leg pain, dysuria, hematuria, rectal bleeding, and obstipation.

Ask all female patients about risk factors for, previous history of, and preventive measures against cervical dysplasia and cancer, including the following:

- Genital warts; previous or current HPV infection
- Previous abnormal cervical Pap test result
- Previous abnormal anal Pap test result
- Previous cervical cancer; when and how treated
- Sexual activity before age 20
- History of multiple sex partners
- Cigarette smoking
- CD4 count of <200 cells/ μ L
- Pregnancy
- Oral contraceptive use
- History of HPV vaccination

O: Objective

Perform a focused examination of the abdomen and pelvis. Examine the external genital and perianal region. Perform speculum and bimanual examinations to evaluate the vagina and cervix. Look for lesions, masses, warts, and cervical inflammation or discharge, as well as exophytic or ulcerative cervical lesions with or without bleeding. Note that simple visual examination may not reveal abnormalities.

A: Assessment

HIV-infected women have an increased risk of cervical dysplasia with progression to cervical cancer. If abnormalities of cervical disease are suspected, an appropriate evaluation should be performed. Because most women with CIN have no symptoms, routine screening should be performed for all women.

P: Plan

Screening

Perform Pap screening for all HIV-infected women. The initial test should be conducted at the time of HIV diagnosis, a second (if the first is normal) should be performed 6 months later. Screening should be repeated annually thereafter throughout life if all results are normal. (For HIV-uninfected adolescents and young women, recent guidelines recommend beginning cervical screening at age 21; for HIV-infected young women, guidelines suggest screening beginning within 1 year of first sexual activity, given the risk of progression of cervical abnormalities.) If a Pap result is abnormal, see below. Also consider screening for anal dysplasia with an anal Pap test (see chapter *Anal Dysplasia*).

Cervical (and anal) cytology usually is graded using the Bethesda 2001 system (see “References,” below), which categorizes disease in increasing order of severity as follows:

- Negative for intraepithelial lesion or malignancy
- Atypical squamous cells of undetermined significance (ASCUS)
- Atypical squamous cells, cannot exclude HSIL (ASC-H)
- Low-grade squamous intraepithelial lesion (LSIL)
- High-grade squamous intraepithelial lesion (HSIL)
- Squamous cell carcinoma (SCC)

Other abnormalities may be noted, including the following:

- Atypical glandular cells (AGCs), including the following subcategories:
 - AGC not otherwise specified (AGC NOS) (includes endocervical, endometrial, or glandular cells)
 - AGC, favor neoplasia (includes endometrial or glandular cells)
 - AIS (endocervical adenocarcinoma in situ)
- Infectious organisms such as *Trichomonas*

Evaluation of Cytologic Abnormalities

Atypical squamous cells of undetermined significance

If ASCUS is present without inflammation or suspected neoplastic process, several options for management exist.

- Most experts recommend that all women with ASCUS be referred for colposcopy and directed biopsy, regardless of their degree of immunodeficiency. If the biopsy result shows no dysplasia (and the examination is adequate), the patient should be monitored by annual Pap tests.
- As an alternative, patients who are considered reliable for follow-up may repeat the Pap test in 6-12 months. If repeat Pap is reported at greater than ASCUS, the woman should be referred for colposcopy.
- There are limited and conflicting data to support the use of HPV DNA testing as part of the management of HIV-infected women with ASCUS. Current OI guidelines (see “References,” below) emphasize that HPV testing alone is not recommended.

Atypical squamous cells, cannot exclude HSIL

Women with abnormalities suggestive of high-grade dysplasia should be referred for colposcopy.

Low-grade squamous intraepithelial lesion

Women with LSIL should be referred for colposcopy and directed biopsy.

High-grade squamous intraepithelial lesion or squamous cell carcinoma

Women with HSIL are at high risk of high-grade intraepithelial neoplasia or cervical cancer and should undergo colposcopy with endocervical assessment and directed biopsy as soon as possible. Refer to an oncology specialist for treatment.

Atypical glandular cells

Because of the high rate of significant lesions in patients with AGS, colposcopy with endocervical sampling is recommended for all subcategories, including AIS. In women over age 35, endometrial sampling is recommended in addition to colposcopy and endocervical sampling. Refer to an appropriate specialist for evaluation.

Treatment

The optimal management of precancerous cervical lesions has not been identified clearly for all classes of CIN. Consult with an HIV-experienced gynecologist, oncologist, or other dysplasia specialist. High-grade lesions in women with satisfactory colposcopy are typically treated with ablation (e.g., cryotherapy, electrocautery, laser vaporization) or excision (e.g., loop electrosurgical excision [LEEP], laser or cold-knife conization). For women with unsatisfactory colposcopy, excisional methods are recommended.

Prevention

Latex or plastic barriers may block transmission of HPV in areas covered by these barriers and have been shown to reduce the risk of infection with oncogenic HPV.

Although infection may occur through bodily contact outside the area covered by the barriers, the use of condoms is recommended to prevent transmission or acquisition of HPV (as well as HIV and other STDs).

Two vaccines have been approved by the U.S. Food and Drug Administration for the prevention of certain HPV strains; these are recommended for HIV-infected women and girls 9-26 years of age. They have been shown to reduce rates of cervical dysplasia; the quadrivalent vaccine also has been shown to protect against vulvar, vaginal, and anal dysplasia (as well as anogenital warts) related to the covered HPV types.

- **Quadrivalent** (Gardasil): includes HPV types 16 and 18 (which cause nearly 70% of cervical cancer, as well as vaginal, vulvar, and anal cancer), and types 6 and 11 (which cause most anogenital warts)
- **Bivalent** (Cervarix): includes HPV types 16 and 18

The quadrivalent vaccine also is recommended for use with males aged 9-26 for prevention of genital warts and anal intraepithelial neoplasia.

These vaccines are not effective against HPV types other than those covered by the vaccine, and they may not be protective against a covered type to which a patient has been exposed previously. For optimal protection, these vaccines should be given before the individual is exposed to HPV through sexual activity. They are likely to be less effective in older adolescents and adults who already may have been infected with one or more of the covered HPV types. There are few data on the use of the vaccines in persons older than 26, and they are not approved for this group. Importantly, women who have been vaccinated should continue to be screened for cervical cancer as described above; vaccination does not protect women perfectly from all oncogenic HPV viruses.

Patient Education

- Recommend the use of latex or polyurethane male or female condoms for vaginal or anal intercourse and plastic or latex barriers for oral sex to reduce the risk of transmitting HPV (the usual cause of cervical cancer) to partners. Barriers also reduce the risk of exposure to other sexually transmitted pathogens.
- Patients who smoke should be advised to quit. Cigarette smoking appears to heighten the risk of cervical cancer and makes HPV more difficult to treat. Discuss options for smoking cessation (see chapter *Smoking Cessation*), and refer patients to the American Lung Association if local programs are available.
- Emphasize the importance of keeping follow-up appointments for Pap screening or colposcopy to allow early detection of precancerous lesions and appropriate monitoring of abnormalities.

- For women with dysplasia who require treatment, emphasize that early treatment is essential for managing the disease and preventing the development of cancer. Advise patients to keep all medical appointments.

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Cryptococcal Disease

Background

Cryptococcosis usually presents as a systemic or central nervous system (CNS) fungal infection caused by the yeast *Cryptococcus neoformans*. The organism is ubiquitous, and is particularly plentiful in soils enriched with bird droppings. It also may be present in fruit skins or juices, and in unpasteurized milk. In immunocompetent patients, cryptococcal infection usually is asymptomatic, self-limited, and confined to the lungs. In persons with advanced HIV infection (e.g., those with CD4 counts of <100 cells/ μL), *Cryptococcus* may cause life-threatening illness, either from a new exposure or through reactivation of a previously acquired latent infection.

In HIV-infected patients, *Cryptococcus* can infect almost all organs in the body, but most commonly causes meningitis or meningoencephalitis. Disseminated disease, pneumonia, and skin lesions also may be seen.

S: Subjective

Symptoms depend upon the locus of infection. In the case of meningitis, the patient typically experiences subacute onset of fever, headaches, and malaise, which worsen over the course of several weeks. These symptoms may be accompanied by nausea with or without vomiting. Classic meningeal signs, nuchal rigidity, and photophobia are present in only about 25% of cases. Cryptococcal meningitis may cause confusion, personality or behavior changes, blindness, deafness, and, if left untreated, coma and death. If the disease involves the lungs, patients may experience cough or shortness of breath, pleuritic chest pain, and fever. Skin lesions may be present.

O: Objective

Perform a thorough physical examination with particular attention to the following:

- Vital signs, hydration status
- Funduscopic findings
- Neck (for nuchal rigidity, which is uncommon)

- Lungs, especially if respiratory symptoms are present
- Neurologic evaluation, including cranial nerves, visual acuity, and mental status
- Skin

Cryptococcal Meningitis

Physical examination may reveal papilledema with loss of visual acuity and cranial nerve deficits (particularly in cranial nerves III and VI).

Cryptococcal Pulmonary Disease

Examination may reveal tachypnea or fine rales.

Cutaneous Infection

Skin lesions are variable and may appear as papules, nodules, or ulcers; they often resemble molluscum lesions.

A: Assessment

The differential diagnosis for cryptococcal meningitis or meningoencephalitis is broad and includes other infectious causes of meningitis (fungal, mycobacterial, bacterial, viral), syphilis, lymphoma, mass lesions, intoxication, HIV encephalopathy, and trauma. (See chapter *Neurologic Symptoms*.)

The differential diagnosis for cryptococcal pneumonia is broad and includes other infectious causes of pneumonia (fungal, mycobacterial, bacterial, viral), malignancy, and congestive heart failure. (See chapter *Pulmonary Symptoms*.)

P: Plan

Diagnostic Evaluation

The workup should include serum cryptococcal antigen (CrAg), which usually is very sensitive, and blood cultures, including bacterial, acid-fast bacilli (AFB), and fungal cultures. Patients with symptoms of disseminated or pulmonary infection should be evaluated by chest X-ray (which may show diffuse or focal infiltrates, sometimes appearing as nodular or miliary; intrathoracic adenopathy; or pleural effusions), sputum culture (including fungal and AFB cultures), and AFB stain. Bronchoscopy and bronchoalveolar lavage may be necessary for diagnosis. For cutaneous lesions, consider biopsy and histopathologic evaluation or culture. As part of the general fever workup, urinalysis and urine cultures should be checked.

Patients with a positive serum CrAg, another positive test for *Cryptococcus*, or signs or symptoms of meningitis should undergo analysis of the cerebrospinal fluid (CSF). If neurologic symptoms or signs are present, obtain a computed tomography (CT) scan of the brain before performing a lumbar puncture (LP) to rule out a mass lesion or increased intracranial pressure (ICP), which could cause herniation upon LP. Always measure the CSF opening pressure; a high ICP contributes to morbidity and mortality and determines the need for serial LP to manage the increased ICP. Send the CSF for the following:

- CrAg (usually positive at high titer in meningitis)
- Fungal culture
- India ink stain (less sensitive than CSF CrAg; perform if CSF CrAg is not available)

- Cell count
- Glucose
- Protein

For exclusion of other etiologies, perform CSF Venereal Disease Research Laboratory (VDRL) test, bacterial culture, AFB smear and culture, or polymerase chain reaction (PCR), if tuberculosis is suspected, and other tests as indicated by the patient's symptoms and exposures.

Treatment

Cryptococcal meningitis

Acute treatment of cryptococcal meningitis consists of two phases: induction and consolidation. Acute treatment is followed by chronic maintenance (suppressive) therapy.

Induction

Patients with cryptococcal meningitis should be hospitalized to start at least 2 weeks of induction therapy.

Preferred therapy:

- Liposomal amphotericin B 3-4 mg/kg IV QD + flucytosine 25 mg/kg PO QID

Lipid formulations of amphotericin B are less nephrotoxic than amphotericin B deoxycholate and appear to be equally effective.

Amphotericin-based therapy, in combination with flucytosine, is recommended. If these are not available, are contraindicated, or are not tolerated by the patient, the other indicated induction therapies may be considered.

Alternative therapy:

- Amphotericin B lipid complex 5 mg/kg IV QD + flucytosine 25 mg/kg PO QID
- Amphotericin B deoxycholate 0.7-1.0 mg/kg IV QD + flucytosine 25 mg/kg PO QID
- Liposomal amphotericin B 3-4 mg/kg IV QD + fluconazole 800 mg PO or IV QD
- Amphotericin B deoxycholate 0.7-1.0 mg/kg IV QD + fluconazole 800 mg PO or IV QD
- Liposomal amphotericin B 3-4 mg/kg IV QD alone
- Fluconazole 400-800 mg PO or IV QD + flucytosine 25 mg/kg PO QID
- Fluconazole 1,200 mg PO or IV QD alone

The primary alternative to amphotericin-based therapy is high-dose fluconazole (800-1,200 mg PO QD), with or without flucytosine. Among the newer antifungal agents, echinocandins have no activity against *Cryptococcus*. Voriconazole and posaconazole have good in vitro activity and may be considered for treatment of relapsed disease but not as first-line agents. The efficacy of alternative regimens is not well defined. See “Potential ARV Interactions,” below, regarding drug-drug interactions between these antifungals and ARVs.

Amphotericin B causes many adverse effects, including fever, rigors, hypotension, nausea, nephrotoxicity and electrolyte disturbances, anemia, and leukopenia. The patient’s hemoglobin, white blood cell (WBC) count, platelets, electrolytes, magnesium, and creatinine must be monitored closely during treatment. Liposomal forms of amphotericin cause fewer adverse effects. These should be used particularly for patients who have difficulty tolerating standard amphotericin B and for those who are at high risk of renal failure. Electrolytes and creatinine should be monitored. Flucytosine is associated with bone marrow and liver toxicity, and complete blood counts and liver function tests

should be monitored during induction therapy. If available, flucytosine levels can be evaluated 3-5 days after the start of therapy, with a target 2-hour post-dose level of 30-80 mg/mL; a level of >100 mg/mL should be avoided. Note that the dosage of flucytosine must be adjusted for patients with renal insufficiency.

Resistance testing may be considered for patients who have relapsed and for those for whom fluconazole failed to sterilize the CSF.

Consolidation

After clinical improvement with 2 weeks of induction therapy, and a negative CSF culture on repeat LP, treatment can be switched to fluconazole (400 mg PO QD for at least 8 weeks). Itraconazole (200 mg PO BID) is an alternative for patients who cannot take fluconazole. It should be noted that itraconazole is less effective than fluconazole and has significant drug interactions with commonly used medications.

Maintenance

After completing acute treatment, the patient should receive chronic maintenance therapy with fluconazole (200 mg PO QD) to prevent recurrence of cryptococcosis.

Maintenance therapy should be continued for life, unless the patient has completed induction and consolidation therapy followed by at least 1 year of maintenance therapy, and has sustained CD4 cell recovery in response to effective antiretroviral therapy (ART) (CD4 count ≥ 100 cells/ μ L for at least 3 months during ART). Maintenance therapy should be restarted if the CD4 count declines to <100 cells/ μ L.

Management of elevated ICP

Elevated ICP significantly increases the morbidity and mortality of cryptococcal meningitis and should be treated by the removal of CSF. The CSF opening pressure should be checked on the initial LP. If the initial opening pressure is >250 mm H₂O,

remove up to 30 mL of CSF to lower the ICP by 50%, if possible. LP and CSF removal should be repeated daily as needed for ICP reduction. A lumbar drain or ventriculoperitoneal shunt may be needed if the initial opening pressure is >400 mm H₂O, or in refractory cases. There is no role for acetazolamide, mannitol, or steroids in the treatment of elevated ICP.

A repeat LP is not required for patients who did not have elevated ICP at baseline and are responding to treatment. If new symptoms develop, a repeat LP is indicated. Serum CrAg titers are not useful in monitoring response to treatment.

Cryptococcal pulmonary disease, with negative CSF CrAg and culture results

After CSF cryptococcal disease has been excluded, treat with fluconazole if symptoms are mild or moderate and chest imaging shows focal infiltrates: 400 mg PO QD for 12 months, then 200 mg QD for maintenance. Otherwise, consider amphotericin induction, as described above with CNS disease. Maintenance therapy should be continued for life, unless the patient has sustained CD4 cell recovery in response to effective ART (CD4 count of ≥ 100 cells/ μ L for at least 6 months during ART) and with a minimum of 12 months of antifungal therapy. Therapy should be restarted if the CD4 count declines to <100 cells/ μ L.

Cutaneous infection, with negative CSF CrAg and culture results

Treat with fluconazole 400 mg PO QD for 6-12 months, then continue with 200 mg QD for chronic maintenance therapy, as discussed above.

Asymptomatic antigenemia

Data are limited for management of asymptomatic antigenemia, which can be associated with development of subsequent disease. Fungal cultures of CSF and blood should be obtained; if either result is positive for cryptococcal growth, treatment should be initiated for symptomatic meningoencephalitis or disseminated disease. If no

meningoencephalitis is found, fluconazole 400 mg PO QD should be given until immune reconstitution occurs; treatment may be discontinued per maintenance guidelines described above.

Cryptococcus IRIS

Immune reconstitution through ART is effective for preventing recurrence of cryptococcal infections. However, initiating ART within the first 1-2 months after starting treatment for cryptococcal infection may result in worsening or recurrence of symptoms because of immune reconstitution inflammatory syndrome (IRIS). IRIS can be life-threatening in cryptococcal meningeal disease. IRIS and relapse of cryptococcal disease (e.g., treatment failure) must be differentiated; in IRIS, the serum and CSF cultures are negative. (See chapter *Immune Reconstitution Inflammatory Syndrome*.)

Optimal timing of ART initiation in cryptococcal CNS disease is not known. Some experts recommend treating severe cryptococcosis with effective antifungal therapy for 2-10 weeks before starting ART, to decrease the risk of IRIS. On the other hand, if the CD4 count is very low (e.g., <50 copies/ μ L), it is important to initiate ART as soon as possible.

Other treatment notes

Pregnancy

Fluconazole and other azole drugs should be avoided during the first trimester of pregnancy, and voriconazole and posaconazole should be avoided throughout pregnancy. During the first and second trimesters, pregnant women should be treated with amphotericin for both induction and consolidation therapy. Flucytosine is teratogenic at high doses in rats and is classified as a pregnancy class C drug; it should be used during pregnancy only if the benefits clearly outweigh the risks.

Preventive therapy

Studies have suggested that routine primary prophylaxis for cryptococcal disease in patients with CD4 counts of <100 cells/ μ L is effective at preventing cryptococcal infection but is not cost efficient. Therefore, it is not routinely recommended.

Potential ARV Interactions

There may be significant drug-drug interactions between certain systemic antifungals, (particularly itraconazole, voriconazole, and posaconazole) and ritonavir-boosted protease inhibitors (PIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), elvitegravir/cobicistat, or maraviroc. Some combinations are contraindicated and others require dosage adjustment of the ARV, the antifungal, or both. Check for adverse drug interactions before prescribing. For example, voriconazole use is not recommended for patients taking ritonavir-boosted PIs, and dosage adjustment of both voriconazole and NNRTIs may be required when voriconazole is used concurrently with NNRTIs. See relevant tables in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, or consult with an expert.

Patient Education

- Cryptococcosis is not curable in persons with low CD4 cell counts and may require lifelong treatment. Patients should be instructed to take their treatment without interruptions.
- Even with therapy, disease may recur. Patients should report fevers or recurrence of other symptoms immediately.
- Antiretroviral therapy and improvement in immune system health are essential for prevention of recurrence.
- Patients should avoid pregnancy while taking any oral antifungal drug. Fetal craniofacial and skeletal abnormalities have been reported.

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Cryptosporidiosis

Background

Cryptosporidiosis is caused by a species of protozoan parasite that typically infects the mucosa of the small intestine, causing watery diarrhea. Diarrhea may be accompanied by nausea, vomiting, abdominal cramping, and occasionally fever. The infection is spread by the fecal-oral route, usually via contaminated water, and is highly contagious. The course of infection depends on the immune status of the host. In immunocompetent individuals, cryptosporidiosis usually is self-limited and can cause a mild diarrheal illness. However, in HIV-infected patients with advanced immunosuppression, cryptosporidiosis can cause severe chronic diarrhea, electrolyte disturbances, malabsorption, and profound weight loss. Infection also can occur outside the intestinal tract and can cause cholangitis, pancreatitis, and hepatitis. In severe cases, cryptosporidiosis can be life-threatening without aggressive fluid, electrolyte, and nutritional support. Patients at greatest risk of acquiring cryptosporidiosis are those with CD4 counts of <100 cells/ μL . Immune reconstitution inflammatory syndrome (IRIS) has not been described in association with cryptosporidiosis.

S: Subjective

The patient may complain of some or all of the following: watery diarrhea (can be profuse), abdominal pain or cramping, flatulence, nausea, vomiting, anorexia, fever, and weight loss.

The history should include questions about the presence and characteristics of the symptoms listed above, as well as the following:

- Stool frequency (typically 6-26 bowel movements daily)
- Stool volume (up to 10 liters per day and can be described as “cholera-like” in some patients with AIDS)
- Duration of symptoms (subacute or acute onset)
- Associated symptoms
- Exposures: recent travel to areas with unsafe water supply; ingestion of possibly contaminated water while swimming, boating, or camping; oral-anal contact, fecal exposures during sexual contact
- Recent CD4 cell count (highest risk is in patients with CD4 counts of <100 cells/ μL)

O: Objective

Perform a thorough physical examination with particular attention to the following:

- Vital signs
- Hydration status (e.g., orthostatic vital signs, mucous membrane moistness, skin turgor)
- Weight (compare with previous values; document weight loss)
- Signs of malnourishment (e.g., cachexia, wasting, thinning hair, pallor)
- Abdominal examination for bowel sounds (usually hyperactive), tenderness (can be diffuse), rebound
- Recent CD4 count

A: Assessment

In HIV-infected patients with advanced immunosuppression, the differential diagnosis includes other infectious causes of subacute or chronic diarrhea or cholangitis, such as microsporidia, *Isospora*, *Giardia*, cytomegalovirus (CMV), and *Mycobacterium avium* complex (MAC), as well as lymphoma.

P: Plan**Diagnostic Evaluation**

- Test the stool for ova and parasites, including *Cryptosporidium*. Diagnosis is made by microscopic identification of the *Cryptosporidium* oocysts in stool.
- Be sure to ask the laboratory to look for *Cryptosporidium*; certain labs do not look for these parasites or their precursor, the oocyst, unless requested.
- Test for fecal leukocytes. The result usually is negative in cryptosporidiosis; if positive, consider the possibility of a second enteric infection, especially if the CD4 count is low, or a different infection.
- Among persons with profuse diarrhea, a single stool specimen usually is adequate for diagnosis. For patients with milder disease, repeat stool sampling may be needed.
- If stool is negative for ova and parasites, consider a referral for biopsy of the gastrointestinal mucosa or flexible sigmoidoscopy.
- If cholangitis is suspected, consider abdominal ultrasound to look for biliary ductal dilatation, and endoscopic retrograde cholangiopancreatography (ERCP).
- Check electrolytes; conduct liver function studies including alkaline phosphatase and bilirubin to check for possible biliary or hepatic infection.
- If fever is present, obtain blood cultures.
- Conduct other diagnostic testing as indicated by the history and physical examination (e.g., evaluation for CMV, MAC, and other infectious causes of diarrhea or cholangitis) (see chapter *Diarrhea*).

Treatment**Preferred Strategy:**

- Effective antiretroviral therapy (ART) with immune reconstitution (and CD4 count of >100 cells/ μ L) can resolve cryptosporidiosis, and it is the primary treatment. All patients with cryptosporidiosis should be initiated on ART (see chapter *Antiretroviral Therapy*). Patients who are on incompletely suppressive ART should have their regimens optimized.
- Provide supportive care and symptomatic relief (this may require hospitalization in cases of severe dehydration), including the following:
 - Aggressive fluid and electrolyte replacement as needed
 - Oral rehydration (solutions containing glucose, sodium bicarbonate, potassium, magnesium, and phosphorus); in severe cases, IV hydration may be required
 - Antidiarrheal agents: atropine/diphenoxylate (Lomotil), loperamide (Imodium), tincture of opium (Paregoric)
 - Antispasmodics
 - Antiemetics
 - Topical treatment for the anorectal area, as needed (witch hazel pads [e.g., Tucks]), sitz baths)

Alternative Management Strategies:

No antiparasitic therapy has been proven to consistently and effectively cure cryptosporidiosis if used without ART. Use of nitazoxanide and paromomycin can be considered. They should be given in conjunction with ART, but never instead of ART; symptomatic treatment and hydration also should be given, as above.

- Nitazoxanide is approved for treatment of diarrhea caused by *Cryptosporidium parvum*, the most common strain of *Cryptosporidium*. It may increase the likelihood of clinical response.

- Usual adult dosage: 500-1,000 mg PO BID for 14 days
- Adverse events associated with nitazoxanide are limited and typically mild; there are no important drug-drug interactions
- Paromomycin 50 mg QID for 14-21 days

For patients with weight loss, nutritional supplementation is a critical aspect of treatment. In some cases, partial or total parenteral nutrition may be necessary while patients are awaiting clinical improvement in response to ART or other therapies. Consult or refer to a dietitian or nutritionist, if available. If not, assess food intake and counsel the patient about increasing caloric and nutritional intake.

Cryptosporidiosis in Resource-Limited Settings

Cryptosporidium infection in HIV-uninfected populations is more common in countries with overcrowding and poor sanitary conditions. The disease also is associated with rainy seasons and is frequent among children <2 years of age.

The prognosis for HIV-infected patients with cryptosporidiosis who lack access to ART is poor. In one study, the mean survival time of coinfecting patients was 25 weeks.

Prevention of Disease and Exposure

- Effective ART with maintenance or restoration of adequate immune function will prevent severe cryptosporidiosis.
- Scrupulous handwashing can prevent the spread of cryptosporidiosis, and HIV-infected patients should be advised to wash their hands after potential contact with human feces (diapering small children, handling pets, gardening, and before and after sex).
- HIV-infected patients should avoid sexual practices that could lead to direct (e.g., oral-anal) or indirect (e.g., penile-anal) contact with feces and should be advised to use barrier methods during sex (e.g., condoms

and dental dams).

- HIV-infected persons should avoid drinking water from lakes or rivers. Waterborne infection also can result from recreational activities such as boating, fishing, and swimming.
- HIV-infected patients should avoid raw oysters as the cryptosporidial oocysts can survive in oysters for >2 months.
- Rifabutin and clarithromycin, when taken for MAC prophylaxis, appear to reduce the risk of cryptosporidiosis. However, current data are insufficient to recommend their use as prophylaxis against cryptosporidiosis.

Patient Education

- Recommend scrupulous handwashing for the patient and all contacts, especially household members and sex partners.
- Explain that effective ART is the best treatment for alleviating symptoms and helping the immune system eradicate the parasite.
- Advise the patient to increase fluid intake (not alcohol), and avoid foods that aggravate diarrhea. A lactose-free diet may improve symptoms.
- Educate the patient about healthful food choices that increase caloric intake and nutrition.
- Provide supportive counseling; discuss how to manage symptoms and the isolation that may accompany chronic diarrhea.

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Cytomegalovirus Disease

Background

Although chronic infection with cytomegalovirus (CMV) rarely causes disease among immunocompetent persons, it is a major cause of morbidity and mortality in HIV-infected patients with CD4 counts of <50 cells/ μ L. CMV infection causes disease in several organ systems, including the central nervous system (CNS) (chorioretinitis, encephalitis, polyradiculopathy, myelopathy) and the gastrointestinal (GI) tract (oral ulcers, esophagitis, hepatitis, colitis, intestinal perforation), as well as life-threatening adrenalitis and pneumonitis. The prevalence of chronic infection with CMV, a member of the human herpesvirus family, is high among sexually active adults (40-60% in resource-rich countries and 80-90% in resource-poor countries). CMV is spread by sexual or other types of close personal contact, blood-to-blood contact (via transfusion or needle sharing), organ transplantation, and perinatal transmission. As with other herpesviruses, CMV is not cleared from the body, but is kept in a state of latency by an intact immune system. Symptomatic disease represents either primary infection or reactivation of latent infection that has escaped immunologic control. Effective antiretroviral therapy (ART) greatly reduces the risk of CMV reactivation and disease.

Immune reconstitution inflammatory syndrome

Although effective ART greatly reduces the risk of CMV reactivation and disease, patients on effective ART may experience CMV-related visual changes.

- Patients without a previous history of CMV disease will occasionally present with full-blown CMV retinitis after starting ART. This is thought to reflect delayed restoration of CMV-specific immunity. It is diagnosed and treated in an identical manner as for patients diagnosed with CMV disease who are not taking effective ART.
- Approximately 20% of patients with previously treated CMV retinitis may experience CMV-related immune reconstitution uveitis (IRU) after starting successful ART. Symptoms include floaters and moderate, occasionally severe, vision loss. The most common causes of vision loss are posterior disease, specifically cystoid macular edema (CME) and epiretinal membrane (ERM) formation, although inflammation of the anterior region and cataract formation also can occur. It is not clear whether treatment with steroids or anti-CMV antivirals is effective. (See chapter *Immune Reconstitution Inflammatory Syndrome*.)

S: Subjective

The patient may present with symptoms involving various organ systems, including the following:

• CNS, including the eye:

- Floaters, scotomata (blind spots), “flashing lights,” loss of peripheral or field vision (chorioretinitis)
- Headache, difficulty concentrating, sleepiness, personality changes (encephalitis, dementia)

- Bilateral lower extremity weakness, urinary retention, incontinence, spasticity (polyradiculopathy)
- Low-back pain, especially radiating to the perianal area (polyradiculopathy, myelitis)
- Family members or caregivers may report confusion, apathy, lethargy, somnolence, withdrawal, or personality changes in the patient (CMV encephalitis, dementia)

• GI tract disease:

- Mouth ulcerations
- Dysphagia or odynophagia (esophagitis)
- Abdominal pain and bloody diarrhea, weight loss, rectal ulcers, fever (colitis)

• Disease outside the CNS or GI tract:

- Persistent fever, fatigue, weight loss (adrenitis)
- Shortness of breath, dyspnea on exertion, dry cough (pneumonia; rare in patients with advanced HIV infection)
- Pancytopenia (bone marrow infection)

The history should include questions about the presence and characteristics of the symptoms listed above, as well as the following:

- Duration of symptoms
- Associated symptoms
- Recent CD4 count; nadir CD4 count (risk is highest when count is <50 cells/ μ L)
- Whether the patient is taking ART; if so, date initiated, specific medications, and CD4 and HIV RNA responses

O: Objective

Perform a thorough physical examination with particular attention to the following:

- **Vital signs:** Document fever.
- **Weight:** Compare with previous values; document weight loss.
- **Eyes:** Funduscopic examination in patients with CMV retinitis may show pathognomonic “cottage cheese in ketchup” yellow-white lesions, representing vascular hemorrhages and exudates.
- **Nervous system:** Evaluate mental status and perform a complete neurologic examination, including cranial nerves, sensation (sensory deficits may occur with preserved vibratory sense and proprioception), motor, deep tendon reflexes, coordination, and gait.

A: Assessment

For HIV-infected patients with advanced immunosuppression, the differential diagnosis includes the following:

- For suspected CMV retinitis: consider cotton-wool spots, HIV retinopathy, and progressive outer or acute retinal necrosis.
- For suspected CMV encephalitis: consider other causes of neurologic deterioration such as progressive multifocal leukoencephalopathy, toxoplasmosis, CNS lymphoma, and other mass lesions.
- For suspected CMV enteritis: consider gastrointestinal pathogens such as *Mycobacterium avium* complex, *Cryptosporidium*, other parasites, and lymphoma.
- For suspected CMV pneumonitis: consider *Pneumocystis jiroveci* and other respiratory pathogens.

P: Plan

Diagnostic Evaluation

CMV can be detected by serology, culture, antigen testing, nucleic acid amplification, or examination of tissue samples. However, serologic tests are not reliable for diagnosing CMV disease because most adults are seropositive and because patients with advanced AIDS may serorevert while remaining infected. Furthermore, for HIV-infected patients, demonstration of CMV in the blood, urine, semen, cervical secretions, or bronchoalveolar lavage (BAL) fluid does not necessarily indicate active disease, although patients with end-organ disease usually are viremic.

Diagnosis of end-organ disease generally requires demonstration of tissue invasion. The recommended evaluation is as follows:

CMV retinitis

Dilated retinal examination should be performed emergently by an ophthalmologist experienced in the diagnosis of CMV retinitis. The diagnosis usually is based on the identification of typical lesions. Diagnosis and monitoring should include serial examinations with photography to assess and follow response to treatment and to detect failure to respond early enough to change therapy. If the diagnosis is uncertain, aqueous or vitreous fluid samples can be sent for polymerase chain reaction (PCR) evaluation for CMV and other possible infectious agents.

Other sites

Detection of CMV at other sites requires visualization of typical lesions (e.g., on endoscopy or BAL) and tissue biopsy. Viral inclusions (“owl’s eye cells”) in tissue biopsy samples demonstrate invasive disease (as opposed to colonization). **Because retinitis is the most common manifestation of CMV disease, patients with CNS, gastrointestinal, or pulmonary disease should undergo ophthalmologic evaluation to detect subclinical retinal disease.**

Neurologic CMV disease

- **Encephalitis:** Magnetic resonance imaging (MRI) of the brain should be done to rule out mass lesions. CMV effects may appear as periventricular or meningeal enhancement. Lumbar puncture should be performed; cerebrospinal fluid (CSF) should be analyzed for CMV (by PCR, which is sensitive and specific), cell count (may show lymphocytic or mixed lymphocytic or polymorphonuclear pleocytosis), glucose (may be low), and protein (may be high). A brain biopsy may be performed if the diagnosis is uncertain after imaging and CSF evaluation.

- **Polyradiculopathy:** Spinal MRI should be done to rule out mass lesions. In CMV disease, nerve root thickening may be present. Lumbar puncture with CSF analysis should be performed, as described above.
- **Myelitis:** Spinal MRI should be done to rule out mass lesions. Cord enhancement may be present. Lumbar puncture with CSF analysis should be performed, as described above.

Gastrointestinal CMV disease (esophagitis or colitis)

- Perform endoscopy with visualization of ulcers and obtain tissue biopsy to look for inclusion bodies.

Pulmonary CMV disease

- Perform chest radiography showing interstitial pneumonia and obtain lung biopsy to look for inclusion bodies.

Treatment

Valganciclovir, ganciclovir, foscarnet, and cidofovir may be effective for treating CMV end-organ disease. The choice of therapy depends on the site and severity of the infection, the level of underlying immunosuppression, the patient’s ability to tolerate the medications and adhere to the treatment regimen, and the potential medication interactions.

Immune reconstitution through ART is a key component of CMV treatment and relapse prevention. CMV flares may occur if patients develop immune reconstitution inflammatory syndrome (see chapter *Immune Reconstitution Inflammatory Syndrome*). Although decisions about the timing of ART should be individualized, in most cases of CMV end-organ disease, ART probably should not be delayed for more than 2 weeks after starting treatment for CMV.

CMV retinitis

Treatment consists of two phases: initial therapy and chronic maintenance therapy.

Initial therapy

For patients with sight-threatening (zone 1) disease, the preferred treatment strategy is a combination of intravitreal and systemic therapy. Intravitreal therapy delivers high doses of drug to the retina immediately. Ganciclovir intraocular implants are no longer available, but patients may be treated with intravitreal injections of ganciclovir or foscarnet.

In the past, about half of patients treated with only local therapy (specifically, ganciclovir implants) developed disease in the contralateral eye, and one third experienced systemic disease within 3 months of implantation. Therefore, patients who receive intravitreal therapy also should be treated systemically with valganciclovir or an alternative therapy as below.

For patients with peripheral retinitis (beyond zone 1), systemic therapy alone may be given. Oral valganciclovir (see below) is the preferred treatment because it is easy to administer and is not associated with the surgery- or catheter-related complications seen with intraocular treatments and IV therapies. This formulation quickly converts to ganciclovir in the body and has good bioavailability. Valganciclovir should be used only if the patient is thought to be capable of strict adherence. Other possible IV treatments include ganciclovir, ganciclovir followed by oral valganciclovir, foscarnet, and cidofovir. See below for dosing recommendations.

For sight-threatening disease:

- Intravitreal injection of ganciclovir (2 mg/injection or foscarnet (2.4 mg/injection) 1-4 doses over the course of 7-10 days **plus** systemic therapy as below

Preferred systemic therapy:

- Valganciclovir 900 mg PO BID for 14-21 days, then QD

Alternative systemic therapy:

- Ganciclovir 5 mg/kg IV Q12H for 14-21 days, then QD
- Ganciclovir 5 mg/kg IV Q12H for 14-21 days, then valganciclovir 900 mg PO QD
- Foscarnet 60 mg/kg IV Q8H or 90 mg/kg Q12H for 14-21 days, then 90 mg/kg Q24H
- Cidofovir IV 5 mg/kg weekly for 2 weeks, then every other week (must be given with probenecid [2 g PO 3 hours before, 1 g PO 2 hours after, and 1 g PO 8 hours after the cidofovir infusion] and IV saline to decrease the risk of renal toxicity)

For peripheral lesions:

- Systemic therapy as above

Note: Valganciclovir, ganciclovir, and foscarnet require dosage adjustment in patients with renal insufficiency. Cidofovir is contraindicated for use by patients with renal insufficiency or proteinuria.

Monitor patients closely to gauge the response to therapy. Repeat the dilated retinal examination after completion of induction therapy, 1 month after initiation of therapy, and monthly during anti-CMV therapy, with photography to document progression or resolution of disease. Consult with a specialist if the response to therapy is suboptimal.

Note: Retinal detachment may occur in up to 50-60% of patients in the first year after diagnosis. Regular follow-up with an ophthalmologist is required for all patients. Patients should be instructed to report any vision loss immediately.

Chronic maintenance therapy

After initial CMV treatment, lifelong maintenance therapy should be given to prevent recurrence, and patients need regular reevaluation by an ophthalmologist. Select the specific treatment in consultation with an ophthalmologist.

Preferred therapy:

- Valganciclovir 900 mg PO QD

Alternative therapy:

- Ganciclovir 5 mg/kg IV 5-7 times per week
- Foscarnet 90-120 mg/kg IV QD
- Cidofovir 5 mg/kg IV every other week (administer with probenecid and IV hydration, as above)

Discontinuation of maintenance therapy can be considered for patients with inactive CMV and sustained immune reconstitution on ART (CD4 count of >100 cells/ μ L for at least 3-6 months). However, the decision should be guided by factors such as the extent and location of the CMV lesions and the status of the patient's vision. An ophthalmologist who is experienced in caring for HIV-infected patients with CMV should be involved in making any decision to discontinue therapy, and patients should receive regular ophthalmologic follow-up. Maintenance therapy should be resumed if the CD4 count drops to <100 cells/ μ L or the patient develops other signs of HIV progression.

Neurologic CMV disease

The optimal treatment for neurologic disease has not been determined. Prompt initiation of dual therapy with IV ganciclovir and foscarnet may be effective for some patients. Chronic maintenance therapy usually is not recommended for patients who recover and are on effective ART, unless the disease recurs.

Gastrointestinal and pulmonary CMV disease

CMV colitis and esophagitis are usually treated with IV ganciclovir or foscarnet for 21-42 days, until symptoms have resolved. Treatment should be changed to valganciclovir (900 mg QD) when the patient is able to absorb oral medications. In mild cases in which patients are able to tolerate and absorb it, valganciclovir may be used from the beginning (refer to the dosing recommendations above).

Some specialists recommend a follow-up endoscopy to verify regression of lesions before discontinuing therapy.

For pulmonary CMV infections, optimal therapy has not been defined. IV ganciclovir or foscarnet is recommended. The efficacy of valganciclovir has not been determined.

Many experts do not recommend maintenance therapy for gastrointestinal or pulmonary CMV infections for patients whose CMV symptoms resolve and who are on effective ART.

Immune reconstitution inflammatory syndrome retinitis or uveitis

Urgent consultation with experts is recommended. Corticosteroids may be beneficial.

Monitoring CMV therapies

The medications used to treat CMV have several important potential adverse effects, and monitoring for these is required. Valganciclovir and ganciclovir have been associated with bone marrow suppression, neutropenia, anemia, thrombocytopenia, and renal dysfunction. Foscarnet has been associated with cytopenia, renal insufficiency, electrolyte abnormalities, and seizures. For patients taking these medications, perform complete blood count with differential and check electrolytes and creatinine twice weekly during initial therapy and once weekly during maintenance therapy. Cidofovir has been associated with renal insufficiency and ocular hypotony. For patients taking cidofovir, check creatinine and blood urea nitrogen and perform urinalysis (for proteinuria) before each dose. Intraocular pressure must be checked at least every 6 months.

Patient Education

- Educate patients about the importance of ART in treating CMV. Urge patients to start ART if they have not done so already.
- Patients with CMV retinitis may have to remain on suppressive therapy for life to prevent blindness. Patients with CMV esophagitis or enteritis usually see improvements within 2-4 weeks after starting therapy.
- Treatment of CMV retinitis halts progression of the infection but does not reverse the damage already done to the retina. Warn patients that vision will not return to pre-CMV status.
- Advise patients to report any visual deterioration immediately. Retinal detachment or progression of CMV must be treated immediately to avoid further vision loss.
- For patients who experience significant vision loss, offer referral to education, training, and support services to help them adjust.
- With gastrointestinal disease, recurrence of symptoms warrants repeat endoscopy. Advise patients to report any recurrence of symptoms.
- Adverse reactions to current therapies are common. Educate patients about these and advise them to promptly report any adverse reactions.
- Help patients cope with the possibility of therapeutic failure, and, in the case of CMV retinitis, permanent loss of vision.
- Teach patients how to maintain indwelling venous access lines, if used. Have patients demonstrate these techniques before discharge.

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Gonorrhea and Chlamydia

Background

Gonorrhea, caused by *Neisseria gonorrhoeae* (GC), and chlamydia, caused by *Chlamydia trachomatis* (CT), are sexually transmitted diseases (STDs). These infections may be transmitted during oral, vaginal, or anal sex; they also can be transmitted from a mother to her baby during delivery and cause significant illness in the infant.

Both organisms can infect the urethra, oropharynx, and rectum in women and men; the epididymis in men; and the cervix, uterus, and fallopian tubes in women. Untreated GC or CT infection in women may lead to pelvic inflammatory disease (PID), which can cause chronic pelvic pain and scarring of the fallopian tubes that results in infertility or ectopic pregnancy (tubal pregnancy). *N. gonorrhoeae* can cause disseminated infection involving the skin, joints, and other systems. Infection with GC or CT may facilitate transmission of HIV to HIV-uninfected sex partners.

Certain strains of CT can cause lymphogranuloma venereum (LGV). This infection is common in parts of Africa, India, Southeast Asia, and the Caribbean. Although relatively uncommon in the United States, outbreaks among men who have sex with men (MSM) have been reported in recent years. LGV may cause genital ulcers, followed by inguinal adenopathy; it also can cause proctocolitis with anorectal discharge, tenesmus, and pain.

Patients with symptoms of gonorrhea or chlamydia should be evaluated and treated as indicated below. Although GC or CT urethral infections in men may cause symptoms, infection in women and oral or rectal infections in men often cause no symptoms. Thus, sexually active individuals at risk of GC and CT exposure should receive regular screening for these infections as well as for syphilis and other STDs; for most patients, this should be at least annually, and every 3-6 months for persons at higher risk (see chapter *Initial and Interim Laboratory and Other Tests*).

S: Subjective

Symptoms will depend on the site of infection (e.g., oropharynx, urethra, cervix, rectum). Symptoms are not present in many patients, thus it is important to screen all patients at risk of STDs.

If symptoms are present, **women** may notice the following (depending on site of infection):

- Vaginal discharge
- Pain with sexual intercourse
- Pain or burning on urination
- Abdominal or pelvic pain
- Sore throat
- Rectal discharge
- Anal discomfort or tenesmus

If symptoms are present, **men** may notice the following (depending on site of infection):

- Pain or burning on urination
- Urethral discharge
- Testicular tenderness or pain
- Sore throat
- Rectal discharge
- Anal discomfort or tenesmus

During the history, ask the patient about the following:

- Any of the symptoms listed above, and their duration
- Previous diagnosis of GC, CT, or other STD
- New sex partner(s); number and gender of partners

- Unprotected sex (oral, vaginal, anal; receptive or insertive)
- For women: last menstrual period, and whether the patient could be pregnant; use of an intrauterine device

O: Objective

Physical Examination

During the physical examination, check for fever and document other vital signs.

For **women**, focus the physical examination on the mouth, abdomen, and pelvis. Inspect the oropharynx for discharge and lesions; check the abdomen for bowel sounds, distention, rebound, guarding, masses, and suprapubic or costovertebral angle tenderness; perform a complete genital and vaginal examination for abnormal discharge or bleeding; check for uterine, adnexal, or cervical motion tenderness; and search for pelvic masses or adnexal enlargement. Check the anus for discharge and lesions; perform anoscopy if symptoms of proctitis are present. Check for inguinal lymphadenopathy. Check the skin for rashes and lesions.

For **men**, focus the physical examination on the mouth, genitals, and anus/rectum. Check the oropharynx for lesions, the urethra for discharge, the external genitalia for tenderness, masses, or lesions, and the anus for discharge and lesions; perform anoscopy if symptoms of proctitis are present. Check for inguinal lymphadenopathy. Check the skin for rashes and lesions.

A: Assessment

A partial differential diagnosis includes the following:

- Urinary tract infection
- Dysmenorrhea
- Appendicitis
- Cystitis

- Proctitis
- PID
- Irritable bowel syndrome
- Pyelonephritis

P: Plan

Diagnostic Evaluation

Test for oral, urethral, or anorectal infection, according to symptoms and anatomic site(s) of possible exposures. Perform testing for both gonorrhea and chlamydia (testing for pharyngeal CT infection generally is not recommended although the CT pharyngeal test often accompanies the GC pharyngeal nucleic acid amplification test [NAAT]). The availability of the various testing methods varies according to the specific clinic site. Consider the following:

- NAAT: urine specimens (first stream) and urethral (men), vaginal, and endocervical swab specimens; also used with pharyngeal and rectal swab specimens (laboratory must meet Clinical Laboratory Improvement Amendments [CLIA] specifications and establish validity in nongenital specimens); recommended unless GC antibiotic resistance is suspected
- GC culture (oropharynx, endocervix, urethra, rectum) – consider especially if antibiotic resistance is suspected
- Gram stain of urethral discharge for evidence of GC
- Serologic tests (complement fixation test) if LGV is suspected

Treatment

Treatments for gonorrhea and chlamydia are indicated below. Fluoroquinolone-resistant GC is widespread in the United States and throughout the world. Thus, the U.S. Centers for Disease Control and Prevention (CDC) recommends that fluoroquinolones not be used for treatment of GC. Similarly, resistance

of GC to cephalosporins is emerging, though third-generation cephalosporins are effective against most GC strains in the United States and remain the only recommended treatment for GC. GC strains with decreased susceptibility to azithromycin also have been reported, and azithromycin should be used to treat GC only for select patients in whom treatment with a cephalosporin should be avoided.

Adherence is essential for treatment success. Single-dose treatments maximize the likelihood of adherence and are preferred. Other considerations in choosing the treatment include antibiotic resistance, cost, allergies, and pregnancy. For further information, see the CDC STD treatment guidelines (see “References,” below); treatments should be given in accordance with these guidelines.

Any sex partners within the past 60 days, or the most recent sex partner from >60 days before diagnosis, also should receive treatment. Patients should abstain from sexual activity for 7 days after a single-dose treatment or until a 7-day treatment course is completed. Reinfection with GC or CT is likely if reexposure occurs; patients with either GC or CT should be rescreened 3 months after treatment.

Treatment of Gonorrhea

Treatment options include the following (see the full CDC STD treatment guidelines, referenced below); the current guidelines emphasize that dual therapy for GC should be given, with ceftriaxone plus either azithromycin or doxycycline. Ceftriaxone is the recommended cephalosporin for GC infection at any anatomic site. Coadministration of azithromycin or doxycycline is intended to improve the likelihood of cure and may decrease the risk of emergent cephalosporin resistance; it should be given, even if test results for CT are negative.

Recommended regimen (for GC of all anatomic sites)

- Ceftriaxone 250 mg IM injection in a single dose, **plus** azithromycin 1 g PO in a single dose or doxycycline 100 mg PO BID for 7 days

Alternative regimens (for GC of pharynx, cervix, urethra, and rectum)*

- If ceftriaxone is not available: cefixime 400 mg PO in a single dose (tablet or oral suspension), plus azithromycin or doxycycline, as above
- If severe cephalosporin allergy: azithromycin 2 g PO in a single dose

* If an alternative regimen is used, a test of cure (TOC) should be done in 1 week: GC culture (preferred) or NAAT. A positive NAAT result should be followed by confirmatory culture and antimicrobial susceptibility testing. Possible cephalosporin treatment failures should be reported immediately to the local or state health department.

If penicillin or cephalosporin allergy:

- Cephalosporins are contraindicated for use only in patients with a history of severe reaction to penicillin.
- Consultation with an infectious disease specialist is recommended.
- Consider azithromycin 2 g PO, with TOC, as above.
- Consider cephalosporin treatment following desensitization.

Note: Fluoroquinolones are not recommended for treatment of gonococcal infection because of widespread resistance in the United States.

Please see full CDC STD treatment guidelines regarding treatment of PID, epididymitis, and disseminated gonococcal infection.

Treatment of Chlamydia

(See the full CDC STD treatment guidelines, referenced below.)

Recommended regimens

- Azithromycin 1 g PO in a single dose
- Doxycycline 100 mg PO BID for 7 days

Alternative regimens

- Erythromycin base 500 mg PO QID for 7 days
- Erythromycin ethylsuccinate 800 mg PO QID for 7 days
- Levofloxacin 500 mg PO QD for 7 days (see Note above)
- Ofloxacin 300 mg PO BID for 7 days (see Note above)

Treatment of LGV**Recommended regimens**

- Doxycycline 100 mg PO BID for 21 days

Alternative regimens

- Erythromycin base 500 mg PO QID for 21 days
- Azithromycin 1 g PO once weekly for 3 weeks (limited data)

For recent sex partners (within 60 days before the onset of patient's symptoms), test for urethral or cervical CT, treat with azithromycin 1 g PO in a single dose or doxycycline 100 mg PO BID for 7 days.

Treatment During Pregnancy

Use of fluoroquinolones and tetracyclines should be avoided during pregnancy.

Recommended GC regimens

- Ceftriaxone 250 mg IM + azithromycin 1 g PO in a single dose

Recommended CT regimens

- Azithromycin 1 g PO in a single dose
- Amoxicillin 500 mg PO TID for 7 days

Alternative CT regimens

- Erythromycin base 500 mg PO QID for 7 days
- Erythromycin base 250 mg PO QID for 14 days
- Erythromycin ethylsuccinate 800 mg PO QID for 7 days
- Erythromycin ethylsuccinate 400 mg PO QID for 14 days

Follow-Up

- For both GC and CT, evaluate the patient's sex partners; treat them empirically if they had sexual contact with the patient during the 60 days preceding the patient's onset of symptoms. Some clinics provide empiric treatment for partners via "partner packs," or a treatment regimen that the patient takes to the partner(s); this approach may be effective, particularly for CT, if the partner(s) is/are unlikely to come to the clinic for evaluation and treatment.
- Most recurrent infections come from sex partners who were not treated.
- The CDC recommends rescreening all patients 3 months after GC or CT treatment (for possible reinfection).
- For pregnant women with CT, retest (by NAAT) 3 weeks after completion of treatment.

- If symptoms persist, evaluate for the possibility of reinfection, treatment failure, or a different cause of symptoms. If treatment failure is suspected, perform culture and antimicrobial sensitivity testing.
- Screen for GC, CT, syphilis, and other STDs at regular intervals according to the patient's risk factors. The sites of sampling (e.g., pharynx, urethra, endocervix, anus/rectum) will be determined according to the patient's sexual exposures.
- Evaluate each patient's sexual practices with regard to the risk of acquiring STDs and of transmitting HIV; work with the patient to reduce sexual risks.

Patient Education

- Instruct patients to take all of their medications. Advise patients to take medications with food if they are nauseated and to call or return to clinic right away if they experience vomiting or are unable to take their medications.
- Sex partners from the previous 60 days need to be tested for sexually transmitted pathogens, and treated as soon as possible with a regimen effective against GC and CT, even if they have no symptoms. Advise patients to inform their partner(s) that they need to be tested and treated. Otherwise, patients may be reinfected.
- Advise patients to avoid sexual contact until the infection has been cured (in themselves and in their partners) at least 7 days.
- Provide education about sexual risk reduction. Instruct patients to use condoms with every sexual contact to prevent reinfection with GC or CT, to prevent other STDs, and to prevent transmission of HIV to sex partners.

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Hepatitis B Infection

Rena K. Fox, MD

Background

Hepatitis B virus (HBV) is the most common cause of chronic liver disease worldwide. Chronic HBV can cause necroinflammation and over time can cause hepatic fibrosis and eventually cirrhosis, end-stage liver disease, and hepatocellular carcinoma (HCC). It is estimated that 350 million people have chronic HBV infection, with approximately 1.25 million of them in the United States. HBV is a DNA virus that is spread through exposure to infected blood and body fluids. It typically is transmitted by parenteral, sexual, and vertical exposures, but may be transmitted through person-to-person contacts among household members, especially because HBV can survive outside the body for long periods of time. Because HIV and HBV share transmission routes, up to 90% of HIV-infected patients have evidence of HBV exposure. In the United States, chronic HBV infection has been identified in 6-15% of HIV-infected persons.

The epidemiology of HBV infection varies by geographic region. In Southeast Asia and sub-Saharan Africa, HBV is highly prevalent and almost all infections occur perinatally or during early childhood. In the United States and Western Europe, most infections occur through sexual exposure or high-risk injection drug-use behavior.

To identify patients with HBV coinfection, and to identify and vaccinate susceptible individuals, all HIV-infected persons should be tested for HBV (see chapters *Initial and Interim Laboratory and Other Tests* and *Immunizations for HIV-Infected Adults and Adolescents*). In addition, all patients with chronic HBV infection should be tested for HIV and all patients with evidence of prior resolved HBV infection should be strongly considered for HIV testing.

It is universally recommended that HBV vaccination should be given to all HIV-infected persons who are susceptible to HBV infection (see “Interpreting HBV test results,” below, and chapter *Immunizations for HIV-Infected Adults and Adolescents*). It is recommended that the vaccine series be given when CD4 counts are >200 cells/ μ L, if possible, as doing so is associated with higher rates of vaccine response, but vaccination should not be delayed for persons with lower CD4 counts.

The natural history of HBV infection is complex and dynamic, with phases of active replication and of inactive replication, and fluctuating alanine aminotransferase (ALT) levels. The likelihood of developing chronic HBV after exposure varies with age, mode of infection, and immunocompromised status. Among newborns born to HBV-infected mothers, 90% develop chronic hepatitis B, whereas 30% of exposed infants and young children and <5% of exposed adults develop chronic infection. Most adults who become infected with HBV are able to clear the virus without treatment, and they subsequently become immune to HBV. Chronic progressive HBV can lead to cirrhosis and then to decompensated liver disease including ascites, portal hypertension, esophageal varices, coagulopathy, thrombocytopenia, and hepatic encephalopathy. HCC can develop in patients with or without cirrhosis; in fact, 30-50% of HCC cases attributable to HBV occur in the absence of cirrhosis.

HRSA HAB Performance Measures

Percentage of patients with a diagnosis of HIV who completed the vaccination series for hepatitis B

(Adult and Adolescent measure)

Factors associated with increased rates of cirrhosis include the following:

- Longer duration of infection
- HBV genotype C
- High levels of HBV DNA
- Alcohol consumption
- Smoking
- Aflatoxin exposure
- Coinfection with HIV
- Coinfection with hepatitis D virus
- Coinfection with HCV

Factors associated with increased rates of HCC include the following:

- Male gender
- Family history of HCC
- Older age
- Presence of HBV envelope antigen (HBeAg); history of reversion from anti-HBe to HBeAg
- High levels of HBV DNA
- Presence of cirrhosis
- HBV genotype C
- Core promoter mutation
- Coinfection with HCV

Among individuals who are not taking ART, HIV infection significantly modifies the natural history of HBV infection. HIV infection appears to increase the risk of developing chronic HBV infection after acute HBV, and it is associated with a higher level of HBV DNA replication and lower rates of spontaneous HBeAg seroconversion. In patients with chronic HBV, HIV coinfection is associated with faster progression of liver disease and cirrhosis and increased rates of liver-related deaths. Although HIV coinfection itself is not known to increase the risk of HCC development, it does increase the risk of cirrhosis, which in turn increases the risk of HCC.

Treatment of HIV infection with effective ART has increased the life expectancy of HIV-infected patients in recent years, and paradoxically has given HIV/HBV-coinfected patients a longer lifespan during which cirrhosis may develop. Partly for this reason, the relative proportion of deaths attributable to liver disease among HIV-infected patients is rising. On the other hand, ART can positively impact the natural history of HBV infection. Effective ART can improve patients' immune responses against HBV. ART also may be used to cotreat HBV in coinfecting patients. Several of the nucleoside analogues (NRTIs) used against HIV also are active against HBV, and these should be included in an ART regimen to treat both HIV and HBV for coinfecting persons (see "Antiviral Treatment of Chronic HBV Infection," below). Withdrawal of NRTIs with anti-HBV activity can precipitate a reactivation of HBV. ART that contains anti-HBV NRTIs also may prevent acute infections in patients who are receiving them. Current U.S. Department of Health and Human Services (HHS) guidelines recommend initiation of ART (and cotreatment of HBV) for all persons with HIV/HBV coinfection.

S: Subjective

Persons with acute HBV infection may have symptoms including fatigue, nausea, vomiting, arthralgias, fever, right upper quadrant pain, jaundice, dark urine, and clay-colored stools. Some patients may have no symptoms at all.

Persons with chronic HBV, even with early cirrhosis, may be asymptomatic or may experience only fatigue or mild right upper quadrant tenderness. Patients with decompensated cirrhosis may experience increased abdominal girth, easy bruising, telangiectasis, pruritus, gastrointestinal bleeding, or altered mentation. Patients with early or small HCC may have no additional symptoms or may develop significant abdominal pain, weight loss, nausea, or bone pain.

Ask patients with known HBV infection about symptoms that suggest complications of HBV such as cirrhosis, decompensation, risk factors for worsening liver disease, and hepatotoxins. Questions should address the symptoms listed above, and the following:

- Fatigue
- Weight loss
- Impaired concentration
- Chronic HCV
- Alcohol intake
- Substance use
- Antiretroviral (ARV) medications that may cause hepatotoxicity (e.g., didanosine, protease inhibitors, nevirapine, maraviroc)
- Medications with potential for hepatotoxicity or accumulation in persons with liver disease (e.g., acetaminophen, benzodiazepines, opiates)

O: Objective

Measure vital signs.

Perform a physical examination to include evaluation of the following:

- Head, ears, eyes, nose, throat (HEENT): temporal wasting, icterus, gum bleeding
- Heart and lungs: signs of congestive heart failure
- Chest: gynecomastia
- Abdomen: caput medusa, venous prominence, distention, signs of ascites, hepatomegaly, splenomegaly
- Extremities: edema
- Neurologic: alertness, mental status, asterixis
- Skin: jaundice, palmar erythema, petechiae, ecchymoses, spider angiomas

P: Plan

HBV Testing

As discussed above, all HIV-infected persons should be screened for HBV surface antigen (HBsAg), HBs antibody (HBsAb), and HBV core antibody (total) (HBcAb-total) and be vaccinated if not immune (see chapter *Immunizations for HIV-Infected Adults and Adolescents*).

Nonimmune persons with elevated transaminases or signs or symptoms of acute or chronic liver disease should be retested for HBV and HCV infection.

Interpreting HBV test results

Routine baseline HBV serologic screening tests for HIV-infected individuals are outlined in Table 1.

Markers of chronic hepatitis B can manifest in a number of patterns (see Table 1).

Table 1. Interpreting HBV Laboratory Tests

	Acute Hepatitis B	Recovery from Acute Hepatitis B	Chronic HBeAg+ Disease	Chronic HBeAg- Disease	Occult Hepatitis B	Successful Vaccination	Isolated HBeAb
HBsAg	X (may clear)		X	X			
Anti-HBs		X				X	
Anti-HBc IgM	X (may be the only marker during window period)						
Anti-HBc	X	X	X	X	X		X
HBeAg	X		X		X		
Anti-HBe		X (in some cases)		X			X (in some cases)
DNA* (PCR if required)	X		X	X	X		(in rare cases, may be +)

* Absence of detectable HBV DNA does not rule out chronic HBV infection in patients who are on ARVs with anti-HBV activity.

Because of the complexity of HBV diagnosis and test interpretation, it is important to test for HBsAg, HBeAb, and HBsAb. If the result for either HBsAg or HBeAb is positive, then test for HBV DNA. The presence of HBsAg for >6 months indicates chronic HBV infection, but detectable HBV DNA is required for the diagnosis. HBV DNA should be tested before initiation of ART, if possible, as NRTIs with anti-HBV activity may suppress HBV viremia and interfere with diagnosis. Some persons with HIV infection can have chronic HBV infection with high HBV DNA levels and hepatic inflammation while testing negative for HBsAg and positive only for HBeAb. This sometimes is termed “occult hepatitis B infection.” Patients with chronic HBV may test either positive or negative for HBeAg. Patients with inactive chronic HBV are positive for HBsAg but have persistently normal ALT levels, low-level or no detectable HBV DNA, and negative HBeAg results. Ongoing viral replication and infectiousness is indicated by the presence of HBV DNA or a positive result for HBeAg.

Markers of immunity or previous exposure to HBV also can manifest in a number of patterns (see Table 1). Successful vaccination to HBV (in someone who has never been infected) will result in positive HBsAb but negative HBeAb results. Prior exposure to HBV may result in positive HBeAb and HBsAb findings, indicating the development of immunity. However, prior exposure may present as positive HBeAb only, with negative results for HBsAb, HBeAg, and HBV DNA. This pattern shows that the patient was previously infected with hepatitis B but did not develop chronic infection, and lost the HBsAb. This sometimes is termed “isolated core Ab,” and it is seen more commonly in patients coinfecting with HIV or HCV. It is not known whether patients who display this pattern would have sufficient immunity to ward off another HBV infection if they were reexposed; current guidelines recommend the standard HBV vaccination series, followed by a check of HBsAb.

In acute HBV infection, HBV DNA will be detectable before HBsAg, if highly sensitive nucleic acid testing is used. Otherwise, HBsAg is the only marker detected during the first 3-5 weeks after infection. HBcAb develops at approximately 6 weeks after infection and both immunoglobulin M (IgM) and immunoglobulin G (IgG) will be evident. The IgM will decline within 6 months but the IgG will persist for life. Among individuals who recover from acute HBV infection, HBeAg typically seroconverts to HBeAb at approximately 3 months whereas, for those who develop chronic HBV infection, HBeAg typically persists for years.

Diagnostic Evaluation of Acute HBV Infection

When approaching the diagnosis of a patient with acute hepatitis B infection, the following steps should be taken:

1. Obtain history and perform physical examination.

Determine the time and route of infection if possible. Take a complete history, including HIV disease course and treatment, and other medical history. Perform physical examination, focusing on evidence of acute liver dysfunction.

2. Assess HBV replication serially.

As soon as acute infection is suspected, check HBsAg, HBV DNA, HBeAg, HBeAb, ALT, HBcAb-IgM, and HBsAb. HBsAg usually can be detected by 4 weeks (the range of detectability is 1-9 weeks). HBcAb-IgM is detectable at the onset of symptoms.

When ALT is abnormal and rising, additional tests of liver function should be serially evaluated until it is clear that ALT is trending back down. Tests should include albumin, total bilirubin, prothrombin time, and platelet count.

3. Determine whether HBV infection resolves or persists as chronic HBV infection.

If the HBsAg is still present at 6 months after acute infection, the HBV infection has persisted and the patient has chronic hepatitis B infection.

Initial Diagnostic Evaluation of Chronic HBV Infection

When approaching the diagnosis of a patient with chronic HBV infection, the following steps should be taken:

- Take a complete history, including family history of HBV or HCC, and HIV disease course and treatment. Perform physical examination.
- Assess HBV replication to determine HBV DNA level, HBeAg and HBeAb serostatus, and ALT level. Note that HBV DNA levels may be difficult to interpret in patients who are on ARVs that have anti-HBV activity (HBV level may be low or undetectable because of these medications).
- Assess liver disease – check complete blood cell count with platelet count, albumin, total bilirubin, transaminases (especially ALT), and prothrombin time.
- Assess for possible overlying liver diseases (e.g., HCV, alcoholic liver disease, fatty liver disease).
- Consider liver biopsy to assess histological degree of inflammation and fibrosis, especially if the result would affect the decision to use treatment.
- Screen for HCC at baseline via ultrasound.
- Test for hepatitis A antibodies (IgG) and vaccinate against hepatitis A if not immune.

Long-Term Monitoring of Chronic HBV Infection

It should be noted that current HHS guidelines strongly recommend treatment of both HIV and HBV in all coinfecting persons. Nonetheless, some patients may wish to defer treatment or may not tolerate treatment. For those patients who are not on treatment for HBV, regular monitoring of HBV replication and liver function should be performed.

For patients with the following seromarkers, recommendations are as indicated:

Negative HBeAg, low ALT, and low-level DNA (<2,000 IU/mL) (inactive HBV):

HBV DNA, HBeAg, and ALT testing should be performed every 3 months for the first year to determine whether the virus is truly inactive. If it remains inactive (with negative HBeAg, normal ALT, and low-level DNA), monitoring can continue every 6-12 months; some specialists recommend more frequent monitoring.

Negative HBeAg, elevated ALT, and high HBV DNA (>20,000 IU/mL):

Biopsy should be considered, and treatment should be considered. If treatment is not started, monitoring should occur every 3 months.

Negative HBeAg, moderately elevated ALT, and moderately elevated DNA (2,000-20,000 IU/mL):

Follow-up should be performed every 3-6 months if treatment is not started.

Positive HBeAg, moderately elevated ALT:

Monitoring should be performed every 3 months and, if ALT is persistently elevated, a biopsy should be considered to guide the decision regarding initiation of HBV treatment.

Positive HBeAg, high HBV DNA (>20,000 IU/mL) but low-level ALT:

Monitoring should be performed every 3-6 months to check for changes in ALT. If ALT rises significantly, treatment should be considered.

Cirrhosis:

Treatment should be considered. For patients who are not treated, monitoring should be performed every 3-6 months.

Antiviral Treatment of Chronic HBV Infection

HHS ARV guidelines and Centers for Disease Control and Prevention opportunistic infection guidelines recommend treatment of both HIV and HBV in all coinfecting persons. The goals and markers of HBV treatment for HIV/HBV-coinfecting patients are the same as for HBV-monoinfecting patients.

The goals of treatment are as follows:

- To decrease progression of liver disease
- To prevent development of cirrhosis
- To prevent development of HCC

Treatment endpoints for the HBV/HIV-coinfecting population are not well defined but efficacy is determined by the following measures:

- HBeAg seroconversion to HBeAb (this is harder to achieve for coinfecting patients than for HBV-monoinfecting persons)
- HBV DNA suppression
- ALT normalization, which usually follows the changes in HBV DNA

The timing of treatment and choice of treatment for HBV/HIV-coinfecting patients are important.

Treatment for HIV and HBV:

- All HIV/HBV coinfecting patients should be treated for both HIV and HBV infections, if possible.
- If treatment for HIV is to be started, HBV should be treated concurrently with the HIV by using a potent ART regimen that includes two NRTIs that are active against both viruses (tenofovir + emtricitabine or tenofovir + lamivudine), if possible. If tenofovir is contraindicated, entecavir or another anti-HBV drug should be used (with emtricitabine or lamivudine) to construct a two-drug therapy for HBV, and the HIV ART regimen should be designed for complete HIV suppression (see Table 2). In this situation, liver biopsy to stage disease is not necessary because HBV treatment will be undertaken (incorporated into the HIV regimen). Note that treatment of HBV with a single NRTI is not recommended, because of the risk of HBV resistance; if tenofovir cannot be used, entecavir (plus combination ART) is the preferred alternative (see Table 2).
- Most patients receiving ART who are treated for HBV will require HBV treatment indefinitely (lifelong).

Treatment for HBV alone:

- If HBV treatment is indicated, HIV infection should be treated concurrently, if possible, as stated above. If treatment for HIV is deferred, the hepatitis B should be treated if the patient otherwise meets criteria for HBV treatment (see below).
- Inactive chronic hepatitis B (HBV DNA is <2,000 IU/mL, HBeAg is negative, and ALT is not elevated): the HBV can be monitored and does not require treatment.
- HBeAg positive, ALT is more than two times the upper limit of normal (ULN), and HBV DNA >20,000 IU/mL: consider HBV treatment.

- HBeAg negative, ALT is more than two times the ULN and HBV DNA >2,000 IU/mL: consider HBV treatment.
- HBeAg positive, HBV DNA >20,000 IU/mL, but ALT is less than two times the ULN: can use a biopsy to determine the need for HBV treatment.
- HBeAg negative, DNA >2,000 IU/mL, but ALT is less than two times the ULN: can use a biopsy to determine the need for HBV treatment.
- Any patient with cirrhosis (if not decompensated) and a detectable DNA level: should be considered for HBV treatment, regardless of HBeAg status and regardless of ALT level.
- Patients with decompensated cirrhosis should not be treated for HBV but should be referred for transplant.
- Some specialists recommend HBV treatment for all patients with detectable HBV DNA, particularly if ALT is elevated or inflammation or fibrosis is seen on liver biopsy.
- If a decision is made to treat HBV but not HIV, HBV treatment should not include agents that are dually active, as that could lead to early HIV resistance. This limits choices to pegylated interferon alfa-2a (although it has not been studied in HIV/HBV-coinfecting patients) or adefovir dipivoxil. Tenofovir, lamivudine, emtricitabine, entecavir, and telbivudine should not be used as monotherapy for HIV/HBV-coinfecting patients, because HIV (and HBV) resistance may develop (see Table 2).

Table 2. Antiviral Therapies for Chronic HBV Infection

	Lamivudine	Emtricitabine	Tenofovir	Adefovir	Entecavir	Telbivudine	Pegylated Interferon
Dual activity against HBV and HIV	Yes	Yes	Yes	No (at the low HBV treatment dosage), but theoretical concern remains	Yes	Possibly	No
Recommended for use in HIV/HBV coinfection	With tenofovir, as part of fully suppressive ART	With tenofovir, as part of fully suppressive ART	With lamivudine or emtricitabine, as part of fully suppressive ART	If HIV is not being treated, or in combination with a lamivudine- or emtricitabine-containing ART regimen, if tenofovir is not used	With fully suppressive ART	With fully suppressive ART	If HIV is not being treated
Loss of HBV DNA	40-44%		76%	21%	67%	60%	25%
HBsAg seroconversion	16-21%		21%	12%	21%	22%	27-32%
Class	Nucleoside analogue	Nucleoside analogue	Nucleotide analogue	Nucleotide analogue	Nucleoside analogue	Nucleotide analogue	Interferon

Additional points about treatment for HIV/ HBV-coinfected patients:

- When lamivudine is used as a single agent, HBV resistance develops in many patients by 1-2 years. Although combination therapy has not been well studied, specialists recommend using dual-NRTI combinations that have activity against HBV (lamivudine + tenofovir, or emtricitabine + tenofovir [Truvada]) as part of the ARV regimen, to treat HBV and to prevent HBV resistance.
- Some patients treated with ART may experience worsening of HBV symptoms

and laboratory markers in the weeks after ART initiation, because of immune reconstitution inflammatory reactions. Hepatic decompensation owing to immune reconstitution must be distinguished from other causes, such as medication toxicity, or other infection. Liver function tests should be monitored closely for patients starting ART.

- Some ARV medications are hepatotoxic and should be avoided or used cautiously. These include nevirapine, tipranavir, and high-dose ritonavir. Numerous other medications (e.g., fluconazole, isoniazid) are hepatotoxic

and can pose problems for patients with impaired liver function.

- Discontinuation of HBV medications in patients with HIV/HBV coinfection may cause a flare of liver disease. Be very cautious when discontinuing HBV-active medications from an anti-HIV ART regimen. If the HBV DNA is suppressed, options include continuing the HBV-active ARVs, even if there is HIV resistance (modify the other parts of the ART regimen for maximal HIV suppression) or substituting other HBV-active medications to avoid rebound liver inflammation and decompensation. For example, if it is decided to discontinue a lamivudine/tenofovir-containing regimen in an HIV/HBV-coinfected patient on ART, consider starting interferon or possibly adefovir to maintain activity against HBV. If HBV therapy is discontinued and a flare occurs, consider reinstating HBV therapy as soon as possible.
- Limited data exist on treatment of HBV in the setting of HIV and HCV. Consider consultation with an expert if optimal timing for treatment of the three infections is not clear.

Screening for HCC in patients with chronic HBV infection:

Persons with chronic HBV are at increased risk of developing HCC. Note that HCC may occur even in the absence of cirrhosis. HCC screening should be performed every 6-12 months using ultrasound (computed tomography [CT] is an alternative); alpha-fetoprotein should be monitored if ultrasound reliability is low.

HBV-infected patients who should be screened for HCC include the following:

- Anyone with cirrhosis
- Anyone over age 40 with elevated ALT or HBV DNA level of >2,000 copies/mL
- Asian men aged >40

- Asian women aged >50
- Persons of African descent aged >20
- Anyone with a family history of HCC

Interventions to slow progression and prevent complications

Persons with HCV infection should be counseled to avoid exposure to hepatotoxins, including alcohol and hepatotoxic medications (e.g., acetaminophen in large doses, fluconazole, isoniazid). Heavy alcohol use is a risk factor for increasing rate of fibrosis. It is not clear what degree of alcohol consumption is safe, so many experts recommend complete abstinence from alcohol.

- No specific dietary measures are recommended.
- Patients who are not already immune to hepatitis A should be vaccinated against hepatitis A.
- Patients should be counseled on ways to avoid infection with hepatitis C.

Preventing transmission

All patients with HBV infection should receive individualized counseling on ways to reduce the risk of HBV transmission (including by sexual or needle-sharing behavior, perinatal routes, or household exposure), as appropriate.

Household members and sexual contacts should be vaccinated against HBV.

Women who are pregnant or considering pregnancy should consult with a specialist in both HBV and HIV to discuss ways of decreasing the infection risk for the fetus; this may include treatment for HBV and HIV. Infants born to coinfecting women should receive HBV immune globulin and start the HBV vaccine series within 12 hours after birth (with subsequent vaccine doses per usual protocol).

Patient Education

- Advise patients that most people with HBV will remain asymptomatic for several years. However, ongoing injury to the liver occurs during this time and can culminate in liver failure. Patients can slow the progression of damage by avoiding alcohol and any medications (including over-the-counter drugs and recreational drugs) that may damage the liver. Patients should contact their pharmacist or health care provider if they have questions about a specific medication or supplement.
- Advise patients that treatment for both HIV and HBV is recommended for anyone with HIV/HBV coinfection. ART can be used to treat both infections.
- As with HIV, patients must avoid passing HBV to others. Instruct patients not to share toothbrushes, dental appliances, razors, sex toys, tattoo equipment, injection equipment, or personal care items that may have blood on them. Emphasize to patients the importance of safer sex to protect themselves and their partners.
- Tell patients to discuss HBV with their sex partners, and suggest that partners be tested for HBV.
- Nonimmune sex partners and individuals in close contact with persons with chronic hepatitis B (e.g., family and household members) should be vaccinated.
- Pregnant women have a high risk of transmitting HIV or HBV to the fetus because each virus makes it easier to transmit the other. Women who are pregnant or considering pregnancy should talk with a specialist in HIV and HBV to discuss ways of decreasing the infection risk for the fetus.

- Advise patients who are on treatment for HBV that abrupt discontinuation of HBV treatment can cause a flare of HBV; they should not stop treatment without medical supervision.
- Certain ARV drugs are more likely than others to cause hepatotoxicity. Advise patients that their liver function should be monitored carefully if they start an ARV regimen, in order to determine whether the body is able to process the medicines.

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Hepatitis C Infection

Rena K. Fox, MD

Background

In the United States, an estimated 2.7-3.9 million people are living with chronic hepatitis C virus (HCV) infection. Without treatment, 15% to 40% of persons living with the virus will develop cirrhosis or cancer, and HCV is the leading cause of liver transplantation in the United States. Hepatitis C-related mortality has been steadily increasing in recent years, and as the baby boomer generation ages, the rates of cirrhosis and hepatocellular carcinoma (HCC) are expected to rise.

As antiretroviral therapy (ART) has reduced AIDS-related mortality among HIV-infected patients, liver disease owing to HCV infection has become a leading cause of death and the sequelae of chronic HCV have increased. HCV is common among persons with HIV infection in the United States. It is estimated that 20-30% of the HIV-infected population in the United States is coinfecting with HCV, but the prevalence varies with risk factor for transmission. Among HIV-infected injection drug users and hemophiliacs, 70-95% may be coinfecting with HCV; among HIV-infected men who have sex with men (MSM), 1-12% are coinfecting with HCV. The U.S. Centers for Disease Control and Prevention and the U.S. Public Health Service recommend that all HIV-infected persons receive screening for HCV.

HCV is a single-stranded RNA virus that is transmitted mainly through blood exposure and, less commonly, through perinatal or sexual exposure. HCV is more likely than HIV to be transmitted via a bloodborne route; there is an approximately 10-fold greater risk of HCV transmission after needlestick exposure compared with the risk of HIV transmission, and the concentrations of HCV in a given volume of blood are greater than those of HIV. Perinatal transmission of HIV is more likely among women who are coinfecting with HIV and HCV than among women with HIV infection alone; similarly, perinatal transmission of HCV is more likely in coinfecting women than in those with HCV monoinfection. Breast-feeding is not known to transmit HCV, although HIV-infected women are advised against breast-feeding because of the risk of transmitting HIV.

Although sexual transmission of HCV is not efficient, 10% of acutely HCV-infected persons report no risk factor other than sexual contact with an HCV-infected partner. Many centers have reported an increase in acute HCV in MSM, and rates of sexual transmission of HCV appear to be higher in MSM than in the general population, especially among persons who are coinfecting with HIV. In HIV-infected MSM, outbreaks of acute HCV have been reported, with sexual activity as the risk factor for transmission. Risk factors associated with sexual transmission of HCV include the presence of coexisting sexually transmitted diseases, unprotected anal receptive sex, and use of recreational drugs.

The natural history of HCV infection is variable. Approximately 20% of monoinfected patients ultimately develop cirrhosis, whereas approximately 80% of patients develop some degree of fibrosis (without progression to cirrhosis); patients without cirrhosis typically remain asymptomatic. HCV can affect organ systems outside the liver, such as dermatological and renal systems, but its effects most commonly are limited to the liver. Coinfection with HIV adversely impacts the natural history of HCV infection. HIV/HCV-coinfecting patients have lower rates of spontaneous HCV clearance, higher HCV viral loads, lower rates of successful HCV treatment with interferon and ribavirin, faster progression to cirrhosis, and greater risk of developing liver decompensation, end-stage liver disease, and hepatocellular carcinoma (HCC). On the other hand, HCV coinfection does not appear to increase HIV- and AIDS-related complications or the success of HIV antiretroviral (ARV) treatment.

Acute HCV Infection

Persons with acute HCV infection typically are asymptomatic or have only mild symptoms. Patients who do present with new onset of jaundice, weakness, anorexia, abdominal pain, or malaise without a known cause should be tested for acute HCV infection. Symptoms usually subside after several weeks. Patients who present after a potential exposure, such as a needlestick injury, should be tested for acute infection whether or not they are symptomatic. Overall, approximately 15-30% of patients acutely infected with HCV will clear the virus spontaneously, and 70-85% of patients will develop chronic infection. However, there are few prospective studies on the natural history of acute HCV infection with preexisting HIV infection. Because it is difficult to establish the precise timing of HCV infection, prospective natural history studies are difficult to perform.

Chronic HCV Infection

For the majority of HCV patients, other than laboratory abnormalities, there are no clinical manifestations of infection until the late stages of cirrhosis. Cirrhosis develops in approximately 20% of HCV-monoinfected patients, usually 20 years or more from the time of infection. A higher proportion of HIV/HCV-coinfected patients are thought to develop cirrhosis, and at a faster rate. Once patients have developed cirrhosis, approximately 50% will decompensate within the first 5 years. Typically, the first sign of decompensation is the development of ascites. Of patients with cirrhosis, approximately 1-4% per year will develop HCC, or approximately 20% of cirrhotic patients in total. The median survival time from the onset of HCC is approximately 5 months, and the 1-year survival rate is 29%.

S: Subjective

Patients with HCV infection, whether acute or chronic, often have no symptoms, and the infection is discovered via screening tests or on workup of an abnormal liver test result. Patients with acute HCV infection typically are asymptomatic but may present with symptoms such as jaundice, abdominal pain, and malaise. If symptoms from acute infection develop, they usually do so within 4 weeks after infection has occurred. Most patients with chronic HCV cannot recall a time when they were acutely symptomatic, and HCV is detected because of an incidental finding of abnormal transaminases or through a screening test.

Ask patients with known chronic HCV infection about symptoms that suggest complications of HCV, such as cirrhosis, decompensated cirrhosis, or hepatocellular carcinoma. Additionally, ask patients about any risk factors for other liver injury, such as alcohol and hepatotoxic drugs, and about drugs whose metabolism may be affected by liver disease.

- Fatigue
- Weight loss
- Impaired concentration
- Chronic hepatitis B
- Alcohol intake
- Substance use
- ARVs that may cause hepatotoxicity (e.g., didanosine, protease inhibitors, nevirapine, maraviroc)
- Medications with potential for hepatotoxicity, or accumulation in persons with liver disease (e.g., acetaminophen, benzodiazepines, opiates)

O: Objective

Measure vital signs. Calculate body mass index (see chapter *Initial Physical Examination*).

Perform physical examination to include evaluation of the following:

- Head, eyes, ears, nose, and throat (HEENT): temporal wasting, icterus
- Heart and lungs: signs of congestive heart failure

- Chest: gynecomastia
- Abdomen: caput medusa, venous prominence, distention, signs of ascites, hepatomegaly, splenomegaly
- Extremities: edema
- Neurologic: alertness, mental status, asterixis
- Skin: jaundice, palmar erythema, petechiae, ecchymoses, spider angiomas

P: Plan

Diagnostic Evaluation

Acute HCV infection

After initial exposure, HCV RNA can be detected in blood within 1-3 weeks and is present at the onset of symptoms. Antibodies to HCV can be detected in only 50-70% of patients at the onset of symptoms, but in >90% after 3 months. Within an average of 4-12 weeks, liver cell injury is manifested by elevation of serum alanine aminotransferase (ALT). It is important to understand the timeline of these diagnostic tests in order to appropriately diagnose acute infection and follow for potential resolution versus persistent infection.

In patients with suspected acute HCV infection, check HCV antibody (IgG), HCV RNA, and ALT immediately and then weekly until the ALT has begun to decline and HCV antibody has seroconverted to positive status; consider checking interleukin-28B (IL28B) (see below). The seroconversion of HCV antibody establishes the diagnosis of acute infection. At that point, check the HCV RNA every 2-4 weeks for the following 3 months. If HCV RNA is still present at 3 months, strongly consider prompt initiation of treatment for acute HCV. If treatment is not initiated and RNA is still present at 6 months after infection, the likelihood of spontaneous clearance is extremely low, and the patient is diagnosed with chronic infection.

Chronic HCV Infection

The following tests are part of the evaluation of HCV infection.

HCV antibodies

All HIV-infected patients should be tested for HCV infection with the HCV antibody test. Patients with risk factors for HCV infection who test negative should be retested at regular intervals. A positive HCV antibody test result does not establish the diagnosis of active HCV infection but is evidence of exposure; HCV RNA must be checked (see below). In HIV-infected patients, the HCV antibody test result can be falsely negative, although this is rare. Therefore, if HCV infection is suspected in spite of a negative HCV antibody finding (e.g., because of a history of high-risk behavior, unexplained elevated ALT, or evidence of cirrhosis), the HCV RNA should be tested even if the HCV antibody result is negative.

HCV RNA

All patients who test positive for HCV antibody should have HCV RNA testing performed. As noted above, if patients have negative results on HCV antibody tests but persistently abnormal transaminases or suspected acute or chronic infection, HCV RNA testing should be performed.

The definition of chronic HCV infection is the presence of HCV RNA 6 months after the estimated time of infection. If a patient is HCV antibody positive but HCV RNA negative, the patient has cleared the HCV and does not have chronic HCV infection. False-positive HCV antibody results are possible but rare; they are more likely to occur in the setting of autoimmune disease.

There are quantitative RNA tests and qualitative RNA tests. Although both types of RNA tests are highly sensitive and specific, the qualitative tests can detect lower levels of viremia than the quantitative tests. The choice of RNA test can be important. The quantitative RNA tests will be reported as a value, with a measured

number of international units per milliliter (IU/mL). Quantitative tests are useful for determining the prognosis of HCV treatment and then monitoring while on HCV treatment. Qualitative RNA tests will be reported as a present or absent value, but without a numerical value. They are useful for serial testing during suspected acute infection and for determining whether spontaneous viral clearance has occurred, a sustained virological response has occurred during treatment, or a relapse has occurred after treatment.

Genotyping

There are six main HCV genotypes, numbered 1-6. Genotype 1 infections account for approximately 75% of HCV infections in the United States. In the absence of treatment, HCV genotypes are not associated with prognosis or progression of liver disease. However, the HCV genotype is one of the strongest predictors of response to HCV treatment and is a major factor in determining the appropriate treatment regimen for a patient. HCV genotyping should be performed once for all patients with detectable HCV RNA; it does not need to be repeated.

Subtyping

HCV genotypes are further divided by subtypes. Subtypes are termed 1a, 1b, 2a, 2b, among others. Subtypes are newly being recognized as predictors of treatment response, particularly with genotypes 1a and 1b. Additionally, a polymorphism, Q80K, in genotype 1a patients may become clinically significant in determining treatment regimens using some of the new HCV drugs.

IL28B testing

IL28B is a host genetic polymorphism on chromosome 19. Three different IL28B polymorphisms exist: C/C, C/T, and T/T. Patients with C/C type have higher rates of spontaneous clearance after acute HCV

infection, and much higher response rates to interferon-based HCV treatment, whereas patients with the C/T or T/T genotype have lower rates of spontaneous clearance and much lower response rates to treatment with interferon. With non-interferon-based regimens, the role of IL28B has not yet been determined. In regimens containing either sofosbuvir (with or without pegylated interferon) or simeprevir (with interferon), better response rates were seen in patients with IL28B CC than in those with non-CC types, but the differences were much less dramatic than in older regimens.

Alanine aminotransferase

Monitoring of ALT can be useful to assess acute infection, chronic liver inflammation, and response to HCV treatment. However, ALT does not always correlate with the degree of fibrosis; in addition, ALT can be persistently normal in 25% of HCV patients, including patients with cirrhosis or advanced liver disease. Small fluctuations in ALT usually are not clinically significant in HCV, though trends can be significant during or following HCV treatment.

Additional tests

Check complete blood cell count with platelet count, albumin, total bilirubin, and prothrombin time.

Test all patients for hepatitis B (HBsAg, anti-HBsAb, and anti-HBcAb). For patients with a positive HBsAg or a positive anti-HBcAb result (absent anti-HBsAb), test for active HBV infection (HBV DNA and HBeAg) (see chapter *Hepatitis B Infection*). Patients with a negative HBsAg and negative anti-HBsAb result should be vaccinated against HBV.

Test for hepatitis A virus (HAV) anti-bodies (IgG or total). All patients with a negative HAV antibody result should be vaccinated against HAV.

Imaging

Ultrasonography can be performed to screen for indications of cirrhosis or focal hepatic masses. Repeated ultrasound every 6 months to screen for HCC is recommended for patients with known cirrhosis or advanced fibrosis (stage 3). For noncirrhotic patients, regular repeated ultrasound is not recommended. Computed tomography (CT), magnetic resonance imaging (MRI), and single-photon emission computed tomography (SPECT) are more expensive and generally are reserved for further evaluation of liver masses detected by ultrasound.

Fibrosis staging

For any patient with HCV, it is useful to determine the degree of fibrosis (scarring) in the liver. Fibrosis stage is one of the most important pieces of information in determining a patient's need for HCV treatment. Fibrosis is scored from F0 to F4, with 0 indicating no fibrosis and F4 indicating cirrhosis.

Tools that may be used to determine the severity of chronic liver disease include biopsy, imaging, and serologic tests.

For HIV/HCV-coinfected patients, liver disease may progress quickly. A biopsy or other fibrosis test may be useful in determining the stage of disease and in planning whether or when to initiate HCV treatment. If the test reveals more advanced fibrosis or cirrhosis, treatment should be considered relatively urgently, using currently available therapeutics. Conversely, if the test reveals only mild-to-moderate fibrosis, it may be preferable to defer treatment and monitor the patient, particularly as more effective and more tolerable therapies are anticipated to become available within the next few years.

Liver biopsy

Liver biopsy is used to define the degree of inflammation (the grade) and degree of fibrosis (the stage) to determine the need for HCV treatment. Biopsy has been the gold

standard method, and is the main technique used in the United States. Liver biopsy carries some risk, primarily from bleeding (the risk of significant bleeding or fatality is approximately 1/10,000). Patients with severe thrombocytopenia or coagulopathy should not undergo liver biopsy.

As HCV therapies evolve and demonstrate higher response rates, a biopsy may prove less of a determinant of when to initiate treatment than in years past. At this time, with few directly acting agents (DAA) available, biopsy may still be useful for determining whether a patient can safely wait for more effective regimens.

Fibroscan

Several noninvasive tests to determine fibrosis have been developed. Fibroscan (elastography) is a radiology test used to assesses liver shear wave speed (expressed in meters per second) and equivalent stiffness (expressed in kilopascal) in a rapid, simple, noninvasive, and painless way. The FDA approved the Fibroscan in 2013. For diagnosing cirrhosis (stage F4), the sensitivity and specificity were 87% and 91%, respectively, whereas for diagnosing moderate stages of fibrosis (F2-F3), the sensitivity and specificity were 70% and 84%, respectively.

Serologic tests

Several different scoring systems have been developed to estimate the degree of liver fibrosis based on serum biomarkers and other patient factors. For example, the Fibrosure test uses the measurements of alpha-2-macroglobulin, alpha-2-globulin (haptoglobin), gammaglobulin, apolipoprotein A1, GGT, and total bilirubin, as well as the age and sex of the patient. The currently available serologic tests are not as accurate as liver biopsy in distinguishing different stages of fibrosis, and none of these have been FDA approved.

Treatment

Overview of the Treatment of HCV

The goal of HCV treatment is to clear the HCV RNA from the bloodstream – making the virus undetectable – in order to slow or halt inflammation, fibrosis, and progression of liver disease, and to reduce risk of cirrhosis and HCC. Treatment success is defined as a sustained virological response (SVR). SVR is achieved when the HCV RNA becomes undetectable during treatment and remains undetectable after the completion of treatment. Originally, SVR was defined as the absence of HCV RNA 24 weeks (“SVR24”) after the completion of treatment. SVR12 (12 weeks after the end of treatment) is 99% predictive of SVR24, so recent studies often report this as the outcome measure. SVR correlates with clinical outcomes such as decreased risk of decompensation, decreased risk of HCC, and decreased risk of liver-related death. Most experts consider SVR to represent “cure” of HCV. It is important, however, to remember that this is a cure of the chronic viral hepatitis infection, but it is not the same as “curing” the damage to the liver.

Pegylated interferon and ribavirin

The standard of care in the treatment of chronic HCV from 2001 to 2011 was the combination of pegylated interferon (PEG-IFN) alfa-2a and ribavirin, for both HCV-monoinfected and HIV/HCV-coinfected patients. Response rates varied by host and viral factors, among them HIV coinfection, HCV genotype, stage of liver disease, HCV viral load, race/ethnicity, and IL28B type. Overall, HCV-monoinfected genotype 1 patients have had SVR rates of 42-46% and monoinfected genotype 2/3 patients have had SVR rates of 70-80% with PEG-IFN + ribavirin. HIV/HCV-coinfected patients have had much lower response rates, in the range of 14-38%. Treatment was limited by these poor response rates as well as by multiple complete

and relative contraindications to interferon or ribavirin, multiple side effects of both drugs but especially interferon, and the cost and complexity of care for both patients and providers.

Telaprevir and Boceprevir

In 2011, the HCV protease inhibitors boceprevir and telaprevir were approved for genotype 1 HCV. These were the first direct acting antivirals (DAAs) available for treatment of HCV. With use of these agents in combination with PEG-IFN and ribavirin, treatment response rates in HCV-monoinfected genotype 1 patients were much higher than with PEG-IFN + ribavirin alone. In HIV/HCV-coinfected patients, smaller studies of boceprevir and telaprevir (plus PEG-IFN and ribavirin) have shown SVRs in the range of 60-75%, substantially higher than with standard therapy. These triple-therapy regimens, however, are complex and burdened with adverse effects and drug interactions.

Sofosbuvir

Sofosbuvir is an HCV polymerase inhibitor that was FDA approved in late 2013 for treatment of HCV in both HIV-coinfected and HCV-monoinfected patients with genotypes 1-4. It is approved for use with ribavirin alone (for genotypes 2 and 3) or with PEG-IFN + ribavirin (for most patients with genotypes 1 and 4), using specific protocols. It also is being studied in combination with other HCV medications, including in several interferon-free regimens. Use of sofosbuvir-containing regimens has resulted in very high SVR rates (80% to >90%) with 12 or 24 weeks of therapy, in both treatment-experienced and treatment-naive patients and in cirrhotic patients. Few significant drug-drug interactions with ARVs have been identified.

Simeprevir

Simeprevir is a HCV protease inhibitor that was FDA approved in late 2013 for treatment of genotype 1 HCV, in combination with PEG-IFN and ribavirin. Study data have shown SVR rates of 82% in treatment-naïve genotype 1 noncirrhotic patients and 58-65% in cirrhotic individuals treated with simeprevir + PEG-IFN + ribavirin. Among patients with the IL28B CC type, 95% achieved SVR. Simeprevir also is being studied in interferon-free regimens.

Simeprevir has markedly reduced efficacy in patients with the Q80K polymorphism, and screening for this is recommended before treatment. Simeprevir also has significant drug-drug interactions with some ARVs, in particular many protease inhibitors, nonnucleoside reverse transcriptase inhibitors, and the pharmacokinetic enhancer cobicistat.

Expansion of DAAs

In 2014-15, several additional HCV DAAs and combinations of DAAs are expected to be considered for FDA approval; many have the potential to be used in regimens that do not include interferon.

Treatment of acute HCV

As mentioned above, in the setting of acute HCV infection, RNA should be tested repeatedly for 12 weeks from the time of infection to ascertain whether spontaneous clearance will occur. If RNA is still present at 12 weeks, treatment should be offered.

With HIV/HCV-coinfected patients, as with HCV-monoinfected patients, early treatment of acute HCV infection yields a much higher rate of SVR than does treatment of chronic HCV infection. In three prospective trials of treatment for acute HCV in HIV-coinfected patients, using PEG-IFN + ribavirin for 24 or 48 weeks, the SVR for genotype 1 HCV was 55-75%, and 100% for genotype 3. By contrast, in the largest study of the same regimen for

chronic HCV treatment in HIV-coinfected patients (n = 868), the SVR was about 29% for genotype 1 and 62% for genotype 2 or 3. Currently, there are no data on the efficacy of DAAs to treat acute HCV infection in HIV-coinfected patients. Given the relatively high SVR rates that result from treatment of acute HCV with pegylated interferon and ribavirin, and the absence of data in this setting, it is not routinely recommended to use DAAs in acute coinfection at this time.

Treatment of chronic HCV

HIV coinfection is a strong indication for treatment of chronic HCV infection, because the risk of accelerated fibrosis and cirrhosis is higher for coinfecting patients. HIV-infected patients with low CD4 cell counts should not be excluded from HCV treatment on the basis of CD4 count alone; this is true particularly for patients already on ART. For timing of HCV treatment, see “Timing of HCV treatment and HIV treatment,” below. Traditional treatment of chronic HCV infection in HIV/HCV-coinfected patients with PEG-IFN + ribavirin yields lower rates of SVR than does treatment of monoinfected patients (see above), but use of newer anti-HCV medications has improved the treatment outcomes in coinfecting patients.

Patients with a high risk of progression to cirrhosis, including coinfecting patients, should receive higher priority for treatment. Patients who have developed cirrhosis but remain compensated should be treated as soon as possible if they otherwise are candidates. Patients with decompensated liver disease should not receive HCV treatment (the likely risks of treatment outweigh potential benefits); appropriate candidates can be considered for liver transplantation. Many patients with minimal fibrosis may be best served by deferring treatment, pending availability of more effective and tolerable therapy options.

Current guidelines recommend treatment of HCV genotype-1-coinfected patients with PEG-IFN + ribavirin + an HCV protease

inhibitor for 48 weeks; because of potential drug interactions between HCV protease inhibitors and antiretroviral medications, the selection of HCV protease inhibitor and ARV drugs must be made with great care (see “Drug Interactions,” below). HCV genotypes 2-6 should be treated with PEG-IFN + ribavirin. However, as discussed above, the recent FDA approval of new DAA agents and the anticipated approval of others means that the paradigm for HCV treatment is in flux. It is anticipated that currently available and anticipated HCV drugs will be combined to construct a number of effective regimens (including all-oral and “interferon-free” regimens) that can be tailored to the treatment needs of particular patients. Based on current data, the emerging era of HCV treatment is expected to be one of higher response rates, lower side-effect profiles, and perhaps shorter courses of treatment.

To determine an appropriate treatment regimen, consultation with a specialist is recommended.

HCV Directly Acting Antivirals: Classes and Agents

FDA approved:

Protease Inhibitors (NS3/4a)

- Boceprevir
- Telaprevir
- Simeprevir

Nucleoside Polymerase Inhibitors:

- Sofosbuvir

Classes with Agents under Investigation

- Protease Inhibitors (NS3/4a)
- Nucleoside Polymerase Inhibitors
- NS5A Inhibitors
- Nonnucleoside Polymerase Inhibitors

Drug Interactions

HCV protease inhibitors and other DAAs may have significant interactions with certain HIV ARVs, particularly with protease inhibitors, nonnucleoside reverse transcriptase inhibitors, and the pharmacokinetic booster cobicistat. Interactions between many DAAs and ARVs have not been studied. Known and expected drug-drug interactions need to be carefully considered before selecting an HCV treatment regimen. Consult with HIV, HCV, and clinical pharmacy specialists. Table 2 shows potential DAA-ARV interactions, based on currently available data.

Table 2. Characteristics of Directly Acting Agents and Potential Interactions with ARVs

DAA	Mechanism	Activity Against HCV Genotype	Barrier to Resistance	Potential ARV Interactions
Telaprevir	NS3/4A protease inhibitor	1	Low	- Contraindicated with all protease inhibitors except atazanavir/ritonavir - Contraindicated with elvitegravir/cobicistat - Requires increased dosage when administered with efavirenz - No dosage adjustment when used with raltegravir
Boceprevir	NS3/4A protease inhibitor	1	Low	Contraindicated with all protease inhibitors, and with efavirenz and elvitegravir/cobicistat
Simeprevir	NS3/4A protease inhibitor	1, 2, 4, 5, 6	Low	- Concentrations decreased by efavirenz, and may be decreased by etravirine and nevirapine; should not be given with these NNRTIs - Concentrations increased by darunavir/ritonavir, ritonavir, and cobicistat; should not be given with any PI or cobicistat - No clinically significant interactions with raltegravir, rilpivirine, tenofovir
Sofosbuvir	NS5B RNA polymerase inhibitor	1-6	High	- Concentrations decreased by tipranavir/ritonavir - No known clinically significant interactions with other ARVs

Adverse effects of treatment

IFN can cause fatigue, flulike symptoms, thrombocytopenia, nausea, depression, hair loss, weight changes, and many other potential side effects. IFN reduces total white blood cell counts, and can cause neutropenia. It also decreases CD4 cell counts, although the CD4 percentage usually does not change. IFN can reduce HIV RNA somewhat (by approximately 0.5 log₁₀ copies/mL).

Ribavirin can cause a hemolytic anemia, sore throat, cough, and other side effects. Zidovudine and didanosine should be avoided with patients taking ribavirin, because of the risk of compounded toxicities (anemia with zidovudine, neuropathy, lactic acidosis, liver toxicity, and pancreatitis with didanosine).

The side effects of boceprevir and telaprevir can include anemia, rash, and altered taste; telaprevir also can cause anorectal discomfort. The most commonly reported adverse effects of sofosbuvir + ribavirin regimens were fatigue, headache, insomnia, and nausea. In treatment arms containing sofosbuvir + PEG-IFN + ribavirin, side effects were similar to those reported with PEG-IFN + ribavirin, with the exception of increased rates of fatigue and nausea. The addition of simeprevir to PEG-IFN + ribavirin resulted in an increased incidence of rash including photosensitivity, pruritus, nausea, dyspnea, and hyperbilirubinemia.

HCV treatment should not be given during pregnancy, and women receiving HCV treatment should avoid pregnancy. IFN may cause fetal growth abnormalities, and

it is abortifacient in animals. Ribavirin is teratogenic, and both women and men must use two forms of contraception consistently during treatment with ribavirin and for 6 months after discontinuation of treatment. Boceprevir and telaprevir are FDA Pregnancy Category B drugs but must be used with PEG-IFN and ribavirin, which are not recommended.

Timing of HCV treatment and HIV treatment

The decision of whether and when to treat HCV among people infected with HIV must be made on an individual basis. When coinfecting patients require treatment for both infections, some experts begin with HIV treatment based on limited data that improved CD4 cell counts will enhance the response to HCV therapy, and this generally is recommended for patients with CD4 counts of <350 cells/ μ L. With patients who do not require ART urgently (e.g., because their CD4 counts are very high), consideration could be given to treating HCV first, with ART delayed until after completion of HCV treatment. This strategy is intended to simplify treatment and improve the tolerability of both therapies, though it brings the risk of HIV disease progression during HCV treatment. Patients already on ART generally should remain on ART throughout the course of HCV treatment, though regimens should be evaluated for adverse drug interactions with HCV drugs (e.g., with boceprevir and telaprevir). Consult with an HCV treatment expert to determine the appropriateness and timing of HCV treatment.

Some patients with HCV will experience worsening of hepatic function during ART, and liver function should be monitored closely. Some ARV medications are hepatotoxic and should be avoided or used cautiously; these include nevirapine, tipranavir, and high-dose ritonavir. Numerous other medications (e.g., fluconazole and isoniazid) are hepatotoxic and can pose problems for patients with impaired liver function.

Other care issues

Acute HAV or HBV infection in persons with chronic HCV can cause fulminant liver disease. All patients with HCV infection should be tested for immunity to HAV and HBV; patients who are not immune should be vaccinated.

Persons with HCV infection should be counseled to avoid exposure to hepatotoxins, including alcohol and hepatotoxic medications (e.g., acetaminophen in dosages >2 g per day, fluconazole, and isoniazid).

As appropriate, all persons with hepatitis C should receive individualized counseling on ways to reduce the risk of infecting others with HCV (including by unprotected sex, by sharing of injection drug equipment, other blood exposures [e.g., from sharing razors or tattoo equipment], and perinatal exposure).

Patient Education

- Advise patients that most people with HCV will be asymptomatic for many years and may never develop symptoms. However, slow progression of fibrosis can be happening in the absence of symptoms and can progress to cirrhosis, so ongoing monitoring is important.
- Patients can slow the development of fibrosis by avoiding alcohol and obesity, as fat in the liver can add to the liver damage.
- As with HIV, patients must avoid passing HCV to others. Emphasize the importance of safer sex to protect themselves as well as their partners. Instruct patients not to share toothbrushes, dental appliances, razors, sex toys, tattoo equipment, injection equipment, or personal care items that may have blood on them.
- Tell patients to discuss HCV with their sex partners and suggest that partners be tested for HCV.
- Women who are pregnant or considering pregnancy should talk with a specialist in HIV and HCV to discuss ways of decreasing the risk of perinatal transmission.
- HCV is not spread by coughing, sneezing, hugging, sharing food and water, or other casual contact.
- HAV can cause severe illness, liver damage, or even death in people with HCV. Patients who are not immune to HAV need to receive the two-part hepatitis A vaccination series.
- HBV can worsen liver function greatly if it is acquired in addition to HCV. Patients who are not immune to HBV need to receive the three-part hepatitis B vaccination series. If patients have been vaccinated in the past, they should have a blood test to confirm immunity.
- HCV treatment aims to clear the HCV virus from the body. That reduces risk of cirrhosis, end-stage liver disease, hepatocellular carcinoma, and liver-related death.
- HCV treatment is rapidly evolving and it is anticipated that several new regimens will be available over the next few years (2014-15). Each patient should talk to his or her health care provider about whether treatment is appropriate.
- Standard HCV treatment until 2011 included two drugs used together, pegylated interferon-alfa and ribavirin, for all patients being treated. In 2011, for genotype 1 patients, boceprevir or telaprevir became available to be used to create a triple-therapy regimen.
- In late 2013, simeprevir was FDA approved for use in combination with pegylated interferon and ribavirin for genotype 1 and 4 patients and sofosbuvir was approved for use in combination with pegylated interferon and ribavirin for genotype 1 patients and for use with ribavirin alone (interferon-free) in genotype 2 or 3 patients and some genotype 1 and 4 patients.
- Pegylated interferon can cause many side effects, including flulike symptoms, body aches, fevers, leukopenia, neuropathy, and depression. Most of these adverse effects are treatable with medications and resolve after therapy is completed.
- Ribavirin can cause side effects including rash, sore throat, and anemia.
- Multiple drug interactions are a concern for direct acting antivirals, including HIV medications. Drug-drug interactions need to be carefully considered before starting HCV treatment and choosing which HCV treatment is right for each patient.
- It is essential that both men and women who are taking ribavirin should use two forms of contraception consistently during ribavirin therapy and for 6 months after completion of treatment.

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Herpes Simplex, Mucocutaneous

Background

Herpes simplex virus (HSV) types 1 and 2 cause both primary and recurrent oral and genital disease. HSV usually appears as a vesicular eruption of the mucous membranes of the oral or perioral area, vulva, perianal skin, rectum, and occasionally the inguinal or buttock areas. The eruption develops into tender or painful ulcerated lesions that frequently are covered with a clear yellow crust. In some patients, however, the typical painful vesicular or ulcerative lesions may be absent. Persons with HIV disease and low CD4 cell counts have more frequent recurrences of HSV and more extensive ulcerations than do HIV-uninfected people. Persistent HSV eruption (lasting >1 month) is an AIDS-indicator diagnosis. HSV facilitates HIV transmission.

S: Subjective

The patient may complain of eruption of red, painful vesicles or ulcers (“fever blisters”) with or without an exudate in the mouth, on the lips (and occasionally in nares), on the genitals, or in the perianal area. The patient may complain of burning, tingling, or itching before eruption of the lesions. In the genital area, symptoms may be nonspecific without any eruption of lesions; most HSV type 1 and 2 infections are asymptomatic, yet virus still can be shed.

The vesicles will rupture and ulcerate, generally crusting over and healing in approximately 7-14 days. The lesions may be pruritic and are often painful. As immunosuppression progresses, the lesions may recur more frequently, grow larger or coalesce, and become chronic and nonhealing.

Perform a history, asking the patient about the symptoms described above, duration, associated symptoms, and history of oral or genital HSV infection.

O: Objective

Look for grouped vesicular or ulcerative lesions on an erythematous base on the mouth, anus, or external genitals, or ones that are visible on speculum or anoscopic examination. When immunosuppression is severe, lesions may coalesce into large, painful, and nonhealing

ulcerations that spread to the skin of the thighs, lips, face, or perirectal region. These chronic erosive lesions may be confused with a chronic bacterial infection or decubitus ulcer, and should prompt consideration of acyclovir-resistant HSV infection. Recurrent lesions may start atypically, first appearing as a fissure, pustule, or abrasion.

A: Assessment

A partial differential diagnosis includes the following:

- Oral: Oral aphthous ulcers
- Genital: Chancroid, syphilis, cytomegalovirus, candidiasis, drug-related eruption, trauma

P: Plan

Diagnostic Evaluation

A clinical diagnosis of HSV can be made on the basis of the patient’s symptoms and clinical appearance only if vesicles and constitutional symptoms are present, but symptoms and signs may be variable, and primary syphilis always must be ruled out. Also, HSV-1 (rather than HSV-2) is increasingly the cause of initial episodes of anogenital herpes. For these reasons, current guidelines recommend laboratory testing to establish the diagnosis of HSV and to determine its type.

For cell culture or polymerase chain reaction (PCR), obtain a specimen from a freshly opened vesicle or the base of an ulcer for culture confirmation. Note that lesions that are >72 hours old or are beginning to resolve may not show HSV in culture. Tzanck smears are not sensitive or specific.

PCR is more sensitive for detection of herpes DNA in ulcerative lesions, but is more expensive to perform and is less widely available than viral culture. If virologic test results are positive, typing should be performed to determine the type of HSV. Negative results do not rule out the possibility of HSV infection.

If cultures are negative, a sample can be taken from a fresh lesion for another culture or for PCR. In addition, type-specific serologic tests may be useful in the evaluation of symptomatic patients in whom a diagnosis of genital HSV is not clear. Current sexually transmitted disease (STD) guidelines also recommend that serologic testing be considered for HIV-infected individuals, for MSM at risk of HIV infection, and for those who present for STD evaluation if there is no history of past genital HSV diagnosis. Glycoprotein G (gG)-based serologic assays are recommended, as older assays do not reliably differentiate HSV-1 antibody from HSV-2 antibody.

In any patient who presents with genital, anal, or oral ulceration, even if the suspicion of HSV is high, syphilis serologic testing (rapid plasma reagin [RPR], Venereal Disease Research Laboratory [VDRL], enzyme immunoassay [EIA], or chemiluminescent immunoassay [CIA]) should be done (see chapter *Syphilis*).

Treatment

Empiric antiviral treatment for new-onset suspicious lesions may be initiated in the absence of laboratory confirmation, especially if symptoms are significant. Dosage reduction of the antivirals is required for patients with renal impairment.

Note: treatment recommendations reflect current CDC/NIH/IDSA opportunistic infections guidelines; the CDC STD guideline recommendations are slightly different (see “References,” below).

Orolabial lesions (5-10 days) or genital lesions (5-14 days)

- Valacyclovir 1,000 mg PO BID
- Famciclovir 500 mg PO BID
- Acyclovir 400 mg PO TID

Severe mucocutaneous HSV disease

Treat initially with acyclovir 5 mg/kg IV Q8H until the lesions have started to regress, then an oral HSV antiviral agent (as above) until all lesions have healed.

Suppressive therapy

Consider suppressive therapy for patients with frequent or severe recurrences and those with HSV-2. Treatment may be continued indefinitely. If acyclovir is used, its dosage may need to be increased to 800 mg BID or TID for individuals whose HSV episodes are not adequately suppressed by 400 mg BID. Suppressive therapy using valacyclovir reduces the risk of HSV transmission between HIV-uninfected heterosexual partners but the extent to which this is true in HIV-infected persons is unknown. Effective antiretroviral therapy (ART) also may reduce the frequency of HSV outbreaks.

- Valacyclovir 500 mg PO BID
- Famciclovir 500 mg PO BID
- Acyclovir 400 mg PO BID

Acyclovir-resistant HSV

The diagnosis of acyclovir-resistant HSV should be suspected if lesions fail to respond to 7-10 days of standard therapy and should be confirmed with culture and sensitivities. Cross-resistance to valacyclovir and ganciclovir will be present, and cross-resistance to famciclovir is likely. The usual alternative treatment is foscarnet (40 mg/kg IV Q8H); other possibilities include IV cidofovir, topical imiquimod, topical trifluridine, and topical cidofovir. An infectious disease or HIV specialist should be consulted.

HSV During Pregnancy

Acyclovir appears to be safe and effective for use by pregnant women and remains the drug of choice. Few data are available on the use of valacyclovir and famciclovir during pregnancy but they appear to be safe.

It is important to avoid peripartum transmission of HSV. For women with recurrent or new genital HSV late in pregnancy, obstetric or infectious disease specialists should be consulted, and suppressive therapy with valacyclovir or acyclovir is recommended. All women should be evaluated carefully for symptoms and signs of genital HSV at delivery.

Patient Education

- Patients should be told that HSV has no cure, but treatment can decrease symptoms and recurrences. Treatment also has been shown to decrease shedding and HSV transmission in HIV-uninfected discordant couples, but it has not been studied in HIV-infected couples. Outbreaks and viral shedding may occur at intervals for the rest of their lives but frequency generally decreases with age of infection.
- HSV may be spread through kissing (if mouth or lips are infected) and sexual contact (oral, anal, or vaginal). Most HSV is transmitted when no genital lesions are present, so it is important that patients inform their sex partners of their herpes infection before sexual activity. Patients must avoid all sexual contact when lesions are visible, because a high volume of virus is present at those times. Correct use of condoms at each sexual encounter reduces the risk of HSV transmission.
- All patients with genital HSV should be encouraged to inform their partners.
- Episodic treatment is most effective when taken early in the outbreak, so patients not taking suppressive therapy should keep medication on hand and start treatment at the first signs of a prodrome or eruption.
- Genital HSV in a pregnant woman around the time of delivery can cause severe illness in the newborn. Women should inform their obstetrician and pediatrician if they have a history of HSV or are exposed to or infected with HSV during pregnancy. Pregnant women who do not have HSV should avoid sexual practices that facilitate HSV transmission in the third trimester with partners who have HSV, and men who have HSV should avoid sexual practices that facilitate HSV transmission with pregnant women in their third trimester who do not have HSV.

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Herpes Zoster/Shingles

Background

Shingles is a skin or mucosal infection caused by the varicella-zoster virus (VZV) that occurs along a dermatome and represents a reactivation of varicella (chickenpox). Zoster is common in patients with HIV infection, including apparently healthy individuals before the onset of other HIV-related symptoms. The incidence may be higher among patients with low CD4 cell counts and during the 4 months after initiating potent antiretroviral therapy.

Zoster may be particularly painful or necrotic in HIV-infected individuals. Disseminated infection, defined as outbreaks with >20 vesicles outside the primary and immediately adjacent dermatomes, usually involves the skin and the visceral organs. Neurologic complications of zoster include encephalitis, aseptic meningitis, cranial nerve palsies, optic neuritis, transverse myelitis, and vasculitic stroke.

S: Subjective

The patient complains of painful skin blisters or ulcerations along one side of the face or body. Loss of vision may accompany the appearance of facial lesions. Pain in a dermatomal distribution may precede the appearance of lesions by many days (prodrome).

Assess the following during the history:

- Duration of pain or blisters (average of 2-3 weeks if untreated)
- Location of pain or blisters; severity of pain
- History of chickenpox (usually in childhood)

O: Objective

Perform a skin and neurologic examination to include the following:

- Vesicular lesions with erythematous bases in a dermatomal distribution; may be bullous or hemorrhagic
- Necrotic lesions; may persist for as long as 6 weeks
- Dermatomal scarring (particularly in dark-skinned individuals)
- Lesions in the eye area or tip of nose,

along the trigeminal nerve; these represent ophthalmic nerve involvement, which requires immediate evaluation and IV treatment (see below)

A: Assessment

- Rule out other causes of vesicular skin eruptions (e.g., herpes simplex virus, severe drug reactions).
- Assess contact exposures (see below).

P: Plan

Diagnostic Evaluation

The diagnosis usually is clinical and is based on the characteristic appearance and distribution of lesions. If the diagnosis is uncertain, perform viral cultures or direct fluorescent antigen or polymerase chain reaction test of samples from a freshly opened vesicle or biopsy from the border of a lesion.

Treatment

- Treatment ideally should begin within 72 hours of an outbreak or while lesions are not yet fully crusted and should be continued for 7-10 days. Early treatment may attenuate a herpes zoster attack.

Localized dermatomal zoster**• Preferred therapy**

- Valacyclovir 1 g PO TID
- Famciclovir 500 mg PO TID

• Alternative therapy

- Acyclovir 800 mg PO 5 times daily
- Dosage reductions of these drugs are required for patients with renal impairment.
- If new blisters are still appearing at the end of treatment, repeat course of PO therapy or consider IV treatment. Adjunctive corticosteroids aimed at preventing postherpetic neuralgia are not recommended.
- Consult an ophthalmologist immediately if lesions appear in the eye area or on the tip of the nose, or if the patient complains of visual disturbances, because VZV-related retinal necrosis can cause blindness. Because of the rapid progression associated with this diagnosis, hospitalization for administration of IV acyclovir and possibly foscarnet is recommended.
- VZV from zoster lesions is contagious, and contact or airborne spread from vesicle fluid may cause chickenpox in nonimmune people. If a zoster patient's household includes a pregnant woman (HIV infected or uninfected) or an HIV-infected child, consult with a specialist immediately for advice on management of exposed household members. (See "Postcontact Chickenpox Prevention," below.)
- Give analgesics for pain; narcotics may be required.
- Postherpetic neuralgia (PHN) is a common sequela of zoster. Antiviral therapy may reduce the risk of PHN, but PHN often requires special treatment for pain control. Treatment options include:
 - Nortriptyline 10-25 mg. To be taken at bedtime and increased by 25 mg every 3-5 days to a maximum dosage of 150 mg QD

until pain is controlled, assuming adverse effects remain tolerable. Other tricyclics may be used.

- Gabapentin 100-300 mg PO BID; this may be increased by 300 mg every 3 days until reaching 3,600 mg total daily dosage. Adjust gabapentin dosage in patients with kidney disease.
- Pregabalin 75 mg BID (or 50 mg TID) in patients with estimated creatinine clearance of >60 mL/minute; this may be increased to 300 mg total daily dosage over the course of a week as needed.
- Lidocaine 5% patches provide good local relief with minimal systemic absorption. Up to 3 patches may be applied simultaneously to the affected area for up to 12 hours in a 24-hour period.
- Capsaicin cream may be applied to the affected area TID or QID. Patients should wear gloves to apply the cream and wash their hands with soap and water afterward.
- Sustained-release opiates may be required.

(See chapter *Pain Syndrome and Peripheral Neuropathy* for more options and specific recommendations.)

Severe or unresponsive cases

- IV acyclovir may be indicated if:
 - The patient is severely immunocompromised
 - The ophthalmic branch of the trigeminal nerve is affected (as noted above)
 - Dissemination has occurred; visceral disease is suspected
 - Lesions are extensive
 - Lesions are not responsive to oral therapy
 - Pain is intractable in the setting of active skin lesions
- The usual adult dosage is 10-15 mg/kg Q8H for 7-14 days based on clinical response; can switch to oral therapy when signs/symptoms are improving. Dosage reduction is required

for patients with renal impairment. Refer to an infectious disease specialist.

- Acyclovir resistance may occur in patients previously treated with acyclovir or related drugs, and foscarnet may be required for effective treatment. Resistance should be suspected if lesions are not resolving after 10 days of therapy or if they develop an atypical appearance. Such lesions should be cultured and drug sensitivities should be obtained.

Prevention

The vaccine for prevention of herpes zoster (Zostavax) has not been recommended by national guidelines for use in persons with HIV infection. Limited data in HIV-infected individuals with CD4 counts of >200 cells/ μL show safety and immunogenicity. The zoster vaccination may be considered for select patients >50 years of age with CD4 counts of >200 cells/ μL who have evidence of varicella immunity (if they have no evidence of varicella immunity, give the primary varicella vaccination). The vaccine is contraindicated in persons with AIDS or clinical manifestations of HIV.

Postcontact Chickenpox Prevention

All HIV-infected susceptible persons, including pregnant women, who have close contact with a patient who has chickenpox or zoster must be treated to prevent chickenpox. Exposed individuals who have no history of chickenpox or shingles or no detectable antibody against VZV should be administered varicella-zoster immune globulin (VariZIG) as soon as possible, but at least within 10 days after contact. Some experts also would

recommend varicella vaccination for exposed patients with CD4 counts of ≥ 200 cells/ μL , or preemptive treatment with acyclovir or valacyclovir; these approaches have not been studied in HIV-infected persons. Even immunocompetent adults with primary VZV (chickenpox) can develop viral dissemination to the visceral organs. HIV-infected patients may develop encephalitis, pneumonia, or polyradiculopathy during primary varicella (chickenpox) or reactivated zoster (shingles).

Patient Education

- Patients should bathe the skin lesions in mild soap and water. For necrotic lesions, use warm, moist compresses 2-3 times a day to remove debris.
- Antibiotic ointments may help prevent secondary infection and keep dressings from sticking.
- Advise patients to take their medications as directed, and to contact the clinic if symptoms worsen.

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Histoplasmosis

Background

Histoplasmosis is caused by *Histoplasma capsulatum*, a fungus that thrives in soil contaminated by droppings from birds and bats. In the United States, *H. capsulatum* is found most often along the Ohio and Mississippi River Valleys, in the central, mid-Atlantic, and south-central states, and from Alabama to southwest Texas. In highly prevalent areas, such as Indianapolis and Kansas City, more than 80% of the population has been exposed to *Histoplasma* through inhalation of airborne infectious elements. Histoplasmosis also is found in the Canadian provinces of Quebec and Ontario, Puerto Rico, Mexico, Central and South America, Africa, East Asia, and Australia.

The initial infection in most cases either produces no symptoms or manifests only as a mild flulike illness. However, immunosuppressed individuals may develop disseminated disease. Progressive disseminated histoplasmosis often represents a reactivation of latent infection, occurs late in the course of HIV disease (the CD4 count usually is <150 cells/ μ L), and is an AIDS-defining illness. Pulmonary histoplasmosis (without dissemination) may occur in people with higher CD4 counts. Within endemic areas, histoplasmosis accounts for 5% of opportunistic infections among patients with AIDS. In hyperendemic areas, the prevalence of histoplasmosis may reach 25% among AIDS patients. The incidence of histoplasmosis in the United States has declined with the use of effective antiretroviral therapy (ART).

Common clinical features that may be associated with histoplasmosis are shown in Table 1.

S: Subjective

Histoplasmosis may be difficult to diagnose because the symptoms are nonspecific. In addition, clinicians may not consider this diagnosis in low-prevalence areas.

Patients may experience fever, weight loss, fatigue, cough, and shortness of breath. They also may develop skin lesions, adenopathy, central nervous system (CNS) changes, oropharyngeal ulcers, nausea, diarrhea, and abdominal pain. Symptoms usually begin several weeks before patients present for care. On occasion, histoplasmosis presents abruptly as a sepsis-like syndrome.

Ask the patient about possible exposures, but note that absence of reported exposures does not rule out histoplasmosis. The following are associated with significant risk of exposure:

- Residence or travel in endemic areas (see above); in the United States, particularly the Ohio and Mississippi River Valleys
- Occupational history of farming or construction/remodeling
- Hobbies that involve contact with caves, bird roosts or nests, or farm areas
- Contact with soil having a high organic content and undisturbed bird droppings, such as that found around old chicken coops and bird roosts

Table 1. Common Clinical Manifestations of Histoplasmosis

Symptom Group	Percentage of Cases	Examples
Constitutional	95%	- Weight loss - Fatigue - Fever
Gastrointestinal	>10%	- Splenomegaly - Diarrhea - Hepatomegaly - Abdominal pain
Respiratory	50-60%	- Pneumonia - Pneumonitis
Hematologic	>50%	- Anemia - Thrombocytopenia - Leukopenia
Neurologic	15-20%	- Meningitis, cerebritis - Focal parenchymal lesions - Encephalopathy
Septic	10-20%	- Hypotension - Disseminated intravascular coagulopathy - Respiratory insufficiency - High fever - Renal or hepatic failure
Dermatologic	<10%	Follicular, pustular, maculopapular, or erythematous lesions

O: Objective

Measure vital signs and document fever.

Perform a complete physical examination, with special attention to the lymph nodes, lungs, abdomen, skin, and neurologic system.

Common findings include enlargement of the liver, spleen, and lymph nodes. Skin lesions and oropharyngeal ulcers may be seen.

A: Assessment

A partial differential diagnosis includes the following:

- Other deep-seated fungal infections, such as cryptococcosis and coccidioidomycosis
- Mycobacterial disease (*Mycobacterium tuberculosis* or *Mycobacterium avium* complex)
- *Pneumocystis* pneumonia
- Lymphoma

P: Plan

Diagnostic Evaluation

- The *H. capsulatum* antigen test is sensitive and specific. The test is most sensitive for urine samples (>95% in disseminated disease), but can be used on serum (>85% sensitive in disseminated disease), bronchial fluids, or cerebrospinal fluid (CSF) specimens. Results may be obtained in a few days' time. Urine antigen levels can be used to monitor the response to therapy.
- Cultures of blood, bone marrow, and specimens from other sources have reasonable sensitivity (about 85%), but obtaining results may take several weeks.
- Wright stain of the buffy coat of a blood specimen may reveal intracellular organisms.
- Biopsies of lymph nodes, liver, cutaneous lesions, and lungs may be diagnostic in up to 50% of cases; bone marrow can be stained with methenamine silver to show the organism within macrophages.

- Meningitis can be challenging to diagnose. Diagnostically, *Histoplasma* antigen or anti-*Histoplasma* antibodies can be detected in CSF in up to 70% of cases, whereas results for cultures are often negative. Nonspecific findings in the CSF include elevated protein and low glucose as well as a lymphocytic pleocytosis. A diagnosis of *Histoplasma* meningitis should be considered if the patient has known disseminated disease and other more common etiologies of meningitis have been ruled out.
- Lactate dehydrogenase (LDH) and ferritin, although not specific, may be markedly elevated in disseminated disease.
- Complete blood count and chemistry panels may show pancytopenia, elevated creatinine, or abnormal liver function.

Treatment

Treatment consists of two phases: induction and chronic maintenance. Treatment should be continued for at least 12 months.

Severe disseminated histoplasmosis

Severe infection requires IV induction therapy with a lipid formulation of amphotericin; standard amphotericin is less effective and is associated with more adverse effects, but may be used as an alternative.

- **Induction therapy (≥2 weeks or clinically improved):**
 - **Preferred:** Liposomal amphotericin B lipid formulation 3 mg/kg IV QD
 - **Alternatives:** Amphotericin B lipid complex or amphotericin B cholesteryl sulfate complex 3 mg/kg IV QD
- **Maintenance therapy:** After ≥2 weeks of therapy or improvement of the patient's clinical status, therapy may be switched to itraconazole 200 mg PO TID for 3 days, then BID for at least 12 months of therapy. Liquid formulation of itraconazole is preferred.

Histoplasma meningitis

Amphotericin B must be used because itraconazole has poor penetration into the CNS:

- **Induction therapy:** Liposomal amphotericin B 5 mg/kg QD for 4-6 weeks
- **Maintenance therapy:** Itraconazole 200 mg PO BID or TID for ≥12 months and until abnormal CSF findings resolve

Mild to moderate disseminated histoplasmosis without CNS involvement

- **Induction and maintenance therapy:** Itraconazole 200 mg PO TID for 3 days followed by itraconazole 200 mg BID for ≥12 months; liquid formulation of itraconazole is preferred

Pulmonary histoplasmosis in patients with CD4 counts of >300 cells/μL

Manage as for non-immunocompromised patients.

See “Potential ARV Interactions,” below, regarding azoles.

Long-term suppressive therapy

Long-term therapy must be given to prevent relapse after 12 months of initial treatment; preferred therapy consists of itraconazole 200 mg PO QD. Fluconazole 800 mg QD is less effective but can be used as an alternative for patients who cannot tolerate or cannot obtain itraconazole. Voriconazole and posaconazole appear to be effective. (See “Potential ARV Interactions,” below, regarding azoles.)

Few data support the discontinuation of chronic maintenance therapy. One small study sponsored by the AIDS Clinical Trials Group demonstrated safety in discontinuing suppressive itraconazole therapy for patients who met the following criteria: had completed >1 year of itraconazole therapy, negative blood cultures, *Histoplasma* serum antigen <2 units, CD4 counts >150 cells/μL, and had been on ART for ≥6 months. Therefore, per U.S. Centers for Disease Control and Prevention guidelines, discontinuing

suppressive therapy for any patient who meets these criteria can be considered. Suppressive therapy should be restarted if the CD4 count drops to <150 cells/ μL .

Monitoring and relapse

Monitor either serum or urine *Histoplasma* antigen, as well as clinical status, to evaluate response to therapy; a rise in the antigen level suggests relapse of histoplasmosis. A drug level of itraconazole should be measured at least once after 2 weeks of therapy as absorption of this drug can be erratic and interactions are expected between itraconazole and some ARVs.

In cases of treatment failure, both voriconazole and posaconazole have been successful in a few case reports; if treatment failure is suspected, an infectious disease specialist should be consulted.

Primary Prophylaxis

Currently, there are no studies that prove any survival benefit in using primary prophylaxis; however, prophylaxis with itraconazole 200 mg PO QD can be considered for high-risk patients whose CD4 counts are <150 cells/ μL (e.g., those with occupational exposure and those who reside in hyperendemic regions). HIV-infected patients with CD4 counts of <150 cells/ μL should be educated about avoiding exposure.

Primary prophylaxis can be discontinued if the CD4 count remains ≥ 150 cells/ μL for 6 months on effective ART; prophylaxis should be restarted if the CD4 count drops to <150 cells/ μL .

Potential ARV Interactions

There may be significant drug-drug interactions between certain systemic antifungals, (particularly itraconazole, voriconazole, and posaconazole) and ritonavir-boosted protease inhibitors (PIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), elvitegravir/cobicistat, or maraviroc. Some combinations are contraindicated and others require dosage adjustment of the ARV, the antifungal, or both, and/or monitoring of drug levels. Check for adverse drug interactions before prescribing. See relevant tables in the U.S. Department of Health and Human Services *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, or consult with an expert.

Patient Education

- Histoplasmosis is not transmitted from person to person, so isolation is not necessary.
- Patients should take all their medications exactly as prescribed by their health care provider.
- Even with maintenance therapy, relapses can occur. Patients should contact their provider immediately if symptoms worsen.
- Persons with histoplasmosis should be treated with antiretroviral therapy.
- The azoles may cause birth defects. Women who are taking azole medications should avoid pregnancy. In addition, itraconazole and other azoles interact with some antiretrovirals and other medications; patients should tell their provider if they begin taking any new medications while receiving itraconazole.

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Kaposi Sarcoma

Background

Kaposi sarcoma (KS) is an endothelial neoplasm that usually occurs as skin or oral lesions but may involve the internal organs. It is the most common AIDS-associated neoplasm and is an AIDS-defining disease. AIDS-associated KS is one of four types of KS, along with classic, endemic, and organ transplant-associated KS. Although the types vary in epidemiology and clinical presentation, all are associated with human herpesvirus type 8 (HHV-8), also known as KS-associated herpesvirus. The clinical manifestations of AIDS-associated KS (sometimes called epidemic KS) range in severity from mild to life-threatening. The progression of disease may be rapid or slow, but the overall prognosis is poor in the absence of treatment. The skin lesions of KS, even when they do not cause medical morbidity, may cause significant disfigurement and emotional distress.

AIDS-associated KS usually occurs in HIV-infected persons with advanced immunosuppression (CD4 count of <200 cells/ μ L), but may occur at any CD4 count. In the United States and Europe, KS occurs in all HIV risk groups, but most frequently among men who have sex with men (MSM). Risk factors for MSM include multiple sexual partners and a history of sexually transmitted diseases (STDs); risk factors for other groups have not been clearly identified. The transmission of HHV-8 is not well understood. Although experts believe HHV-8 is transmitted sexually, it apparently also passes from person to person by other routes.

The incidence of KS in resource-abundant countries has declined markedly since the early 1990s, in part because of the widespread availability of effective combination antiretroviral therapy (ART). In parts of sub-Saharan Africa, where endemic KS has long existed in people with normal immune function, the incidence of KS has risen sharply in people with HIV. ART appears to be effective in reducing the risk of AIDS-associated KS, particularly when initiated before the development of advanced immunosuppression.

S: Subjective

Skin Lesions

The cutaneous presentation of KS is the most common, occurring in 95% of cases. Lesions may occur anywhere on the skin. Common sites include the face (particularly under the eyes and on the tip of the nose), behind the ears, and on the extremities and torso. Lesions may be macules, papules, plaques, or nodules. At first, the lesions are small and may be flat. Their color may vary from pink or red to purple or brown-black (the latter particularly in dark-skinned individuals), and they are nonblanching, nonpruritic, and painless (lesions may become painful in the setting of immune reconstitution inflammatory

syndrome [IRIS] associated with KS). Over time, the lesions often increase in size and number, darken, and rise from the surface; they may progress to tumor plaques (e.g., on the thighs or soles of the feet), or to exophytic tumor masses, which can cause bleeding, necrosis, and extreme pain.

Oral Lesions

Oral lesions may be flat or nodular and are red or purplish. They usually appear on the hard palate, but may develop on the soft palate, gums, tongue, and elsewhere. Oral lesions, if extensive, may cause tooth loss, pain, and ulceration.

Lymphedema

Lymphedema associated with KS usually appears in patients with visible cutaneous lesions, and edema may be out of proportion to the extent of visible lesions. Lymphedema also may occur in patients with no visible skin lesions. Common sites include the face, neck, external genitals, and lower extremities. A contiguous area of skin usually is involved. Lymph nodes may be enlarged.

Pulmonary KS

Pulmonary KS may be asymptomatic or cause intractable cough, bronchospasm, hemoptysis, chest pain, and dyspnea. The patient may exhibit difficulty breathing, bronchospasm, cough (sometimes with hemoptysis), and hypoxemia.

Gastrointestinal KS

Gastrointestinal KS may arise anywhere in the gastrointestinal tract. Patients usually are asymptomatic except in cases of intestinal obstruction or bleeding. KS may cause protein-losing enteropathy. Visceral disease is uncommon in the absence of extensive cutaneous disease.

During the history, ask about the symptoms noted above and associated characteristics, including the following:

- Duration of lesions
- Pain
- Frequency of new lesions
- Respiratory or gastrointestinal symptoms
- Edema or swelling

O: Objective**Physical Examination**

Perform a careful physical examination, with particular attention to the following:

- Vital signs
- Skin (examine the entire skin surface including the scalp and conjunctiva)
- Oropharynx
- Extremities and external genitals (look for lesions, edema)
- Lymph nodes

Examine the lungs, abdomen, rectum, and other systems as indicated.

A: Assessment

The partial differential diagnosis depends on the type of symptoms present.

For cutaneous, oral, and lymph node presentations, consider the following:

- Bacillary angiomatosis
- Lymphoma
- Dermatofibromas
- Bacterial or fungal skin infections
- Venous stasis

For pulmonary symptoms, consider the following:

- *Pneumocystis jiroveci* pneumonia (PCP)
- Cytomegalovirus (CMV) pneumonia
- Pulmonary lymphoma (rare)

P: Plan**Diagnostic Evaluation**

For cutaneous or oral KS, the diagnosis often is suggested by the appearance of skin or mucous membrane lesions. Biopsy of a lesion (or a suspect lymph node) is required to verify the diagnosis and rule out infectious or other neoplastic causes. Biopsy is particularly

important if the lesions are unusual in appearance or if the patient has systemic or atypical symptoms.

If respiratory symptoms are present, obtain chest X-rays or computed tomography (CT) studies. The chest X-ray typically shows diffuse interstitial infiltrates, often accompanied by nodules or pleural effusion. Radiographic findings may be suggestive of KS, but cannot provide a definitive diagnosis. Bronchoscopy with visualization of characteristic endobronchial lesions usually is adequate for diagnosis.

For patients with gastrointestinal symptoms and suspected KS, perform endoscopy.

If the patient has fever or respiratory, gastrointestinal, or constitutional symptoms, evaluate for other infectious and malignant causes (e.g., by culture or biopsy) as suggested by the history and physical examination.

Treatment

Treatment of KS is not considered curative, and no single therapy is completely efficacious. ART is a key component of the treatment of KS and should be initiated promptly (or optimized to achieve complete HIV RNA suppression) for all persons with KS (for further information, see chapter *Antiretroviral Therapy*). KS often regresses and sometimes resolves in patients treated with effective ART. Some data suggest that protease inhibitors may have an anti-KS effect; however, non-PI-containing regimens also lead to KS regression; the role of specific antiretroviral agents beyond HIV control in KS remains unclear.

KS-associated IRIS has been described, and patients may experience painful enlarged lesions or progression of KS lesions during the first months of ART; they should be advised of this possibility.

Specific treatment of KS depends on various factors such as the number, extent, severity, and location of lesions; cosmetic considerations; and presence of visceral

involvement. The goals of therapy may vary according to the clinical presentation and may include controlling symptoms, improving cosmetic appearance, reducing edema, eliminating pain, and clearing lesions. ART alone may be effective in mild-to-moderate KS. Local treatment (in conjunction with ART) may be given to patients who have bothersome symptoms from a few small lesions. Systemic therapy (in conjunction with ART) is needed for more extensive or more severe disease, including symptomatic visceral disease, widespread skin involvement, significant edema, and rapidly progressive KS. Consultation with a KS-experienced oncologist or dermatologist is recommended.

Local treatment of limited disease

Options for local treatment of limited disease include the following:

- ART with observation for response (limited, stable cutaneous disease may require no specific treatment)
- Intralesional chemotherapy (e.g., vinblastine)
- Radiation therapy, for localized or facial lesions (may cause mucositis when used for oropharyngeal lesions)
- Cryotherapy
- Laser therapy

Treatment of extensive or rapidly progressing disease

Extensive or rapidly progressing disease may include lymphedema, intraoral or pharyngeal disease that interferes with eating, painful or bulky lesions, and symptomatic pulmonary or visceral disease. Options for treatment include the following:

- Intralesional chemotherapy (e.g., vinblastine)
- Systemic chemotherapy (e.g., liposomal formulations of doxorubicin or daunorubicin, or paclitaxel)

- Numerous experimental agents are under evaluation
- Consultation with an oncologist is recommended for optimal treatment of extensive disease

Patient Education

- KS often responds to treatment. Educate patients that ART is a cornerstone of treatment; encourage them to start and adhere to ART.
- Swollen or edematous lesions increase the risk of cellulitis, whereupon lesions can become infected and progress rapidly. Advise patients to avoid injuring swollen or edematous lesions, to keep them clean, and to call their health care provider if lesions appear to be spreading or if swelling worsens.
- Advise patients to return to the clinic if respiratory or gastrointestinal symptoms develop.
- Patients may use cosmetic preparations to cover facial lesions. Refer patients to support groups or counseling services if they are having difficulty coping with their physical appearance.

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Molluscum Contagiosum

Background

Molluscum contagiosum is a viral infection of human epidermal keratinocytes, caused by a double-stranded DNA virus of the Poxviridae family. Molluscum appears as papules or nodules and sometimes is called “molluscum warts.” It is seen most frequently in HIV-uninfected children (up to 5% of children in the United States), in sexually active young adults, and in immunocompromised persons. It occurs in 5-18% of HIV-infected persons. Molluscum is benign but may cause extensive and cosmetically bothersome lesions, particularly in persons with advanced HIV infection.

Transmission occurs by person-to-person skin-to-skin contact (e.g., sexual activity, contact sports [especially wrestling], or simply touching) or via fomites (towels, bedclothes, clothing [including underwear], soft toys, shaving utensils, electrolysis equipment, tattooing tools, and sponges). The virus may be spread to other areas via self-inoculation (e.g., scratching, shaving, or touching a lesion).

In immunocompetent persons, the infection usually resolves spontaneously after 6-12 months, though genital lesions may remain longer. In HIV-infected persons, the lesions may be more extensive and persistent. There is a strong correlation between the degree of immunosuppression and the risk of molluscum infection, the number of lesions, and the ability of lesions to resist treatment.

S: Subjective

Patients complain of new papules on the trunk, axillae, antecubital and popliteal fossae, face, or genital/crural area. Papules of molluscum contagiosum may cause no symptoms but also can be intensely pruritic or tender to the touch. Ask patients whether others in the home (especially children and adolescents) or their sex partners have similar papules. Genital lesions are transmitted sexually; patients may recall seeing such lesions on the genitals of a previous partner.

Ask about fever or other systemic symptoms to evaluate for other causes of the papules.

O: Objective

Perform a thorough evaluation of the skin, genitals, and mouth. Molluscum commonly presents as multiple grouped lesions. The lesions are white, pink, or flesh colored; shiny, smooth surfaced, firm, pearly, and spherical (dome-shaped) papules (2-5 mm) or nodules (6-10 mm), with umbilicated, or dimpled, centers. Patients with HIV infection may develop giant lesions (>1 cm) or clusters of hundreds of small lesions. Occasionally, molluscum will have a polyp-like appearance. Lesions are usually found on the head, face, or neck or in the genital area, but may affect every part of the body except the palms and soles. Molluscum may occur inside the mouth, vagina, and rectum, and around the eyes. Lesions on the eyelids can cause conjunctivitis.

A: Assessment

A partial differential diagnosis includes the following:

- Disseminated cryptococcosis
- Histoplasmosis skin lesions
- *Penicillium marneffei*
- Other fungal skin lesions
- Folliculitis
- Syphilis, condyloma acuminata, vulvar syringoma for multiple small molluscum genital lesions
- Squamous or basal cell carcinoma

P: Plan**Diagnostic Evaluation**

The diagnosis of molluscum usually is based on the characteristic appearance of the lesions. Perform histologic or other laboratory testing to confirm the diagnosis or to exclude other infections or malignancies. Special staining will show keratinocytes containing eosinophilic cytoplasmic inclusion bodies. Electron microscopy will show poxvirus particles.

Treatment

Because molluscum does not cause illness and rarely causes symptoms, the treatment usually is undertaken primarily for cosmetic purposes. For individuals with large or extensive lesions, molluscum may be disfiguring or stigmatizing, and treatment may be important for their well-being. Treatment (particularly of genital lesions) can be considered in order to prevent transmission to others.

In HIV-infected patients, molluscum is difficult to eradicate and lesions often recur, particularly if immune suppression persists. Effective antiretroviral therapy may achieve resolution of lesions or significant improvement in the extent or appearance of molluscum and should be recommended for all.

Lesions that remain after weeks of antiretroviral therapy should be treated to prevent further spread. Refer complex cases to a dermatologist.

Choice of treatment modality is based on age, likelihood of compliance, number and size of lesions, and potential adverse effects of treatment. Therapeutic options include the following:

- **Local excision:** May be done by curettage, cryotherapy, electrocautery, or visceration. Adverse effects include pain, irritation, soreness, and mild scarring. Repeated treatments are necessary. Curettage appears to be most efficacious (even for children) but is painful and requires anesthesia and a large time commitment over the course of several visits; it also has a risk of scarring. Relapse is common.
- **Imiquimod 5% (Aldara):** An immune response modifier; stimulates production of interferon-alfa and other proinflammatory cytokines, inducing a tissue reaction associated with viral clearance from the skin. Apply TIW for up to 16 weeks or QPM for 4 weeks. Clearing can take up to 3 months. Limited studies; painless.
- **Podophyllotoxin:** Can be administered by a health care provider and washed off after 1-4 hours. This treatment is caustic, may cause significant irritation, and has limited effectiveness. It is contraindicated for use during pregnancy. Patient-administered podophyllotoxin (Podofilox) may be a safer alternative to podophyllum. Adverse effects include burning, pain, inflammation, erosion, and itching.
- **Cantharidin 0.7%:** Can be applied by a health care provider. One study of 300 children found that lesions cleared after two visits. This treatment may cause allergic reactions, stinging, and blistering. Do not use cantharidin around the eyes.

- **Tretinoin (Retin-A) 0.1% cream:** Can be applied to lesions BID. Adverse effects include drying, peeling, irritation, and soreness.
- **Trichloroacetic acid:** Can be administered by a health care provider. Controlling the depth of acid penetration is difficult. Adverse effects include pain and irritation; mild scarring is common.
- **A combination of salicylic and lactic acid:** Response is highly variable and recurrence is common.
- **Laser therapy:** Safe, efficient, tolerable, and efficacious.
- **Cidofovir 1-3% topical cream:** Applied BID for 2 weeks, followed by a 30-day rest period and then two additional cycles. This treatment has been shown to be effective in several small studies and case reports, but it is expensive and difficult to compound. No systemic adverse effects are noted.
- **Silver nitrate paste:** May be used to burn each lesion individually.

Patient Education

- Molluscum infection is benign but may be distressing.
- Molluscum infection may be transmitted both sexually and nonsexually, through direct contact with lesions. Molluscum also can be transmitted indirectly by contact with infected objects.
- Latex condoms or barriers may not prevent transmission of genital molluscum.
- To prevent the spread of molluscum, instruct patients to take the following precautions:
 - Avoid close contact between their molluscum lesions and the skin, mouth, and genitals of other people.
 - Avoid picking at, squeezing, or puncturing the lesions, as a lesion's central plug is full of viral particles that can be spread easily by coming into contact with other parts of the body. In addition, lesions may become secondarily infected.
 - Wash hands frequently.
 - Keep fingernails short.
 - Avoid shaving in areas with lesions because shaving could result in lesions spreading to other areas.
 - Avoid sharing towels, bedclothes, clothing, shaving utensils, bathing equipment, or other objects that have been in contact with molluscum lesions.
 - Wash all contaminated items in very hot, but not scalding, water.
 - Cover lesions with clothing, if possible.

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Mycobacterium avium Complex Disease

Background

Mycobacterium avium complex (MAC) disease is an opportunistic infection caused by species of *Mycobacterium* that can produce severe illness in people with advanced AIDS but rarely affects others. The risk of disseminated MAC (DMAC) is directly related to the severity of immunosuppression. DMAC typically occurs in persons with CD4 counts of <50 cells/μL, and its frequency increases as the CD4 count declines. In the absence of antibiotic prophylaxis, DMAC occurs in up to 40% of AIDS patients with CD4 counts of <50 cells/μL. Antimicrobial therapy, especially if given in conjunction with antiretroviral therapy (ART) that achieves immune reconstitution, can be successful in treating MAC disease. Specific antimicrobial prophylaxis and effective ART also may be used to prevent MAC in patients with advanced AIDS (see chapter *Opportunistic Infection Prophylaxis*).

MAC organisms are common in the environment. They are found worldwide and have been isolated from soil, water, animals, birds, and foods. They usually enter the body through the respiratory or gastrointestinal tract and disseminate to cause multisystem infection, typically manifested by nonspecific symptoms and signs such as fever, sweats, weight loss, abdominal pain, fatigue, chronic diarrhea, and anemia and other cytopenias. MAC also can cause local disease such as central nervous system infection, lymphadenitis, soft-tissue or bone infections, and rarely, isolated pulmonary disease. Focal MAC disease is more common among patients on ART, whereas DMAC is the more common manifestation among those with low CD4 cell counts who are not on ART. Unlike *Mycobacterium tuberculosis*, *Mycobacterium avium* is not thought to be transmitted via person-to-person contact. In patients with subclinical or incompletely treated MAC who have recently started ART, an immune reconstitution inflammatory syndrome (IRIS) may occur with localized lymphadenitis or paradoxically worsening symptoms (see chapter *Immune Reconstitution Inflammatory Syndrome*).

S: Subjective

The patient complains of one or more of the following symptoms:

- Persistent or cyclic fever
- Night sweats
- Unintentional weight loss
- Anorexia
- Chronic diarrhea
- Weakness
- Fatigue
- Abdominal pain
- Lymph node enlargement

When taking the history, ask about the following:

- Any symptoms as described above, including duration and intensity; other symptoms of infection
- Whether the patient is taking MAC prophylaxis or ART

O: Objective

Perform a full physical examination with particular attention to the following:

- Vital signs (temperature, heart rate, blood pressure, respiratory rate)
- Weight (compare with previous measurements)

- General appearance (cachexia, wasting, signs of chronic illness, jaundice, pallor)
- Lymph nodes (lymphadenopathy)
- Abdomen (hepatosplenomegaly, tenderness)

Review previous laboratory values, particularly the CD4 count (usually <50 cells/ μ L).

A: Assessment

Rule out other infectious or neoplastic causes of constitutional symptoms, anemia, or organomegaly. A partial differential diagnosis would include the following:

- *M. tuberculosis* infection
- Cytomegalovirus infection
- Lymphoma
- Bartonellosis
- Disseminated fungal infection
- Pyogenic abscess
- Other septicemia

P: Plan

Diagnostic Evaluation

Definitive diagnosis requires identification of MAC in blood or other normally sterile body fluids or tissues (*M. avium* cultured from sputum, bronchial washing, or stool may represent colonization rather than infection). Send blood for acid-fast bacilli (AFB) culture (sensitivity of a single blood culture for MAC bacteremia is 91%, sensitivity increases to 98% if two samples [drawn at different times] are sent). Because MAC may take weeks to grow in culture, ancillary studies should be performed. The following are not specific, but may be helpful in reaching a presumptive diagnosis:

- AFB smear
- Complete blood count (CBC) for anemia, lymphopenia, and thrombocytopenia
- Serum alkaline phosphatase (often elevated in DMAC)

- Computed tomography (CT) scan of the chest and abdomen (intraabdominal and mediastinal lymphadenopathy or hepatosplenomegaly often are present)

If blood cultures are negative and MAC is suspected (or if results of blood cultures are pending), consider biopsy of the lymph nodes, bone marrow, liver, or bowel (via endoscopy) to detect DMAC by microscopic examination for AFB and culture. If the evidence suggests pulmonary MAC, consider bronchoscopy and bronchoalveolar lavage. Note that in MAC IRIS, MAC bacteremia usually is absent and a tissue-based diagnosis is required.

Perform additional studies as indicated to rule out other causes of the patient's symptoms, including bacterial blood cultures, sputum for *M. tuberculosis*, *Bartonella* studies, lymph node cytology for lymphoma, and stool cultures, as appropriate.

Treatment

Because antimicrobial resistance develops quickly with single-drug therapy, multidrug regimens must be administered for DMAC.

Preferred regimens:

- Clarithromycin 500 mg BID + ethambutol 15 mg/kg QD
- Azithromycin 500-600 mg QD + ethambutol 15 mg/kg QD (see below)

Clarithromycin is the preferred cornerstone of MAC therapy, as it has been studied more extensively and is associated with more rapid clearance of MAC bacteremia. If clarithromycin cannot be tolerated or if there is concern regarding drug interactions, azithromycin may be substituted for clarithromycin, as above. Clarithromycin dosages should not exceed 1 g per day, as high-dose clarithromycin has been associated with excess mortality.

Some experts recommend including a third agent for patients with more advanced HIV disease or higher MAC burden in blood cultures, and for those who are not receiving

effective ART. The addition of rifabutin (300 mg QD) has been associated with a mortality benefit in one study and with reduced emergence of mycobacterial resistance in two other trials; however, these studies were done before potent ART was available; the possible benefit of rifabutin in patients treated with effective ART has not been established. A fluoroquinolone (e.g., levofloxacin, moxifloxacin), amikacin, or streptomycin may be used instead of rifabutin as a third agent, or in addition to rifabutin as a fourth agent; however, studies have not confirmed the

clinical benefit of these medications.

Because immune reconstitution is essential for controlling MAC, all patients who are not already receiving ART should begin ART, if possible. Current guidelines recommend initiation of ART after 2 weeks of MAC treatment, for patients who are not already on ART. This strategy may decrease the risk IRIS and it serves to forestall interactions between DMAC and ARV drugs and the additive toxicities of those medications. Patients who are receiving suboptimal ART should be changed to suppressive regimens, if possible.

Potential ARV Interactions

Clarithromycin and rifabutin have a number of significant drug interactions, including interactions with some commonly prescribed ARVs. These interactions should be reviewed prior to initiation of MAC therapy. Dosage adjustments or alternative medications may be required. Azithromycin does not have significant interactions with ARVs.

Interactions of concern include the following:

Clarithromycin:

- **Atazanavir** may raise clarithromycin levels by 90%; some experts recommend using azithromycin in place of clarithromycin, or dosage reduction of clarithromycin by 50%.
- **Darunavir** increases clarithromycin levels; alternative agent (azithromycin) or dosage reduction of clarithromycin is recommended for patients with renal impairment.
- **Lopinavir/ritonavir and other protease inhibitors** may increase clarithromycin levels; alternative agent (azithromycin) or dosage reduction of clarithromycin is recommended for patients with renal impairment.
- **Efavirenz** may lower clarithromycin levels; avoid this combination if possible.
- **Etravirine** may lower clarithromycin levels, while clarithromycin may in turn increase etravirine levels. Avoid this combination, if possible.
- **Nevirapine** may decrease clarithromycin levels and increase levels of its active metabolite. Avoid this combination, if possible.
- **Elvitegravir/cobicistat** may increase clarithromycin levels. Dosage reduction of clarithromycin is required for patients with renal insufficiency.

Protease inhibitor-based ART (e.g., lopinavir or darunavir) or integrase inhibitor-based ART may be the preferred HIV treatment for patients on MAC therapy, because of limited drug interactions associated with those ARV classes.

Rifabutin has significant interactions with many drugs, including nonnucleoside reverse transcriptase inhibitors, protease inhibitors, and elvitegravir/cobicistat; therefore, dosage adjustments or alternative agents may be needed (for further information, see chapter *Mycobacterium tuberculosis*).

The patient should show clinical improvement within the first weeks of treatment. If there is not a response to treatment after 2-4 weeks, assess adherence, consider adding one or more drugs, and consider evaluation for other or additional causes of the patient's symptoms. Repeat a blood culture with antimicrobial sensitivities for patients whose clinical status has not improved after 4-8 weeks of treatment. Interpretation of MAC drug susceptibility testing should be undertaken in consultation with an infectious disease or HIV specialist, because laboratory evidence of drug resistance does not always correlate with clinical drug resistance.

If immune reconstitution inflammatory reactions are suspected, consider adding antiinflammatory medications, including corticosteroids if moderate to severe MAC IRIS symptoms do not improve with NSAIDs (see chapter *Immune Reconstitution Inflammatory Syndrome*).

Treatment of MAC generally is required for the remainder of the patient's life in the absence of immune reconstitution with effective ART. It may be reasonable to discontinue MAC therapy if patients complete at least 12 months of MAC treatment, have no further symptoms, and demonstrate immune restoration in response to ART (an increase in CD4 counts to >100 cells/ μ L for at least 6 months). If MAC treatment is discontinued, the patient must be monitored carefully for any decrease in CD4 cell count or recurrence of MAC symptoms. Treatment should be resumed if the CD4 count drops to <100 cells/ μ L or if symptoms recur.

Prevention

Primary prevention using azithromycin or clarithromycin should be initiated in persons with CD4 cell counts of <50 cells/ μ L. See chapter *Opportunistic Infection Prophylaxis*.

Patient Education

- Advise patients that antimycobacterial therapy alone will not eradicate MAC infection, but should decrease symptoms and improve quality of life. A response to treatment may take up to 4 weeks. If medications are discontinued, the disease almost always recurs, unless the CD4 count has increased to >50-100 cells/ μ L in response to ART.
- Patients must take all medicines exactly as prescribed. If doses are missed, or if the medication is stopped and restarted, MAC can develop resistance to the medications. If patients are having trouble taking the medications on schedule, they should contact their health care provider promptly.
- Advise patients that MAC IRIS is a common complication of effective ART and MAC therapy, and its occurrence in the course of treatment should be anticipated.
- Urge patients to contact the clinic immediately if they notice worsening of existing symptoms or the development of new symptoms.
- DMAC is an opportunistic infection of late-stage HIV and it is indicative of profound immunosuppression. Some patients may not respond to MAC treatment or to ART. Because this is a life-threatening disease, clinicians should discuss advance directives and durable power of attorney with patients. Referral to a social worker, mental health clinician, or chaplain experienced in such issues may facilitate the discussion.

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Mycobacterium tuberculosis

Background

In HIV-infected individuals, tuberculosis (TB) causes more deaths worldwide than any other condition. A biologic synergy exists between HIV and TB such that HIV-induced immunosuppression increases susceptibility to active TB infection, whereas active TB infection increases HIV progression and risk of death. The populations infected by these two pathogens overlap in many respects, creating epidemiologic synergy. Poverty, crowded living conditions, and inadequate interventions to reduce transmission and treat latent TB infection (LTBI) combine to enhance the transmission of both organisms.

In the United States, more than 60% of TB cases occur in foreign-born individuals, with the majority of these cases attributed to reactivation of LTBI. In 2010, only 8% of active TB cases occurred in patients known to be infected with HIV, and TB is a relatively infrequent AIDS-defining illness. Nevertheless, TB remains important to HIV clinicians in the United States because it can be highly infectious and challenging to diagnose, and because improper treatment may lead to drug resistance both in the infected patient and in individuals to whom that patient transmits. Although other conditions increase the risk of TB disease (e.g., malnutrition, diabetes, end-stage renal disease, pulmonary silicosis, and iatrogenic immunosuppressive drugs [especially inhibitors of tumor necrosis factor]), HIV infection remains an important risk factor.

TB is an infection caused by *Mycobacterium tuberculosis* (MTB) complex. These organisms grow slowly and can be identified only with special staining techniques, a trait that led to the name “acid-fast bacteria.” This chapter focuses on disease caused by *M. tuberculosis*; other chapters describe diagnosis and management of latent MTB infection (see chapter *Latent Tuberculosis Infection*) and diagnosis and management of disease caused by *Mycobacterium avium* (see chapter *Mycobacterium avium Complex Disease*).

MTB most often causes a chronic pneumonia, but it can affect organs other than the lungs as well. The lung destruction caused by MTB may create cavities, similar to abscesses; these contain huge numbers of organisms. TB is transmitted almost always by persons with active pulmonary TB who release large numbers of organisms in their sputum. Patients with smear-positive sputum are the most infectious; however, transmission from patients with AFB smear-negative, culture-positive sputum has been well documented. Extrapulmonary tuberculosis generally is not considered contagious.

MTB organisms are inhaled and infect the lung. In most people, the initial lung infection is contained by an effective immune response. It usually is asymptomatic but leads to foci in the lung (and sometimes in other organs) of latent TB, which may reactivate and cause active TB disease years later. Shortly after the onset of infection with MTB, before its containment in the lung by the immune system, organisms can spread to other organs and establish latent infection in those areas as well. Reactivation in these other organs can lead to local disease (e.g., in the lymph nodes, meninges, bone, pericardium, peritoneum or intestine, and urogenital tract).

Persons with impaired immunity, such as persons with HIV-associated immunosuppression and very young children, are at high risk of developing progressive primary TB at the time of initial MTB infection. Primary progressive MTB usually causes pulmonary disease, but also can

cause meningitis or disseminated disease (blood, liver, spleen, lung, and other organs). Persons who have latent TB infection and then develop immunodeficiency are at high risk of developing reactivation disease. For example, compared with the <10% lifetime risk of developing active TB in immunologically normal persons, an HIV-infected person with latent TB has about a 10% chance each year of developing active disease. Even with immune reconstitution through antiretroviral therapy (ART) and a normalized CD4 cell count, HIV-infected patients remain at elevated risk of reactivation TB, compared with the background community risk of TB.

Classical pulmonary tuberculosis, with upper-lobe infiltrates and cavitary lesions, may occur in HIV-infected persons with relatively intact immunity. As the CD4 count decreases (particularly to <200 cells/ μ L), TB is more likely to manifest atypically in the chest (without cavitary disease) or with lower-lobe disease, adenopathy, pleural effusions, or interstitial or military infiltrates), and as extrapulmonary or multiorgan disease (particularly in lymph nodes, peritoneum, pericardium, and meninges). Granulomas may be seen in the tissues; in persons with advanced immunodeficiency, these may be poorly formed and non-caseating. Bone, joint, and urogenital TB are less-commonly associated with HIV-induced immunosuppression. Symptoms and signs in HIV-infected persons therefore can vary widely and can be difficult to distinguish from HIV-related opportunistic infections and malignancies.

Appropriate use of modern chemotherapy with rifampin-containing TB treatment applied to drug-susceptible MTB disease cures at least 95% of these patients, including those with HIV coinfection. However, drug resistance seriously reduces the cure rate. Drug resistance usually is caused by improper or erratic treatment. It is spreading rapidly and becoming more severe. Effective diagnosis and cure of drug-susceptible TB not only reduces the disease burden in the individual and reduces further transmission, it also is crucial to avoiding drug resistance.

MTB resistance to a single drug may extend or complicate treatment but usually does not prevent successful treatment of TB. Resistance to both isoniazid and rifampin, with or without resistance to other first-line drugs, is called **multidrug resistance (MDR)**, and it makes treatment especially difficult. **Extreme drug resistance (XDR)** occurs when, in addition to isoniazid and rifampin resistance, there is resistance to specific second-line drugs: a fluoroquinolone plus an injectable agent (kanamycin, amikacin, or capreomycin). Treatment of drug-resistant TB should be managed by experts or in consultation with experts. MDR TB is uncommon in the United States; it occurred in 1.3% of cases in 2010, and the great majority of these were foreign-born patients (82.6%). XDR is very rare in the United States, with only 4 cases reported in 2010.

Effective antiretroviral treatment (ART) is a critical component of the care of persons with TB, and ART should be initiated or optimized in all persons with active TB, regardless of their current CD4 cell count.

This chapter will discuss the evaluation and management of TB in the United States and other high-income settings. For management of TB in resource-limited settings, see the relevant World Health Organization guidelines and other resources.

S: Subjective

Persons with TB generally describe an illness lasting several weeks to months, associated with systemic features such as high fevers, night sweats, loss of appetite, and weight loss. These symptoms are nonspecific, but should raise the possibility of TB.

- Pulmonary TB presents with a chronic productive cough and sometimes with hemoptysis; shortness of breath occurs late in the disease course.
- TB adenitis presents with enlarged lymph nodes (usually asymmetric involvement in one region) that may suppurate and drain but usually are not painful, hot, or erythematous.
- TB meningitis presents with headache, gradual change in mental status, and at times with cranial nerve abnormalities such as double vision or decreased hearing.
- Disseminated TB may occur with systemic manifestations such as fever, sweats, and weight loss, with no localizing features.

Risk factors for TB infection include known prior contact with an active case, exposure in congregate settings (such as homeless shelters and prisons, but also in health care facilities), travel or residence in countries with high rates of endemic TB, and birth in a TB-endemic country (more than half of foreign-born individuals diagnosed with TB in the United States originated from one of the following five countries: Mexico, the Philippines, Vietnam, India, or China). In the United States, persons with active or past substance-use disorders and persons of color are more likely than others to have had exposure to TB. History of a prior positive tuberculin skin test (TST) or interferon-gamma release assay (IGRA) result provides evidence of previous TB exposure; however, up to 35% of patients with active TB will have a negative TST or IGRA result (see chapter *Latent Tuberculosis Infection*). Risks for active TB disease include any degree of HIV-associated immunosuppression, immunosuppression

associated with other diseases (e.g., leukemia, lymphoma) or caused by medical therapies (e.g., tumor necrosis factor-alpha blockers such as etanercept), and malnutrition.

O: Objective

- Measure vital signs, including oxygen saturation.
- Measure weight; compare with previous values.
- Perform thorough physical examination with particular attention to the lungs, heart, abdomen, lymph nodes, skin, and neurologic system.

Systemic signs of chronic disease and inflammation are common, including cough, fever, night sweats (which may occur without awareness of the high fever that precedes them), and weight loss.

In patients with pulmonary TB, the breath sounds may be normal or focally abnormal; tachypnea and hypoxia occur only with extensive lung damage.

Extrapulmonary TB may present with focal adenopathy without local signs of inflammation, but perhaps with a draining sinus.

TB meningitis presents as subacute or chronic meningitis, with neck stiffness and changes in mental status. Symptoms may include cranial nerve palsies owing to inflammation at the base of the brain or increased intracranial pressure.

Pericardial disease can cause the pain and friction rub of pericarditis or signs of pericardial tamponade.

Infiltration of the bone marrow can produce pancytopenia.

Disseminated TB may cause diffuse adenopathy, hepatic or splenic enlargement, and abnormal liver function, although hepatic failure is rarely attributable to TB alone. Infection of the adrenal glands can cause adrenal insufficiency.

A: Assessment

Note: If pulmonary TB is suspected, the patient should wear a mask while in the medical facility and the care provider should wear an N95 respirator during the examination to reduce transmission risk.

The differential diagnosis of TB is extensive and depends in part on the degree of immunosuppression (as indicated by the CD4 cell count) of the individual. It includes a broad range of bacterial, mycobacterial, viral, and fungal infections in addition to noninfectious causes. A partial differential diagnosis of pulmonary TB includes the following:

- Bacterial pneumonia
- Pulmonary *Mycobacterium* pneumonia (nontuberculous)
- *Pneumocystis jiroveci* pneumonia (PCP)
- *Cryptococcus neoformans* pneumonia/pneumonitis
- Pulmonary Kaposi sarcoma
- *Toxoplasma* pneumonitis
- Disseminated histoplasmosis
- Disseminated coccidioidomycosis
- Cytomegalovirus pneumonia
- Bronchogenic carcinoma
- Non-Hodgkin lymphoma
- Influenza
- Pulmonary embolus
- Chronic obstructive pulmonary disease
- Reactive airway disease
- Congestive heart failure
- Lactic acidosis

P: Plan

Diagnostic Evaluation

Initial evaluation

Suspected TB should be evaluated aggressively.

- During the initial evaluation, check complete blood count (CBC) and differential, sputum gram stain, sputum acid-fast bacilli (AFB) stain, culture, and nucleic acid amplification (NAA) test (see below), blood cultures, and chest X-ray.
- For patients with lymphadenopathy, consider fine-needle aspiration biopsy for bacterial and AFB stains and culture, and cytologic evaluation.
- For patients with meningitis or central nervous system (CNS) abnormalities, perform lumbar puncture (LP) and cerebral spinal fluid (CSF) analysis including cell count, protein, glucose, AFB smear and culture, and bacterial and fungal cultures.
- Computed tomography (CT) is recommended for all patients with HIV prior to LP, particularly if focal neurologic abnormalities are present.
- Perform other diagnostic tests as suggested by the clinical presentation.

Imaging

Pulmonary TB can be associated with any chest X-ray appearance, including a normal X-ray image. However, the chest X-ray classically demonstrates upper-lobe infiltrates with or without cavities. Patients with HIV infection (especially advanced HIV and low CD4 cell counts) are more likely to have atypical chest X-ray presentations, including absence of cavities, presence of lower-lobe disease, hilar or mediastinal adenopathy, and pleural effusions.

In disseminated TB, the chest X-ray may show a miliary pattern with small nodules (“millet seeds”) scattered throughout both lungs.

AFB testing

TB should be diagnosed by identification of the organism in stained sputum smears or stains of tissue and confirmed by culture or NAA test. All positive cultures should undergo drug susceptibility testing. Proof of the diagnosis is important because other opportunistic diseases can mimic TB, and mycobacterial infections other than TB (e.g., MAC) can occur; these require different treatment. TB drug susceptibility testing is necessary to ensure appropriate treatment, to reduce the risk of developing further TB drug resistance, and to decrease the risk of transmission of drug-resistant TB. Three specimens of expectorated sputum should be sent for acid-fast staining and mycobacterial culture. A presumptive diagnosis of pulmonary TB can be made if AFB are seen, but confirmation is

required. Sputum induction with nebulized saline (e.g., by respiratory therapists) can be used for patients who do not have spontaneous sputum production. (Sputum induction has been successful in children, but for young children who cannot produce sputum, gastric lavage on three successive mornings can be performed to obtain swallowed sputum for smear [although false-positive results can occur] and culture.)

Current U.S. guidelines for treatment of opportunistic infections recommend NAA testing on at least one respiratory specimen (regardless of smear status) from each patient with signs and symptoms of pulmonary TB. The algorithm in Table 1 is recommended by the U.S. Centers for Disease Control and Prevention (CDC) for interpretation of NAA test results.

Table 1. Nucleic Acid Amplification Testing and Interpretation Algorithm

1. If the NAA result is positive and the AFB smear result is positive, presume the patient has TB and begin anti-TB treatment while awaiting culture results. The positive predictive value of FDA-approved NAA tests for TB is >95% in AFB smear-positive cases.
2. If the NAA result is positive and the AFB smear result is negative, use clinical judgment in deciding whether to begin anti-TB treatment while awaiting culture results and determine whether additional diagnostic testing is needed. Consider testing an additional specimen using NAA to confirm the NAA result. A patient can be presumed to have TB, pending culture results, if two or more specimens are NAA positive.
3. If the NAA result is negative and the AFB smear result is positive, a test for inhibitors should be performed and an additional specimen should be tested with NAA. Sputum specimens (3-7%) might contain inhibitors that prevent or reduce amplification and cause false-negative NAA results.
 - a. If inhibitors are detected, the NAA test is of no diagnostic help for this specimen. Use clinical judgment to determine whether to begin anti-TB treatment while awaiting results of culture and additional diagnostic testing.
 - b. If inhibitors are not detected, use clinical judgment to determine whether to begin anti-TB treatment while awaiting culture results and determine whether additional diagnostic testing is needed. A patient can be presumed to have an infection with non-TB mycobacteria if a second specimen is smear positive and NAA negative and has no inhibitors detected.
4. If the NAA result is negative and the AFB smear result is negative, use clinical judgment to determine whether to begin anti-TB treatment while awaiting results of culture and additional diagnostic tests. Currently available NAA tests are not sufficiently sensitive (detecting 50-80% of AFB smear-negative, culture-positive pulmonary TB cases) to exclude the diagnosis of TB in AFB smear-negative patients suspected of having TB.

Adapted from U.S. Centers for Disease Control and Prevention. *Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis*. MMWR Morb Mortal Wkly Rep. 2009 Jan 16;58(1):7-10. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm. Accessed December 1, 2013.

Sensitivity of the NAA tests in smear-positive specimens is high but decreases to 50-80% in smear-negative, culture-positive specimens. The rapid identification of MTB facilitates appropriate respiratory infection control precautions, contact tracing, and immediate treatment of MTB. NAA tests also are useful in making a presumptive diagnosis in smear-negative patients who are suspected to have active pulmonary TB, pending culture results. However, these tests can yield false-positive results, particularly with persons in whom pulmonary TB is unlikely. Also, false negatives can occur in both smear-positive and smear-negative patients. NAA testing is not available in all laboratories and in some it is restricted to AFB smear-positive specimens.

The Xpert MTB/RIF is a rapid NAA test that was recently reviewed by the FDA and allowed to be marketed the United States. This assay identifies TB and at the same time identifies rifampicin (RIF) resistance from a direct sputum sample. Data from high-prevalence TB settings show a sensitivity of >98% for TB in smear-positive specimens. Sensitivity in smear-negative specimens is 70% with a single test, and up to 90% with three tests, with a specificity of 99%. Other NAA tests can be used to rapidly identify clinically significant non-TB mycobacteria such as MAC and *Mycobacterium kansasii*. If a non-TB mycobacteria is diagnosed, respiratory precautions can be discontinued, and treatment for the specific or suspected organism can be started.

In patients with suspected pulmonary TB, negative sputum microscopy or NAA results do not rule out TB; and consideration should be given to starting empiric TB treatment while further evaluation is undertaken.

A diagnosis of extrapulmonary TB generally requires an examination of infected tissue or body fluid by microscopy and culture. NAA tests are approved for testing of sputum

samples, but have been used on tissue and body fluids (such as CSF); specimens that are fresh or frozen generally are preferable to specimens preserved in formalin or a similar chemical. Specimens of organs with suspected TB can be obtained by peripheral lymph node aspiration, CT-guided or other guided aspiration and biopsy, liver biopsy, bone marrow biopsy, or thoracoscopy- or laparoscopy-guided biopsies of pleura or peritoneum. In some cases, surgery is required to obtain appropriate specimens. Blood cultures for mycobacteria (using appropriate mycobacterial media rather than standard blood culture media) may be positive in disseminated TB, particularly with advanced HIV disease; the technique is the same as in culturing blood for MAC organisms. Urine culture is used to diagnose renal TB, although this condition is rare among HIV-infected persons.

Initial growth of MTB on culture may occur within 3-8 weeks. A nucleic acid probe can confirm a positive culture as MTB within few days of culture growth; otherwise, speciation may take several weeks. Susceptibility testing generally takes 3-4 weeks after the initial culture growth, depending on what laboratory procedures are used. Rapid tests for diagnosis of drug resistance allow early identification of resistance and optimization of treatment. The Xpert MTB/RIF assay is available in the United States, and others (including line probe assays, nitrate reductase assay, and phage-based assays) are available in other countries. Some health departments have in-house assays for rifampin resistance. NAA tests for TB drug resistance are efficient at screening for resistance against drugs for which a single mutation (e.g., rifampin) or a few mutations (e.g., isoniazid) are responsible. Rapid assays to detect mutations that confer resistance to other first- and second-line drugs are in development.

Note that a positive TST or IGRA result confirms TB infection but does not prove active disease (see chapter *Latent Tuberculosis*).

Similarly, a negative result may occur in up to 35% of HIV-infected persons with active TB and does not rule out TB disease. When a specific microbiologic diagnosis cannot be made or may be delayed (as with TB meningitis testing, for which CSF culture results may take weeks to obtain or may be negative), a positive TST or IGRA result can help support the diagnosis and implementation of therapy; however, a negative result on these tests does not rule out active TB.

Respiratory Precautions

Respiratory infection control precautions should be implemented for HIV-infected patients with an undiagnosed chronic cough or undiagnosed inflammatory infiltrate on chest X-ray. Individual institutions have specific guidelines that should be followed; patients usually are housed in single negative-pressure rooms and persons entering the rooms are required to wear protective respirators. Patients seen in the outpatient setting should wear a mask while in the medical facility, and providers should wear an N95 respirator when evaluating the patient. If three sputum smears yield negative results on AFB staining, or if a single deep specimen (bronchial lavage or tracheal aspirate) is smear negative, infectious TB is unlikely and respiratory precautions can be discontinued. Patients who are highly suspect for MTB and lack an alternative diagnosis may be kept on precautions and empiric treatment may be started, as transmission of TB from AFB smear-negative, culture-positive TB patients is well documented. Persons who have responded to treatment for an alternative diagnosis (e.g., bacterial pneumonia), and those who cannot produce the requisite three sputum samples, may be released from the TB precautions.

The impact of TB transmission is greater in a health care setting, where immunosuppressed persons may be exposed, than at home, where exposure has occurred prior to the TB evaluation. Of course, children younger than age 5 and immunosuppressed persons in the home are at increased risk.

Treatment

Treatment for TB should be instituted promptly when TB is considered likely and the proper specimens to prove the diagnosis have been obtained. It is ideal to have a positive smear result (and confirmation by NAA testing) prior to initiating treatment, but empiric treatment should be started while the initial specimens are collected from patients in whom the suspicion of TB is high, in severely ill persons, or in circumstances in which positive smear results are unlikely (e.g., suspected TB meningitis with AFB smear-negative CSF).

Randomized trials have demonstrated that ART decreases mortality in HIV-infected persons with active TB regardless of initial CD4 cell count; thus, effective ART should be initiated or optimized in everyone with TB/HIV coinfection; see “Coordinating with antiretroviral therapy,” below.

Adherence is the most important treatment issue once the decision to treat is made and an appropriate regimen is selected. *It is the responsibility of the treating clinician to ensure that the patient completes a full course of therapy.* Therefore, it is strongly recommended that patients be referred to public health departments for TB treatment. Health departments usually can provide free TB treatment and have specific resources and systems to promote adherence. It is recommended that all patients receive directly observed therapy (DOT), an approach by which the taking of every dose of anti-TB medication is observed and documented. Clinical trials have documented that DOT with enhancements to maximize adherence not only improves the rate of completion of therapy but also reduces mortality among HIV-infected TB patients. If a health department manages the TB treatment, the HIV clinician must coordinate with the health department for the following reasons: 1) to coordinate TB and HIV treatment regimens; 2) to avoid or adjust for drug interactions; 3)

to assist the health department in avoiding diagnostic or treatment confusion in the event of immune reconstitution inflammatory syndrome (IRIS) or incident opportunistic diseases; and 4) to maximize adherence with the TB medications, ART, opportunistic infection treatment or prophylaxis, and any other medications.

Treatment consists of two phases: intensive and continuation. Several intermittent therapy regimens have been designed to simplify DOT; however, use of TIW and BIW regimens during the intensive phase of treatment have led to higher rates of treatment failure and resistance, as have weekly or BIW continuation

phase regimens. **Thus, daily (or 5-7 days per week) dosing by DOT is recommended during the intensive phase of treatment,** and 5-7 days per week or TIW dosing is recommended during the continuation phase.

Preferred therapy (drug-susceptible pulmonary TB)

- **Intensive Phase:** Isoniazid + rifampin (or rifabutin) + pyrazinamide + ethambutol QD (5-7 days per week) for 8 weeks, by DOT
- **Continuation Phase:** isoniazid + rifampin or rifabutin 5-7 days per week or TIW

Table 2. Recommended Dosages of First-Line Antituberculosis Drugs for Adults

Drug	Daily	3 Times Weekly
Isoniazid	5 mg/kg (usual dose 300 mg)	15 mg/kg (usual dose 900 mg)
Rifampin[†]	10 mg/kg (usual dose 600 mg)	10 mg/kg (usual dose 600 mg)
Rifabutin*		
without HIV protease inhibitors, efavirenz, rilpivirine, or elvitegravir/cobicistat	5 mg/kg (usual dose 300 mg)	5 mg/kg (usual dose 300 mg)
with HIV protease inhibitors	150 mg	300 mg
with efavirenz	450-600 mg	450-600 mg
with elvitegravir/cobicistat*	150 mg	150 mg
Pyrazinamide		
40-55 kg body weight	1,000 mg (18.2-25.0 mg/kg)	1,500 mg (27.3-37.5 mg/kg)
56-75 kg body weight	1,500 mg (20.0-26.8 mg/kg)	2,500 mg (33.3-44.6 mg/kg)
76-90 kg body weight	2,000 mg (22.2-26.3 mg/kg)	3,000 mg (33.3-39.5 mg/kg)
>90 kg body weight	2,000 mg [#]	3,000 mg [#]
Ethambutol		
40-55 kg body weight	800 mg (14.5-20.0 mg/kg)	1,200 mg (21.8-30.0 mg/kg)
56-75 kg body weight	1,200 mg (16.0-21.4 mg/kg)	2,000 mg (26.7-35.7 mg/kg)
76-90 kg body weight	1,600 mg (17.8-21.1 mg/kg)	2,400 mg (26.7-31.6 mg/kg)
>90 kg body weight	1,600 mg [#]	2,400 mg [#]

[†] Rifampin is not recommended for patients receiving HIV protease inhibitors, efavirenz, rilpivirine, or elvitegravir/cobicistat. Dolutegravir, raltegravir, and maraviroc require dosage adjustment.

* Avoid coadministration of rifabutin with elvitegravir/cobicistat, if possible. If used together, consider therapeutic drug monitoring and dosage adjustment as indicated. Do not coadminister with rilpivirine.

[#] For patients weighing >90 kg, monitor for therapeutic response can consider therapeutic drug monitoring.

Adapted from Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. *Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America*. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Four anti-TB drugs are administered for the first 2 months, then two drugs are administered for an additional 4 months (if the organism is susceptible to standard medications). The initial phase of TB treatment usually consists of isoniazid, rifampin or rifabutin (see below), pyrazinamide, and ethambutol; the continuation phase typically is simplified to isoniazid and rifampin. Pyridoxine (vitamin B6) at a dosage of 10-50 mg QD usually is included to minimize the risk of isoniazid-induced peripheral neuropathy. If drug resistance or MDR is suspected, more drugs can be used initially, and treatment should be directed by experts. Resistance may be suspected among persons exposed to TB in countries with high rates of endemic resistance, those for whom previous treatment has failed, those who have been on and off treatment erratically, those who may have had a specific exposure to drug-resistant TB, and those who have been diagnosed during an outbreak. If drug susceptibility testing shows sensitivity to isoniazid and rifampin, ethambutol can be discontinued during the intensive phase.

In certain circumstances, treatment duration is extended. In cavitary TB or TB in an HIV-infected person that remains sputum culture positive after 2 months of treatment, the two-drug continuation phase should be extended to 7 months for a total treatment course of 9 months. For extrapulmonary TB in HIV-infected persons, a 6- to 9-month course of treatment is recommended. Exceptions include meningeal TB, which is treated for 9-12 months. If cultures obtained prior to treatment demonstrate drug resistance, the regimen and the duration of therapy may need to be changed.

For TB meningitis or pericarditis, a course of corticosteroids may be given in addition to specific anti-TB therapy: dexamethasone 0.3-0.4 mg/kg/day for 2-4 weeks then tapered over

the course of 8-10 weeks or prednisone 1 mg/kg/day for 3 weeks followed by a taper over the course of 3-5 weeks. For adrenal insufficiency, replacement corticosteroids should be given.

Considerations During pregnancy

Pyrazinamide has not been formally proven safe for use during pregnancy; however, it is used during pregnancy in many countries and there have been no reports of problems. Some health departments in the United States avoid the use of pyrazinamide for pregnant women and extend the continuation phase to 7 months, whereas others prescribe the standard regimens shown in Table 2 during pregnancy. Streptomycin and certain second-line drugs should be avoided during pregnancy. HIV-infected women in the United States are instructed not to breast-feed, so there usually are no issues regarding TB treatment of HIV-infected women during breast-feeding. ART should be started as early as possible; consult with an expert.

Coordinating with Antiretroviral Therapy

ART and TB treatment must be coordinated for both to be successful. ART is strongly recommended for all adults and adolescents with active TB, and both randomized and nonrandomized trials have demonstrated reduction in mortality when ART is combined with anti-TB chemotherapy.

The optimal timing of ART initiation in relation to TB treatment has been established with several randomized controlled trials. Adults and adolescents with active TB and CD4 counts of <50 cells/ μ L should start ART within 2 weeks of starting TB treatment. All patients with CD4 counts of $\geq$ 50 cells/ μ L should start ART within 8-12 weeks of starting TB therapy, but those who have CD4 counts of 50-200 cells/ μ L and severe disease should start within 2-4 weeks, if possible. Further, current HHS ARV guidelines recommend consideration of early ART (within 2-4 weeks)

for patients with CD4 counts of >200 cells/μL and severe disease. In all cases, TB treatment should be started immediately.

Timing of ART initiation in CNS TB infection is not clear. In one randomized trial, there was not a mortality benefit to starting ART at 2 weeks after TB treatment initiation compared with starting after 2 months of TB treatment, and more severe adverse events occurred in the earlier ART arm. Given the capacity for close monitoring that exists in the United States, many experts recommend initiating ART as with non-CNS TB.

Although paradoxical immune response (i.e., IRIS, see below) appears to be more common in patients who start ART earlier in the course of TB treatment, IRIS generally is not fatal.

Drug-drug interactions

Drug interactions between TB medications and ARVs may require dosage adjustments or modifications in treatment (see Table 3). Rifampin is a potent inducer of cytochrome P450 enzymes and has many clinically important drug interactions. It reduces the blood levels of nonnucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), integrase inhibitors, and the CCR5 antagonist maraviroc, but does not affect nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) or the fusion inhibitor enfuvirtide. Triple-nucleoside regimens can be administered safely during rifampin treatment but are less potent than first-line ARV combinations and generally are not recommended. Current guidelines recommend the use of efavirenz plus a two-drug NRTI backbone if cotreatment with rifampin is planned (see Table 3). Efavirenz blood levels may be reduced 25% by concomitant rifampin, but the majority of available clinical data suggest that the standard efavirenz dosage of 600 mg/day is appropriate for rifampin coadministration, particularly in African-American and Asian populations. Limited clinical data support

the use of nevirapine at standard dosages in combination with rifampin. This is not a favored approach because nevirapine levels are reduced up to 50% when combined with rifampin. In one study, 20% of patients on ARV and TB treatment with rifampin had trough nevirapine levels that were below target, although they achieved the same rates of HIV RNA suppression as did patients on efavirenz. Plasma levels of the integrase inhibitors raltegravir and dolutegravir also are reduced when they are given with rifampin but the interaction can be overcome by increasing the dosage of the integrase inhibitor; few clinical data are available on the use of integrase inhibitors with rifampin.

To avoid rifampin-ARV interactions, rifabutin typically is used in place of rifampin. Rifabutin has fewer marked effects on the pharmacokinetics of other drugs, although its own blood concentrations can be affected by certain ARVs. Dosing recommendations for rifabutin with ARVs are found in Table 3. Acquired rifamycin resistance has been reported with coadministration of rifabutin with protease inhibitors, leading to the recommendation that the rifabutin dosage be at least 150 mg daily when given with ritonavir-boosted PIs and that monitoring of serum rifabutin levels be considered. Rifabutin is expensive; some public health systems do not provide rifabutin as part of TB treatment and it often is not available in resource-limited countries. The FDA characterizes rifabutin in pregnancy category B: it has been safe in animal studies of pregnancy but has not been proven safe for humans. For pregnant women who require both TB and ARV therapy, the use of rifabutin rather than rifampin allows the use of non-efavirenz-based ARV regimens.

Persons who are already on ART when TB treatment is begun must have their ARV regimens reassessed; the appropriate dosages of rifampin or rifabutin must be chosen or the ARV regimen must be modified, at least until completion of TB treatment (see Table 3).

Table 3. Interactions Between Antiretroviral Medications and Rifampin or Rifabutin: Contraindicated Combinations and Dosage Adjustments*

Antiretroviral Agent	Rifampin	Rifabutin* (Preferred in combination with PIs)
Nonnucleoside Reverse Transcriptase Inhibitors		
Efavirenz**	↓ efavirenz AUC; use standard efavirenz dosage 600 mg QD with monitoring for virologic efficacy (consider 800 mg QD if weight >60 kg).	Use standard efavirenz dosage. Increase rifabutin to 450-600 mg daily.
Etravirine	↓ etravirine levels expected; do not coadminister.	Etravirine without ritonavir-boosted PI: rifabutin 300 mg QD. Etravirine with a boosted PI: avoid, or consider therapeutic drug monitoring or rifabutin.
Nevirapine	↓ nevirapine levels; avoid if possible. If used, initiate nevirapine at 200 mg BID (no lead-in dosage); do not use nevirapine extended-release formulation.	↓ nevirapine and ↑ rifabutin levels. No dosage adjustment recommended; use cautiously.
Rilpivirine	↓ rilpivirine levels; do not coadminister.	↓ rilpivirine levels; do not coadminister.
Protease Inhibitors		
All protease inhibitors	↓ protease inhibitor levels; do not coadminister.	↑ rifabutin levels; adjust rifabutin dosage to 150 mg QD. Monitor for anti-TB efficacy, consider therapeutic drug monitoring.
Integrase Inhibitors		
Dolutegravir	↓ dolutegravir levels; increase dolutegravir to 50 mg BID for integrase-naïve patients (avoid if integrase resistance).	No dosage adjustment.
Elvitegravir/cobicistat	↓ elvitegravir and cobicistat levels expected; do not coadminister	↓ elvitegravir and ↑ rifabutin levels; do not coadminister.
Raltegravir	Increase raltegravir dosage to 800 mg BID; monitor for virologic response.	No dosage adjustment.
CCR5 Receptor Antagonists		
Maraviroc	↓ maraviroc levels; coadministration not recommended. If maraviroc must be used: Without a strong CYP 3A4 inhibitor: maraviroc 600 mg BID. With a strong CYP 3A4 inhibitor: maraviroc 300 mg BID.	Possible ↓ maraviroc levels. Without a strong CYP 3A4 inhibitor: maraviroc 300 mg BID. With a strong CYP 3A4 inhibitor: maraviroc 150 mg BID.
Fusion Inhibitors		
Enfuvirtide	No dosage adjustment.	No dosage adjustment.

Note: Rifapentine should not be coadministered with NNRTIs, PIs, or maraviroc.

* If available, rifabutin may be substituted for rifampin when TB treatment and ART are combined.

** Avoid use of efavirenz during early pregnancy and with women who may become pregnant while on therapy. Both rifampin and rifabutin significantly reduce estrogen and progestin levels for women on hormonal contraceptives; efavirenz raises estrogen levels moderately. Two forms of birth control, including one barrier method and either a mid- to high-dose hormonal contraceptive or an intrauterine device, are recommended most often.

Adapted from Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. *Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America*. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Monitoring for efficacy

Ideally, every dose of anti-TB therapy is observed and documented by a health care agent or responsible individual, particularly during the intensive phase. Patients' adherence should be evaluated by a health care team member at least weekly during the initial phase of treatment and at least weekly or monthly during the continuation phase. If gaps in medication use occur, the cause must be evaluated and a plan to improve adherence must be implemented.

In treatment of pulmonary TB, monthly sputum specimens should be obtained for smear and culture until two sequential specimens are sterile on culture. Patients with extrapulmonary and disseminated TB usually are monitored clinically and with imaging studies. Biopsies are not repeated but other specimens (CSF and other body fluids) may be obtained for repeat AFB smear and culture. Monitoring of patients with extrapulmonary and disseminated TB should be done in consultation with an expert.

Immune reconstitution inflammatory syndrome

Patients on treatment for active TB who begin ART may experience a paradoxical increase in signs and symptoms of TB (fever, dyspnea, increased cough, enlarging lymph nodes, worsening chest X-ray findings, increased inflammation at other involved sites, or enlargement of CNS tuberculomas). These often are attributable to an enhanced immune response against remaining MTB organisms that occurs because of immunologic improvement from ART. IRIS may occur at any point from within 2 weeks up to several months after ART is initiated. TB treatment failure (potentially owing to an inappropriate treatment regimen, inadequate adherence, or drug resistance) must be ruled out, and the possibility of drug toxicity should be considered. In addition, new presentation

of opportunistic infection or malignancies should be considered. Paradoxical IRIS is a clinical diagnosis, and it can be made only after alternative diagnoses are excluded. If IRIS is diagnosed, TB and HIV treatment should be continued and symptoms can be managed with nonsteroidal antiinflammatory drugs or, in severe cases, with corticosteroids. Many experts recommend the use of corticosteroids particularly in the case of TB IRIS involving the CNS (see chapter *Immune Reconstitution Inflammatory Syndrome*).

Adverse effects of anti-TB medications

Anti-TB medications may have significant adverse effects. The most important adverse reactions reported for the commonly used anti-TB medications are listed in Table 4. The most frequent toxicities of first-line TB medications include hepatic enzyme elevations. Before initiating TB treatment, conduct a complete blood count with platelet count, serum creatinine count, liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT], bilirubin, alkaline phosphatase), and hepatitis B and C serology. Newly diagnosed TB patients with unknown HIV status should be tested for HIV infection.

Patients should be monitored monthly with a symptom review to assess possible toxicity, and laboratory tests should be performed if symptoms suggest adverse effects. For patients with liver disease, it may be prudent to perform routine laboratory monitoring after 1 month on treatment and every 3 months thereafter. Persons with symptoms and aminotransferase elevations ≥ 3 times the upper limit of normal, and asymptomatic persons with aminotransferase elevations ≥ 5 times the upper limit of normal, should have therapy interrupted and should be managed thereafter in consultation with an expert.

Patients should be monitored for isoniazid-induced peripheral neuropathy; this adverse

effect is rare if pyridoxine is administered with isoniazid, as recommended. Testing of visual acuity and red-green color vision is recommended at the start of therapy with ethambutol. Persons on standard ethambutol dosages with normal baseline examinations

should be asked monthly about visual disturbances. Patients on higher ethambutol dosages and those who have been on ethambutol for more than 2 months should have periodic eye examinations for acuity and color discrimination.

Table 4. Adverse Events Associated with Common Anti-TB Medications

Medication	Common Toxicity	Rare Toxicity
First-Line Agents		
Isoniazid	Transient transaminase elevation, hepatitis, positive antinuclear antibody (ANA)	Peripheral neurotoxicity, lupus-like syndrome, CNS effects, hypersensitivity, rash, monoamine poisoning
Rifampin	Transient bilirubin elevation, transaminase elevations, anorexia, nausea, vomiting, hepatitis, red-orange discoloration of urine and tears	Acute renal failure, shock, thrombocytopenia, rash, “flu” syndrome from intermittent doses, pseudomembranous colitis, pseudoadrenal crisis, osteomalacia, hemolytic anemia
Rifabutin	Elevated liver function tests, nausea, red-orange discoloration of urine and tears	Cytopenias, uveitis, rash
Ethambutol	Optic neuritis	Skin rash, joint pains, peripheral neuropathy
Pyrazinamide	Joint pains, gout, hepatitis	Gastrointestinal symptoms, skin rash, sideroblastic anemia
Streptomycin	Auditory and vestibular nerve damage, renal injury	Rash
Second-Line Agents		
Moxifloxacin	Nausea, diarrhea, dizziness	Tendon rupture, hepatotoxicity, renal damage, prolonged QT interval, skin reactions
Amikacin/ Kanamycin	Auditory, vestibular, renal injury	

Adapted from American Thoracic Society; CDC; Infectious Diseases Society of America. *Treatment of Tuberculosis*. MMWR Recomm Rep. 2003 Jun 20;52(RR-11):1-77; and Harries A, Maher D, Gramm S; World Health Organization. *HIV/TB: A Clinical Manual, 2nd Edition*. Geneva: World Health Organization; 2004:131-2.

Patient Education

- All patients with TB-positive sputum or bronchoscopy specimens can infect others with TB. All close contacts, especially children, should be screened for TB as soon as possible and given medication to prevent (or treat) active disease.
- The health department will be notified of each TB case and will provide the required follow-up care.
- Patients must take all medicines exactly as prescribed. If doses are missed, or if the medication is stopped and restarted, the TB bacteria can develop resistance to even the best medications and become even more dangerous. If patients are having trouble taking the medication on schedule, they should contact their health care provider immediately.
- If patients become ill, if their skin or eyes turn yellow, or if their urine darkens to a “cola” color, they should contact their health care provider immediately.
- Patients must keep all follow-up appointments. Blood tests will be done regularly to ensure that the liver is working well, and patients will be checked for medication adverse effects. They should show their health care provider all medications, vitamins, and supplements they are taking so that the provider can check for drug interactions.
- Rifampin and rifabutin will make urine, sweat, and tears turn orange; this is not harmful. They will cause staining of plastic contact lens; patients should avoid wearing contact lenses if they are taking rifamycins.
- Rifampin and rifabutin may cause birth control pills to become ineffective. An alternative method of contraception should be used when the patient is undergoing treatment.
- The use of alcohol should be avoided during treatment with TB drugs to avoid the risk of liver damage.

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Pelvic Inflammatory Disease

Background

Pelvic inflammatory disease (PID) is the syndrome resulting from the ascent of microorganisms from the vagina and cervix to the uterine endometrium, fallopian tubes, ovaries, or contiguous abdominal structures. Many episodes of PID go unrecognized, because of lack of symptoms or mild, nonspecific symptoms (e.g., dyspareunia, abnormal bleeding, and vaginal discharge). Infecting organisms may include *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT), which are sexually transmitted, as well as anaerobic bacteria (*Gardnerella vaginalis* or *Haemophilus influenzae*), gram-negative rods (*Escherichia coli*), *Streptococcus agalactiae*, gastrointestinal flora, and mycoplasmas (*Mycoplasma hominis*). It is thought that PID generally is caused by sexually transmitted diseases (STDs) and that additional organisms become involved after infection spreads and protective immunological barriers are disrupted.

Between 20% and 40% of women with cervical chlamydial infection and 10-20% of women with gonococcal infection eventually develop PID, but accurate estimates of the incidence of PID and infertility resulting from GC and CT are difficult to obtain. Hospitalizations for PID declined steadily throughout the 1980s and 1990s but remained relatively constant between 2000 and 2006, at approximately 80,000 annually.

PID is co-epidemic with HIV among some urban populations of reproductive age. Data on PID outcomes among HIV-infected women are limited. Many studies have documented no difference in length or severity of lower abdominal pain, vaginal discharge, fever, abnormal vaginal bleeding, or low back pain between HIV-infected and HIV-uninfected women with PID. However, there is a higher rate of tubo-ovarian abscesses and severe salpingitis and pyosalpinx among HIV-infected women.

Clinical presentation may include salpingitis, endometritis, tubal and ovarian abscess, and pelvic peritonitis, although PID may present with subtle or mild symptoms even in HIV-infected women. Long-term complications of PID may include infertility, ectopic pregnancy, pelvic adhesions, and chronic pain. After a single episode of PID, a woman's risk of ectopic pregnancy increases sevenfold. Approximately 13% of women are infertile after a single episode of PID, 25-35% after two episodes, and 50-75% after three or more episodes.

Diagnosis of PID usually is based on clinical findings, and providers should maintain a low threshold for diagnosing and promptly treating this disease, as it can wreak havoc on a woman's reproductive health. All women who are diagnosed with PID should be tested for GC and CT.

S: Subjective

The patient may complain of mild-to-moderate lower abdominal pain and tenderness, pain with intercourse, vaginal discharge, fever, chills, heavy menstrual bleeding, or other abnormal vaginal bleeding.

Inquire about the following during the history:

- Symptoms listed above, and duration
- Sexual history including new sex partner(s)

and episodes of unprotected sex

- Last menstrual period
- Previous diagnosis of gonorrhea or chlamydia
- Previous abdominal or gynecologic surgery
- History of recent intrauterine device (IUD) placement (the risk of PID associated with IUD use is confined primarily to the first 3 weeks after insertion)

O: Objective

Check vital signs with special attention to temperature (may be elevated or normal).

Perform a focused physical examination.

Check abdomen (bowel sounds, distention, rebound, guarding, masses, suprapubic and costovertebral angle [CVA] tenderness); perform complete pelvic examination looking for abnormal bleeding or discharge; uterine, adnexal, or cervical motion tenderness; pelvic masses or adnexal enlargement.

A: Assessment

A partial differential diagnosis includes the following:

- Pregnancy, uterine or ectopic
- Ruptured or hemorrhagic ovarian cyst
- Dysmenorrhea
- Appendicitis
- Pyelonephritis
- Diverticulitis
- Irritable bowel syndrome
- Cystitis
- Uterine fibroids/leiomyomas
- Ovarian torsion
- Mittelschmerz
- Kidney stones
- Pyelonephritis

P: Plan**Diagnostic Evaluation**

A diagnosis of PID usually is based on clinical findings; however, the following can support a diagnosis and help rule out other causes of abdominal pain:

- Pregnancy test
- Nucleic acid amplification tests (NAAT) or culture for GC and CT
- Microscopic examination of saline preparation of vaginal secretions

Often, diagnosis must be made and treatment initiated on the basis of clinical criteria. Current guidelines identify “minimal criteria” found on pelvic examination in patients with PID:

- Cervical motion tenderness, or
- Uterine tenderness, or
- Adnexal tenderness

The following signs support a diagnosis of PID:

- Oral temperature $>101^{\circ}\text{F}$ ($>38.3^{\circ}\text{C}$)
- Abnormal cervical or vaginal mucopurulent discharge
- Presence of abundant numbers of white blood cells on saline microscopy of vaginal secretions (this also can detect concomitant infections such as bacterial vaginosis and trichomoniasis)
- Elevated erythrocyte sedimentation rate (ESR)
- Elevated C-reactive protein (CRP)
- Laboratory documentation of cervical infection with GC or CT (the absence of infection from the lower genital tract, where samples are usually obtained, does not exclude PID and should not influence the decision to treat)

Definitive diagnosis may be made on the basis of:

- Endometrial biopsy with histopathologic evidence of endometritis
- Transvaginal sonogram or other imaging showing thickened, fluid-filled tubes with or without free pelvic fluid or tubo-ovarian complex
- Laparoscopic abnormalities consistent with PID

Treatment

Because clinical diagnostic criteria for PID are not always conclusive, presumptive diagnosis and early empiric treatment is common. The positive predictive value of a clinical diagnosis is 65-90%.

Empiric therapy for PID should be started in women who have one or more of the minimal criteria, plus pelvic or lower abdominal pain and risk factors for PID (sexually active young women, women at risk of STDs), unless another cause for the symptoms is identified.

Treatment considerations

Antimicrobial regimens must be broadly effective against likely pathogens (see below). HIV-infected women appear to respond as well to standard antibiotic regimens as do HIV-uninfected women. It is not known whether HIV-infected women with advanced immunosuppression should be treated more aggressively; decisions about whether to use oral or parenteral therapy must be individualized.

In the United States and elsewhere GC commonly is resistant to fluoroquinolone; thus, this class of antibiotics is no longer recommended for treatment of PID.

No evidence suggests that IUDs should be removed in women diagnosed with PID. However, caution should be used if the IUD remains in place, and close clinical follow-up is recommended.

The goals of treatment include the following:

- Alleviate the pain and systemic malaise associated with infection
- Achieve microbiological cure
- Prevent development of permanent tubal damage with associated problems, such as chronic pelvic pain, ectopic pregnancy, and infertility
- Prevent the transmission of infection to others

Indications for hospitalization of patients with PID include the following:

- Unsure diagnosis; surgical emergency cannot be excluded
- Pregnancy
- Patient does not respond clinically (within 72 hours) to oral antimicrobial therapy
- Tubo-ovarian abscess
- Severe illness with nausea and vomiting or high fever
- Inability to follow or tolerate outpatient regimen

Pregnancy

If the patient is pregnant, aggressive treatment is essential to prevent preterm delivery, fetal loss, and maternal morbidity. Some medications should be avoided to reduce the risk of fetal toxicity; these include doxycycline and gentamicin. Hospitalization for parenteral antibiotic therapy is recommended.

Antibiotic Regimens

Recommended Oral/Outpatient Regimens

- Ceftriaxone 250 mg IM in a single dose + doxycycline 100 mg PO BID for 14 days, with or without metronidazole 500 mg PO BID for 14 days
- Cefoxitin 2 g IM in a single dose and probenecid 1 g PO concurrently in a single dose + doxycycline 100 mg PO BID for 14 days, with or without metronidazole 500 mg PO BID for 14 days
- Other parenteral third-generation cephalosporin (e.g., ceftizoxime or cefotaxime) + doxycycline 100 mg PO BID for 14 days, with or without metronidazole 500 mg PO BID for 14 days

Alternative Oral Regimens

If parenteral cephalosporin therapy is not feasible, consult with an expert. Limited evidence supports the use of amoxicillin/clavulanic acid with doxycycline, and azithromycin with or without metronidazole or ceftriaxone. Because of the prevalence of fluoroquinolone-resistant GC, use of fluoroquinolones is no longer recommended but may be considered, with or without metronidazole, if the community prevalence is low, the patient's risk of gonorrhea is low, and follow-up can be assured if the GC test result is positive. For more information, see the *CDC Sexually Transmitted Diseases Treatment Guidelines* (see "References," below).

Recommended Parenteral Regimens

- Cefotetan 2 g IV Q12H + doxycycline 100 mg PO BID

- Cefoxitin 2 g IV Q6H + doxycycline 100 mg PO BID
- Clindamycin 900 mg IV Q8H + gentamicin loading dose IV or IM (2 mg/kg of body weight), followed by a maintenance dose (1.5 mg/kg) Q8H; single daily dosing (3-5 mg/kg) may be substituted

Alternative Parenteral Regimen

- Ampicillin/sulbactam 3 g IV Q6H + doxycycline 100 mg PO BID

Women who are started on oral antibiotics but do not respond within 72 hours should be reevaluated to confirm the diagnosis of PID and should be administered parenteral therapy on either an outpatient or inpatient basis. Patients who are treated with parenteral antibiotics usually can be transitioned to oral antibiotics within 24 hours of clinical improvement.

Follow-Up

- Patients should show significant clinical improvement within 3 days of initiation of therapy (e.g., improvement in fever, abdominal tenderness, and uterine, adnexal, and cervical motion tenderness). If the patient has not improved, consider hospitalization, additional diagnostic testing, or surgical intervention. Patients who are hospitalized for treatment initially may be switched to an oral regimen and be discharged on oral therapy after they have improved clinically.
- Evaluate sex partners and offer them treatment if they had sexual contact with the patient during the 60 days preceding the patient's onset of symptoms. Treat empirically for both chlamydia and gonorrhea.
- If the GC or CT test results are positive, rescreening for GC and CT 3 months after therapy is recommended. Provide education about sexual risk reduction. Instruct patients

to use condoms with every sexual contact to prevent reinfection with GC and CT, to prevent other STDs, and to prevent passing HIV to sex partners.

- Studies of patients treated for CT infection show reinfection rates as high as 13% within 4 months of treatment, highlighting the need for follow-up and partner treatment.

Patient Education

- Instruct patients to take all of their medications. Advise patients to take medications with food if they feel nauseated, and to contact the clinic promptly if they experience vomiting or are unable to take their medications.
- Sex partners from the previous 60 days need to be tested for CT, GC, and syphilis (as well as HIV, if uninfected) and treated empirically, as soon as possible, with a regimen effective against GC and CT, even if they have no symptoms. Advise patients to inform their partners that they need to be tested and treated. Otherwise, they may be reinfected.
- Advise patients to avoid sexual contact until the infection has been cured.
- Provide education about sexual risk reduction. Instruct patients to use condoms with every sexual contact to prevent becoming reinfected, to prevent other STDs, and to prevent passing HIV to sex partners.
- Advise patients that PID can recur, and that they should contact the clinic if symptoms such as pain or fever develop.
- Patients must not drink beer, wine, or any other alcoholic beverage while taking metronidazole, and for at least 24-48 hours after the last dose. Metronidazole may cause a disulfiram-like reaction, resulting in severe nausea and vomiting. Note that patients taking ritonavir capsules may experience symptoms caused by the small amount of

alcohol in the capsules; advise patients to contact the clinic if nausea and vomiting occur.

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Pneumocystis Pneumonia

Background

Pneumocystis jiroveci pneumonia (previously called *Pneumocystis carinii* pneumonia, and still abbreviated PCP), is caused by an unusual fungus, *P. jiroveci*. Many humans appear to be infected in childhood, but clinical illness occurs only in people with advanced immunosuppression, either through new infection or reactivation of latent infection. More than 90% of PCP cases occur in patients with CD4 counts of <200 cells/ μ L. Cases of PCP in otherwise healthy young men who have sex with men were among the first recognized manifestations of AIDS, in 1981. The organism can affect many organ sites, but pneumonia is by far the most common form of disease. In the United States, the incidence of PCP has declined sharply since the use of prophylaxis and effective antiretroviral therapy (ART) became widespread, but PCP is still many patients' initial presenting opportunistic infection, and it is a significant cause of morbidity and mortality among HIV-infected patients.

S: Subjective

The patient reports fever, shortness of breath, particularly with exertion, nonproductive cough, night sweats, weight loss, or fatigue. Typically, the symptoms worsen over the course of days to weeks. Pleuritic pain and retrosternal pain or burning also may be present. There may be minimal symptoms early in the disease course of PCP.

Ask the patient about fever, fatigue, and weight loss, which may be present for weeks, with gradual worsening of shortness of breath. PCP may present less commonly with acute onset symptoms of fevers, chills, sweats, dyspnea, and cough.

Note: Given the possibility of HIV-associated tuberculosis (TB), patients with cough should be kept in respiratory isolation until TB is ruled out.

O: Objective

Perform a full physical examination, with particular attention to the following:

- Vital signs, including temperature, heart rate, blood pressure, respiratory rate, oxygen saturation at rest and after exertion (there is often a sharp drop in oxygen saturation with exertion)

- Appearance
- Lung examination

Patients may appear relatively well, or acutely ill. Tachypnea may be pronounced, and patients may exhibit such a high respiratory rate (e.g., >30 breaths per minute) that they are unable to speak without stopping frequently to breathe. Chest examination may be normal, or reveal only minimal rales, although coughing is common on deep inspiration. Cyanosis may be present around the mouth, in the nail beds, and on mucous membranes. Cough is either unproductive, or productive of a thin layer of clear or whitish mucus.

A: Assessment

A partial differential diagnosis includes the following:

- Pneumococcal pneumonia
- Other bacterial pneumonias
- TB
- Influenza Lymphocytic interstitial pneumonitis
- Bronchitis
- Cytomegalovirus (CMV) pneumonitis
- Histoplasmosis

- Other fungal pneumonia, especially cryptococcosis
- Pulmonary Kaposi sarcoma
- *Mycobacterium avium* complex
- Asthma, chronic obstructive pulmonary disease
- Congestive heart failure
- Pulmonary hypertension

P: Plan

Diagnostic Evaluation

- **CD4 cell count:** Check records for a recent CD4 count (CD4 is <200 cells/ μ L in $>90\%$ of PCP cases). Note that a CD4 count obtained in the setting of acute illness (e.g., when the patient presents with pneumonia) may be substantially lower than the usual baseline, and may be difficult to interpret.
- **Pulse oximetry at rest and after exercise:** Oxygen desaturation with exercise suggests an abnormal alveolar-arterial O_2 gradient (A-a gradient).
- **Arterial blood gas (ABG):** Hypoxemia is common, as is elevation in A-a gradient. Generally, PO_2 levels and A-a gradient are associated with disease severity. Poorer outcomes are seen with $PO_2 <70$ mm Hg and A-a gradient >35 mm Hg.
- **Lactate dehydrogenase (LDH):** Elevated serum LDH (>300 – 500 IU/L) is common.
- **Chest X-ray:** Typically shows bilateral interstitial infiltrates, but atypical patterns with cavitation, lobar infiltrates, nodules, or pneumothorax may occur, and chest X-ray findings may be normal in some cases. Upper-lobe predominance is common if the patient is receiving aerosolized pentamidine for PCP prophylaxis.
- **Thin-section chest computed tomography (CT) scan:** May show patchy ground-glass opacities; in a patient with clinical signs or symptoms of PCP, these are suggestive but not diagnostic of PCP.
- **Sputum induction:** The patient inhales saline mist to mobilize sputum from the lungs. The respiratory therapist collects expectorated sputum, which is stained and examined for *P. jiroveci* organisms. This technique is useful because of its noninvasive approach, but it requires an experienced technician, and is not available at all centers. Sensitivity varies widely (10–95%), depending on the expertise level of the staff at a particular center. (If there is any chance that the patient has TB, sputum induction should be performed in a confined space in a negative pressure area or near an exhaust fan vented safely outside, and samples should be sent for acid-fast bacilli [AFB] smear and culture.)
- **Bronchoscopy with bronchoalveolar lavage (BAL):** Definitive diagnosis usually can be made through detection of organisms in BAL fluid obtained during bronchoscopy. Sensitivity is $>95\%$ at centers with an experienced staff. BAL fluid can be evaluated for bacteria, mycobacteria, and fungi, as well as for *P. jiroveci*. Polymerase chain reaction (PCR) testing increasingly is used; its specificity has not been well established.
- **Transbronchial biopsy:** May be performed if BAL is not diagnostic and if lung disease is progressive despite treatment, to look for diagnoses other than PCP. Open lung biopsy rarely is performed.

Treatment

Presumptive treatment often is initiated on the basis of clinical presentation, chest X-ray findings, and ABG results, while definitive diagnostic tests are pending. The standard and alternative treatment regimens are shown below. Duration of treatment is 21 days for all regimens.

Trimethoprim-sulfamethoxazole (TMP-SMX, Bactrim, Septra, cotrimoxazole) is the drug of choice, administered IV or PO for 21 days (a typical PO dose is 2 double-strength tablets taken TID). Adverse effects of TMP-SMX (e.g., rash, fever, leukopenia, anemia, gastrointestinal intolerance, hepatotoxicity, hyperkalemia) are common, mostly mild, and usually “treated through” successfully. Patients who have had previous reactions to sulfa drugs also may be desensitized successfully (see chapter *Sulfa Desensitization*). TMP-SMX

requires dosage adjustment for patients with renal insufficiency.

Pentamidine has similar efficacy to TMP-SMX but greater toxicity (nephrotoxicity, pancreatitis, glucose dysregulation, cardiac arrhythmias). It usually is reserved for patients with severe disease who require IV therapy.

Adjunctive corticosteroids

Adjunctive corticosteroids should be given if the patient’s PO_2 is <70 mm Hg (breathing room air) or the A-a gradient is ≥ 35 mm Hg. Corticosteroids should be given as early as possible (preferably before or with the first dose of antibiotic therapy) and within 36-72 hours of the start of anti-PCP therapy:

- Prednisone 40 mg BID days 1-5; 40 mg QD on days 6-10; 20 mg QD on days 11-21. Alternatively, IV methylprednisolone can be given, at 75% of the prednisone dosage.

Moderate to Severe PCP
Preferred therapy • TMP-SMX (TMP 15-20 mg/kg/day + SMX 75- 100 mg/kg/day) IV in divided doses Q6H or Q8H (switch to PO after clinical improvement) Alternative therapy • Pentamidine 4 mg/kg IV QD (dosage reduction to 3 mg/kg QD may be needed if toxicities develop) • Clindamycin 600 mg IV or 900 mg IV Q8H (or 300 mg PO Q6H or 450 mg PO Q8H) + primaquine* base 30 mg PO QD
Mild to Moderate PCP
Preferred therapy • TMP-SMX (TMP 15-20 mg/kg/day + SMX 75- 100 mg/kg/day) PO, in divided doses TID • TMP-SMX double-strength (DS), 2 tablets TID Alternative therapy • Dapsone* 100 mg PO QD + TMP 15 mg/kg/day PO in 3 divided doses • Clindamycin (300 mg PO Q6H or 450 mg PO Q8H) + primaquine* base 30 mg PO QD • Atovaquone 750 mg PO BID with food

* Test for G6PD deficiency before use (most common among patients of African or Mediterranean descent); caution with use in patients with G6PD deficiency.

Other therapy notes

- Patients started on IV therapy can be switched to a PO treatment regimen to complete the 3-week course when they are afebrile, have improved oxygenation, and are able to take oral medications.
- For patients not already on ART, ART generally should be started within 2 weeks of initiating treatment for PCP.
- Paradoxical worsening of PCP resulting from presumed immune reconstitution inflammatory syndrome (see chapter *Immune Reconstitution Inflammatory Syndrome*) has been reported; monitor patients for worsening symptoms after ART initiation.
- Consultation with HIV experts is advisable when initiating of ART in the setting of PCP.

Treatment failures

The average time to clinical improvement for hospitalized patients is 4-8 days, so premature change in therapy should be avoided. For patients who fail to improve on appropriate therapy, it is important to exclude other diagnoses, rule out fluid overload, and consult an infectious disease specialist.

Secondary Prophylaxis

Anti-PCP prophylaxis (chronic maintenance therapy) should be given to all patients who have had an episode of PCP. Prophylaxis should be continued for life, unless immune reconstitution occurs as a result of ART and the CD4 count has been >200 cells/ μ L for more than 3 months.

In patients with stable CD4 count of >200 cells/ μ L on effective ART, it is recommended that PCP prophylaxis be discontinued because it offers little clinical benefit but may cause drug toxicity, drug interactions, and selection of drug-resistant pathogens, plus it

adds to the cost of care and to the patient's pill burden.

If PCP occurred at a CD4 count of >200 cells/ μ L, it is recommended to continue prophylaxis for life despite immune reconstitution; however, data to support this approach are limited.

Prophylactic therapy**Preferred:**

- TMP-SMX DS, 1 tablet PO QD, or 1 single-strength tablet PO QD

Alternative:

- TMP-SMX DS: 1 tablet PO TIW (e.g., Monday, Wednesday, Friday)
- Dapsone* 100 mg PO QD, or 50 mg PO BID
- Dapsone* 50 mg PO QD + pyrimethamine 50 mg PO once weekly + leucovorin 25 mg PO once weekly
- Dapsone* 200 mg PO + pyrimethamine 75 mg + leucovorin 25 mg, all once weekly
- Aerosolized pentamidine 300 mg once monthly, via Respigard II nebulizer (note: does not prevent toxoplasmosis) (Warning: May increase the risk of extrapulmonary pneumocystosis, pneumothorax, and bronchospasm.)
- Atovaquone 1,500 mg PO QD (with or without pyrimethamine 25 mg PO QD + leucovorin 10 mg PO QD)

* Use with caution in G6PD deficiency.

Primary Prophylaxis

- Primary prophylaxis against PCP should be given to all HIV-infected patients with a CD4 count of <200 cells/ μ L, CD4 percentage of $<14\%$, or a history of oral candidiasis; see chapter *Opportunistic Infection Prophylaxis*.

Patient Education

- Patients should be instructed to take all medications exactly as prescribed.
- Patients should call their health care provider if symptoms worsen.
- Patients being treated with TMP-SMX or dapsone who develop rash, fever, or other new symptoms should call their provider to be evaluated for a drug reaction.
- Patients should understand that taking anti-PCP prophylaxis is extremely important for preventing repeat episodes of illness. Patients should not stop taking these medicines without talking with their health care provider, and should not let their supply of medications run out.
- Patients should be counselled about the importance of ART in restoring immune system function to reduce the likelihood of illness and death from PCP and other OIs.

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Progressive Multifocal Leukoencephalopathy

Background

Classic PML

Progressive multifocal leukoencephalopathy (PML) is a demyelinating disease of the central nervous system (CNS) caused by reactivation of latent infection with JC virus, a polyomavirus that infects and lyses oligodendrocytes. Demyelination can occur along any part of the white matter, and often does so at multiple sites (hence the term multifocal). The severity of symptoms increases as demyelination progresses.

Among HIV-infected patients, PML occurs classically and most frequently in those with CD4 counts of <200 cells/ μL who are not receiving antiretroviral therapy (ART), but it can occur in patients with higher CD4 counts and in those on suppressive ART. Patients typically present with multiple focal deficits of the cerebrum and brainstem, such as cognitive decline, focal weakness, and cranial nerve palsies, with one focal deficit often predominating. Symptoms typically progress over the course of several weeks. Imaging studies show noninflammatory, nonenhancing white matter lesions, without mass effect, with an anatomical location that maps to deficits on the neurological examination. A presumptive diagnosis of PML often can be made on the basis of the patient's clinical presentation and results of neuroimaging studies. Cerebrospinal fluid (CSF) often tests positive for JC virus DNA by polymerase chain reaction (PCR), although brain biopsy is sometimes needed for definitive diagnosis.

Among untreated patients, the interval between the first manifestation of neurologic symptoms and death may be as short as 3-4 months. Although the prognosis for patients with PML has improved with the use of potent ART, there is no specific treatment for PML, and mortality rates remain high. Patients who survive PML are likely to have permanent neurologic deficits.

Inflammatory PML

Whereas PML in the absence of ART usually is not an inflammatory condition, initiation of ART may cause an immune reconstitution inflammatory syndrome, involving new or worsening neurologic deficits and inflammatory changes seen on brain imaging and biopsy specimens. (See chapter *Immune Reconstitution Inflammatory Syndrome*.) The initiation of ART in a patient with late-stage HIV-related disease may even reveal previously undetected PML. Although many patients with inflammatory PML improve or at least stabilize, some suffer exacerbation of symptoms, rapid progression of disease, cerebral edema, herniation, and death.

S: Subjective

The patient or a caregiver may note symptoms such as weakness, gait abnormalities, difficulties with speech, visual changes, altered mental status, personality changes, and seizures. Hemianopia, ataxia, dysmetria, and hemiparesis or hemisensory deficits often are seen. The onset is likely to be subacute, with progression over the course of weeks, though neurologic disturbances may become profound. PML is not associated with headache or fever (except in cases of immune reconstitution PML); this may help to distinguish it from other opportunistic illnesses of the CNS.

O: Objective

- Measure vital signs.
- Perform a full physical examination, including a thorough neurologic and mental status evaluation. Look for focal or nonfocal neurologic deficits, particularly cranial nerve abnormalities, visual field defects, weakness, gait abnormalities, and abnormalities in cognitive function, speech, or affect; deficits are likely to be multiple. The patient typically is alert.
- Review previous laboratory values, particularly CD4 count (usually <200 cells/ μ L in patients with PML).

A: Assessment

Rule out other causes of the patient's neurologic changes. A partial differential diagnosis includes the following:

- CNS lymphoma
- Toxoplasmosis
- HIV encephalopathy
- HIV dementia
- Other (non-HIV) forms of dementia
- Cerebrovascular disease
- Neurosyphilis
- CNS opportunistic infection (e.g., tuberculosis, cryptococcosis, and cytomegalovirus)
- Multiple sclerosis

P: Plan**Diagnostic Evaluation**

Presumptive diagnosis of PML often is made on the basis of clinical presentation, brain imaging, and laboratory tests.

Definitive diagnosis requires detection of JC virus DNA in CSF of patients with radiographic and clinical findings consistent with PML or a brain biopsy and identification of characteristic pathological changes. Definitive diagnosis should be attempted in all patients, if possible, and particularly in those patients for whom the diagnosis is unclear.

Radiographic Studies

CNS imaging may reveal changes typical of PML, but is nonspecific. Magnetic resonance imaging (MRI) is more sensitive than computed tomography (CT) for detecting PML. Classic PML presents as single or multiple hypodense lesions in the subcortical white matter, with no surrounding edema. On MRI, lesions show increased T2 signal and little or no enhancement with gadolinium. On CT, PML lesions typically are nonenhancing. In some patients, and particularly in

patients taking ART, PML lesions may show inflammatory changes, such as enhancement, and there may be cerebral edema.

CSF Evaluation

- CSF cell count, protein level, and glucose level generally are normal or show mild pleocytosis and slightly elevated protein.
- JC virus PCR assays are approximately 75–85% sensitive (lower in patients on ART); detection of JC virus in a patient whose clinical presentation and radiographic imaging results are consistent with PML is adequate to make a diagnosis. A negative result with JC virus PCR does not rule out PML.

Other Studies

- Other diagnostic tests should be performed as indicated to rule out other potential causes of the patient's symptoms.
- A brain biopsy should be considered if the diagnosis is unclear.

Treatment

- There is no specific treatment for JC virus. Potent ART with maximal virologic suppression and effective immune reconstitution is the only treatment that may be effective for patients with PML. Even with ART, however, mortality rates approach 40–50%, and neurologic deficits are unlikely to be reversed.
- Initiate ART for patients who are not already receiving treatment. It is not clear whether antiretroviral agents with good CNS penetration are more effective than those that are less likely to cross the blood-brain barrier.
- For patients who are on ART with incomplete virologic suppression, change the ART regimen appropriately to achieve virologic suppression, if possible. (See chapter *Antiretroviral Therapy*.)

- If symptoms are caused by immune reconstitution, consider adding corticosteroids (e.g., dexamethasone or methylprednisolone) to help decrease inflammation.
- The following agents have been proposed as specific therapy for PML, but have not been shown to be effective by prospective studies and are not recommended for treatment: cidofovir, cytarabine, and topotecan. Few data exist to assess the potential benefit of interferon-alfa and inhibitors of the serotonergic 5-HT_{2a} receptor.
- Depending on the patient's cognitive and physical status, he or she may need a care provider in the home to assure that medications are taken on schedule.
- The patient is likely to need supportive care for personal hygiene, nutrition, safety, and prevention of accidents or injury; refer as indicated.

Patient Education

- Most patients diagnosed with PML will need supportive treatment for an undetermined period of time, and hospice referral should be considered if the patient does not show clinical improvement in response to ART.
- If the patient is receiving ART, be sure that caregivers, family members, and friends are taught about the medications and are able to help the patient with adherence.
- When a diagnosis of PML has been established or suspected, initiate a discussion of plans for terminal care (including wills, advanced directives, and supportive care and services) with the patient and family members or caregivers.

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Seborrheic Dermatitis

Background

Seborrheic dermatitis is one of the most common skin manifestations of HIV infection. It occurs in 3-5% of the general HIV-uninfected population but in up to 85-95% of patients with advanced HIV infection. Among HIV-infected individuals, seborrheic dermatitis often begins when their CD4 counts drop to the 450-550 cells/ μ L range. The disease is more likely to occur among young adults (because they have oilier skin) and males, and is more common in areas with cold, dry winter air. It is rarely found in African blacks, unless the person is immunocompromised. It is more common during times of mental stress and severe illness.

Seborrheic dermatitis is a scaling, inflammatory skin disease that may flare and subside over time. It is characterized by itchy reddish or pink patches of skin, accompanied by greasy flakes or scales. It most commonly occurs in the scalp and on the face, especially at the nasolabial folds, eyebrows, and forehead, but also may develop on the ears, chest, upper back, axillae, and groin. Dandruff is considered to be a mild form of seborrheic dermatitis. Occasionally, seborrheic dermatitis may be severe, may involve large areas of the body, and may be resistant to treatment. Severe manifestations are more likely with advanced HIV infection.

The etiology of seborrheic dermatitis is not entirely clear. *Malassezia* yeast (formerly called *Pityrosporum ovale*), a fungus that inhabits the oily skin areas of 92% of humans, is the most likely culprit. This same yeast also is thought to cause tinea versicolor and *Pityrosporum* folliculitis. Overgrowth of the *Malassezia* yeast in the oily skin environment, failure of the immune system to regulate the fungus, and the skin's inflammatory reaction to the yeast overgrowth appear to be the chief factors that cause the dermatitis.

S: Subjective

The patient complains of a new rash, sometimes itchy, or of "dry skin" that will not go away despite the application of topical moisturizers.

O: Objective

Perform a thorough evaluation of the skin with special attention to the scalp, medial eyebrows, eyelashes and eyelids, beard and other facial hair areas, nasolabial folds, postauricular areas, the concha of the auricle, glabella, umbilicus, central chest, back, axillae, and groin. Seborrheic dermatitis appears as white to yellow greasy or waxy flakes over red or pink patches of skin; however, discrete fine scales may indicate a mild form of the

disease. Around the eyes, seborrheic dermatitis can cause eyelid erythema and scaling. The distribution usually is symmetrical.

A: Assessment

The diagnosis of seborrheic dermatitis is based on the characteristic appearance. A partial differential diagnosis includes psoriasis, atopic dermatitis, contact dermatitis, erythrasma, tinea capitis (can be present on the scalp without hair loss), rosacea, and rarely, dermatomyositis.

P: Plan Treatment

- Initiate antiretroviral therapy (ART) for patients not on ART

- Specific treatments are divided into three types: antimycotic (first choice), antiinflammatory (second choice), and keratolytic. Shampoos may be used on the entire body, with avoidance of eyes and mucous membranes.
- Topical antifungal medications: The azoles and ciclopirox have been well studied and shown to have both antifungal and antiinflammatory activity. Various preparations are available; selection can be based on cost and availability. Antifungals may be used in combination with topical corticosteroid therapy (see below). Effective antifungals include but are not limited to the following:
 - Ketoconazole (Nizoral) 2% cream or shampoo; ketoconazole is one of the most widely studied of all topical treatments
 - Bifonazole ointment, miconazole cream (Monistat), terbinafine (Lamisil) 1% solution or cream, or clotrimazole (Lotrimin) 1% cream, lotion, or solution
 - Ciclopiroxolamine (Loprox) 1% shampoo, gel, or cream
 - Zinc pyrithione (keratolytic/antifungal) shampoo or cream
- Topical corticosteroids generally are effective and may be used in combination with topical antifungal therapy (see above). Low-potency agents (e.g., hydrocortisone 1%) rather than high-potency corticosteroids (e.g., betamethasone dipropionate, triamcinolone), are recommended, especially for the face, to reduce the risk of adverse effects associated with all corticosteroids (e.g., atrophy, telangiectasias, and perioral dermatitis). Corticosteroid shampoos also may be considered for scalp involvement.
- Selenium sulfide/sulfur preparations (the most common is selenium sulfide shampoo).
- Whole coal tar, crude coal tar extract: shampoos, creams, and gels.
- Lithium succinate or lithium gluconate ointment, available in some countries as a combination of lithium succinate 8% and zinc sulfate 0.05% (may have antifungal or antiinflammatory effects). Not for use on the scalp.
- Honey, 90% diluted with warm water, may be used to treat seborrheic dermatitis and dandruff.
- Azelaic acid, 15% gel or 20% cream, has sebosuppressive, antimicrobial, antifungal, and antiinflammatory activity (also used for acne and rosacea).
- Noncorticosteroid topical immunomodulators (calcineurin inhibitors):
 - Tacrolimus
 - Pimecrolimus
- Oral therapy may be used for patients who are refractory to topical treatment (may interact with protease inhibitors and nonnucleoside reverse transcriptase inhibitors; check for possible drug-drug interactions with antiretroviral and other medications before prescribing). There are limited data regarding the efficacy of systemic medication.
 - Fluconazole 300 mg once weekly for 2 weeks
 - Itraconazole 200 mg QD for 7 days
 - Ketoconazole 200 mg QD for no more than 4 weeks
 - Terbinafine 250 mg QD for 4 weeks

Potential adverse effects:

- With all topical products: skin burning, stinging, dryness; allergic or contact dermatitis. Tar shampoos may discolor light hair, leave an oily film on hair, and leave an odor. Coal tar may be carcinogenic; use shampoo no more than twice a week, leave on skin or hair for 5 minutes, and rinse well.
- Topical corticosteroids may cause skin atrophy, telangiectasias, folliculitis, striae, and excessive hair growth. Risk of adverse effects can be mediated by using product infrequently, diluting the product, or limiting the amount of time the product is on the skin.
- With oral therapy, monitor for hepato-toxicity.

Patient Education

- Although topical and oral medicines can relieve symptoms, recurrence is common. Effective antiretroviral therapy should be considered to control the effects of HIV on the immune system and thereby decrease exacerbations and the severity of seborrheic dermatitis associated with immunosuppression.

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Sinusitis

Background

Sinusitis is defined as an inflammation involving the membrane lining of any sinus, and it occurs more frequently in people with HIV infection than in the general population. It commonly occurs as part of a viral upper respiratory infection (URI), and usually is self-limited. Bacterial sinusitis usually occurs as a secondary complication of a viral URI, which causes decreased patency of the nasal ostia, decreased nasal ciliary action, and increased mucus production. Acute sinusitis is defined as lasting up to 4 weeks, whereas chronic sinusitis persists for at least 12 weeks.

HIV-infected patients are susceptible to sinusitis for a number of reasons related to their immunosuppression. Pathophysiologic mechanisms for this susceptibility may include proliferation of lymphatic tissue contributing to nasal obstruction, defects in B-cell and T-cell immunity owing to HIV, and defects in production of immunoglobulins, specifically IgE, resulting in an exaggerated allergic response in the nasal mucosa. As in the general population, the most common pathogens causing acute bacterial sinusitis are *Streptococcus pneumoniae*, *Moraxella catarrhalis*, and *Haemophilus influenzae*. However, HIV-infected patients have a greater incidence of sinusitis caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The bacterial causes of chronic sinusitis are not well defined, but may involve more polymicrobial and anaerobic infections. In patients with severe immunosuppression, particularly those with CD4 counts of ≤ 50 cells/ μ L, sinusitis may be caused by *Aspergillus* and other fungal pathogens.

S: Subjective

The patient may complain of facial pain, frontal or maxillary headache, postnasal drip, or fever.

Ask the patient about specific symptoms, the duration and progression of symptoms, and treatments attempted.

- Fever
- Facial pain or pressure, headache; positional pain (worse when patient bends forward)
- Purulent or bloody nasal discharge
- Postnasal drip
- Nasal congestion
- Recent URI
- Malaise
- Chronic cough

- Maxillary tooth pain
- Ear pressure
- History of chronic sinusitis, seasonal allergies, antibiotic allergies, atopy
- Tobacco use, inhaled recreational drugs

O: Objective

- Document vital signs.
- Perform a careful physical examination focusing on the head and face, neck, and lungs. Examine the nose, mouth, ears, and sinuses.
 - Look for nares inflammation and drainage from sinus ostia.
 - Examine the tympanic membranes and external auditory canals.

- Evaluate the oropharynx for mucus drainage, lesions, and exudates.
- Check the teeth and gums for tenderness and erythema.
- Palpate for tenderness over frontal and maxillary sinus cavities.
- Examine the face and orbits for swelling or erythema.
- Perform cranial nerve examination.
- Auscultate the chest for abnormal lung sounds.

A: Assessment

A partial differential diagnosis includes the following:

- Allergic rhinitis
- Sinus blockage by other lesions such as Kaposi sarcoma or lymphoma (particularly if the CD4 count is <200 cells/ μ L) or fungal infections (if the CD4 count is <50 cells/ μ L)
- Dental abscess, caries
- Meningitis
- Vasculitis
- Trauma

P: Plan

Diagnostic Evaluation

Uncomplicated acute sinusitis usually is a clinical diagnosis. There are no symptoms, physical findings, or tests that reliably distinguish bacterial from viral sinusitis. Patients generally can be assumed to have bacterial sinusitis if symptoms do not resolve, or if they worsen, over the course of 7-10 days. Any patient with high fever or severe or unusual symptoms should be evaluated urgently for other causes of illness.

Imaging studies usually are not indicated for uncomplicated acute sinusitis. In patients with a poor response to empiric antibiotic

therapy for acute bacterial sinusitis, worsening symptoms, and those with suspected chronic sinusitis, computed tomography (CT) scans of the paranasal sinuses are the best initial radiologic study. Standard X-rays (sinus series) can detect cloudiness or air-fluid levels and will show mucosal thickening (a nonspecific finding in HIV-infected individuals).

Cultures of nasal aspirates are not useful for diagnosis, because nasal fluids do not accurately represent pathogens in the paranasal sinuses. Sinus aspirate cultures will give definitive diagnosis of a specific organism in the majority of cases; this may be considered in complicated cases. Definitive diagnosis of invasive fungal sinusitis requires tissue for culture.

Treatment

Treatment is multimodal. For viral sinusitis, treatment is based on symptom suppression; for bacterial sinusitis, an antibiotic can be added to other therapies, e.g., if symptomatic treatment has not resulted in improvement after 10 days.

- Nasal irrigation with saline solution 1-2 times daily (solution should be prepared from sterile or bottled water)
- Nasal steroid (e.g., budesonide, fluticasone, mometasone, or triamcinolone) (see “Potential ARV Interactions,” below)
- Nonsteroidal antiinflammatory drugs (NSAIDs): ibuprofen or other
- Mucolytic agent: guaifenesin
- Cough suppressant as needed
- Antihistamine: chlorpheniramine or other
- Decongestant: e.g., ephedrine, pseudoephedrine

If acute bacterial sinusitis is suspected (e.g., symptoms have not improved within 10 days), treat as above and add an antibiotic for a 5-7 day course of therapy:

- Amoxicillin/clavulanate (Augmentin) 825/125 mg PO BID or 500/125 mg PO TID (more effective against resistant species of pneumococcus and *H. influenza* than amoxicillin)
- Doxycycline 100 mg PO BID
- Levofloxacin 500 mg QD or moxifloxacin 400 mg QD

For chronic sinusitis, administer multimodal treatments as listed above for 3-4 weeks.

The value of antibiotics in chronic sinusitis is unclear; consider especially if a trial of antibiotics has not been undertaken.

If symptoms persist or worsen, refer patients to an otolaryngologist for further evaluation and treatment.

Potential ARV Interactions

Protease inhibitors (PIs) (particularly ritonavir-boosted PIs) or cobicistat may increase serum glucocorticoid levels if used concurrently with nasal steroids. Fluticasone (e.g., Flonase) nasal spray or inhaler should not be used with ritonavir-boosted PIs or cobicistat, and should be avoided, if possible, in patients taking unboosted PIs. Budesonide (Rhinocort Aqua) nasal spray also should be avoided with ritonavir-boosted PIs or cobicistat. Interactions between PIs or cobicistat and other nasal steroids have not been well studied, though available data suggest that beclomethasone has no clinically significant interaction with protease inhibitors.

Patient Education

- Instruct patients in the correct use of medications used to treat sinusitis, including proper technique for nasal irrigation, as required.
- Advise patients that drinking eight glasses (8-12 oz each) of fluid daily helps to keep the mucus thin enough to drain from the sinus passages.
- Instruct patients to take antibiotics on schedule until the entire prescription is gone in order to prevent recurrence of the infection. Advise patients to call or return to clinic for swelling of the face or swelling around the eyes, increased facial tenderness, new or worsening fever, or other concerning symptoms.

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Syphilis

Background

Syphilis is a sexually transmitted disease (STD) caused by the spirochete *Treponema pallidum*. It is a complex disease with protean variations that can mimic many common infections or illnesses. HIV infection may alter the natural history and management of syphilis, causing a more rapid course of illness, higher risk of neurologic complications, and potentially greater risk of treatment failure with standard regimens. Because many individuals with syphilis have no symptoms, or have symptoms that subside without treatment, sexually active individuals at risk of syphilis should receive regular screening for syphilis, as well as for other STDs.

There has been a resurgence of syphilis in the United States, particularly among men who have sex with men (MSM). This trend is concerning, because syphilis can have major health consequences if it is undetected and untreated, and because it increases the risk of HIV transmission. Risk assessment should be conducted at each patient visit for unprotected sex (including oral, anal, and vaginal sex), multiple sex partners, and use of recreational drugs (methamphetamine and cocaine, in particular, are associated with high-risk sexual practices among MSM). Sexually active persons with HIV who are at risk of acquiring syphilis should be screened at least annually, as discussed below. MSM with multiple partners should be tested every 3-6 months.

The natural history of untreated syphilis infection is divided into stages based on length of infection.

Primary Syphilis

Primary syphilis usually manifests after an incubation period of 1-3 weeks from exposure and is characterized by a painless self-limiting ulcer (chancre) at the site of inoculation, which usually occurs during sexual contact. The organism disseminates shortly after exposure via the lymphatics to the bloodstream and beyond. HIV-infected individuals often have multiple or atypical syphilitic lesions that could be misidentified. Some patients have no primary lesion, or have a primary lesion that is not visible. Associated regional lymphadenopathy can occur. Without treatment, the primary lesion generally lasts a few days to a few weeks. Individuals sometimes have a resolving chancre concurrently with a rash of secondary syphilis.

Secondary Syphilis

Secondary syphilis usually develops 2-8 weeks after initial infection and is caused by ongoing replication of the spirochete at disseminated sites of infection that may involve multiple organ systems but most commonly involves the skin and mucous membranes. Rash is the most common presenting symptom; skin lesions may be macular, maculopapular, papular, or pustular, or they may appear as condyloma lata (which may look like condyloma acuminata caused by human papillomavirus). The rash often appears on the trunk and extremities and may involve the palms and soles of feet. Constitutional symptoms, lymphadenopathy, arthralgias, and myalgias are common and neurologic or other symptoms may occur. In the absence of treatment, the manifestations of secondary syphilis last days to weeks, then usually resolve to the latent stages.

HRSA HAB Performance Measures

Percentage of adult patients with a diagnosis of HIV who had a **test for syphilis** performed within the measurement year

(Adult and Adolescent measure)

Latent Syphilis

Latent syphilis follows resolution of secondary syphilis. As in HIV-uninfected individuals, latent syphilis is asymptomatic and the diagnosis is determined by positive serologic tests. Latent syphilis is further classified as “early latent” if the infection is known to be <1 year in duration, “late latent” if the infection is known to be >1 year in duration, or “latent syphilis of unknown duration” if the duration of infection is not known.

Late or Tertiary Syphilis

Late or tertiary syphilis is caused by chronic infection with progressive disease in any system causing serious illness and death in untreated patients. The most common manifestations include cardiovascular syphilis, gummatous syphilis, and the late forms of neurosyphilis (tabes dorsalis and general paresis) (see the “Neurosyphilis” section, below).

Neurosyphilis

Neurosyphilis can occur at any time after initial infection, owing to early spread of the spirochete to the central nervous system (CNS) in approximately 30–40% of patients. The vast majority of these patients has no neurologic signs or symptoms and clears this site of infection. The early forms of neurosyphilis occur within weeks to a few years after infection, including during the secondary stage of syphilis. Early neurosyphilis can manifest as syphilitic meningitis (symptoms may include headache, confusion, nausea, vomiting, and a stiff neck); cranial nerve abnormalities (particularly extraocular or facial muscle palsies, causing visual changes, and facial weakness, tinnitus, and hearing loss) also may be present. The second manifestation of early neurosyphilis is meningovascular syphilis, which presents with stuttering stroke symptoms owing to increasing inflammation of the cerebral arteries causing intermittent occlusion. Ocular syphilis (uveitis, retinitis, retinal detachment, and other eye abnormalities) may occur early after infection with or without the early forms of neurosyphilis. Although these early forms of neurosyphilis, including ocular syphilis, occur in patients without HIV, they may be more common among HIV-infected individuals.

S: Subjective

Symptoms depend on the site of initial infection, the stage of disease, and whether neurosyphilis is present. Symptoms are not present in most patients.

If symptoms are present, the patient may experience the following:

- Painless sore(s), ulcer(s), or abnormal lesions in the genital area, vagina, anus, or oral cavity
- New rash, usually on the trunk, often on extremities, soles of the feet, or palms
- Wart-like growths, mucus patches, or patchy hair loss
- Fever, malaise, swollen glands, arthralgias, myalgias

- Neurosyphilis: vision changes, eye pain, tinnitus, hearing loss, headaches, dizziness, facial weakness, motor or sensory loss, altered mental status, changes in personality or affect, lightning-rod pains in the lower extremities

Conduct a targeted history of patients at risk of syphilis, those who are contacts to a case, or those with positive syphilis serologies, asking about symptoms listed above, including duration; inquire about other or associated symptoms. Ascertain the following:

- Previous diagnosis of syphilis, stage, treatment (including facility where diagnosed and treated), and last titer result
- New sex partners in past 90 days (for primary or secondary syphilis)
- Date of last negative syphilis test, and where obtained
- Pregnancy status

O: Objective

Check for fever, document other vital signs.

Perform a complete examination including the following:

- Skin and mucosal areas (including the palms and soles, genitals, perianal area): chancre/ulcers, abnormal lesions, rash, condyloma lata, patchy hair loss
- Oropharynx: chancres, mucus patches, condyloma lata
- Lymph nodes
- Ophthalmic examination (including slit-lamp examination for persons with ocular complaints; uveitis, retinitis, retinal detachment)
- Neurologic examination (mental status, cranial nerves [including visual acuity], sensory, motor, reflexes, coordination, gait): abnormal mental status, visual acuity changes, extraocular movement abnormalities, neurosensory hearing loss, facial palsy, paraesthesias, sensory or motor loss, hyperactive reflexes, ataxia

A: Assessment

Because syphilis has a wide range of manifestations, the differential diagnosis is broad. It is important to consider syphilis as a possible cause of many presenting illnesses. A partial differential diagnosis includes the following:

- Other causes of maculopapular rashes: pityriasis, tinea versicolor, drug eruption, folliculitis, scabies, psoriasis, acute HIV infection
- Other causes of genital ulcerative disease: herpes simplex virus (HSV), chancroid, trauma, other skin infections (e.g., those caused by *Staphylococcus* or *Candida*)
- Other causes of ocular disease; cytomegalovirus (CMV) retinitis, CMV immune reconstitution uveitis, HSV keratitis

- Other causes of neurologic disease: Bell palsy, CNS lymphoma, toxoplasmosis, other causes of meningitis, stroke
- Other causes of systemic symptoms (e.g., fever, malaise, adenopathy): acute HIV infection, acute hepatitis, other infections or malignancies

P: Plan

Diagnostic Evaluation

Darkfield examination and direct fluorescent antibody

Darkfield examination, direct fluorescent antibody (DFA), or polymerase chain reaction (PCR) testing of a sample from suspicious genital or anal chancres or moist dermatologic lesions (not oral lesions) are definitive tests for syphilis, although these are not available in most clinic settings.

Serologic tests

Nontreponemal tests (rapid plasma reagin [RPR] or Venereal Disease Research Laboratory [VDRL]) traditionally have been used as initial serologic tests for syphilis. Because false-positive results may occur, particularly in the setting of HIV infection, positive nontreponemal test results must be confirmed with a treponemal test. Treponemal antibody tests (TP-PA [*T. pallidum* particle agglutination], EIA [enzyme immunoassay], or CIA [chemiluminescence immunoassay]) should be used to confirm a positive nontreponemal test. Many high-volume laboratories have begun to use a treponemal test as an initial screen for syphilis infection, followed by a quantitative nontreponemal test, to reduce the workload from the titration required for nontreponemal titers. The FTA-ABS (fluorescent treponemal antibody absorption) may lack specificity and is no longer recommended as the gold standard treponemal test.

Nontreponemal tests may be falsely negative in primary and secondary syphilis, before a sufficient antibody response has developed;

treponemal tests may be slightly more sensitive and should be ordered if the nontreponemal test result is negative in a patient with signs or symptoms suggestive of primary or secondary syphilis. Another possible cause of a false-negative nontreponemal result is the prozone phenomenon, seen when antibody concentrations are very high (usually in secondary syphilis) and the specimen is not diluted sufficiently. If serologic test results are negative and suspicion of syphilis is high, request that the laboratory perform additional dilutions on nontreponemal test specimens; if the diluted serum is nonreactive, perform other diagnostic tests (e.g., biopsy).

A nontreponemal test titer should be obtained on the day of treatment to use in determining response to treatment; a fourfold change in titer is considered a significant change. Although fluctuating titers after treatment in HIV-infected patients have been seen, a sustained (>2 weeks) fourfold increase in titer raises concerns about reinfection or treatment failure. Note that the same nontreponemal test should be used consistently for a single patient; RPR titers cannot be compared with VDRL titers.

Cerebrospinal fluid evaluation

HIV-infected patients with neurologic or ocular signs or symptoms of syphilis or tertiary syphilis should undergo lumbar puncture (LP) for cerebrospinal fluid (CSF) analysis. CSF evaluation also is indicated for patients in whom treatment for early syphilis fails (see below). Routine CSF evaluation is not indicated for HIV-infected patients who have syphilis without neurologic or ophthalmic signs or symptoms. CSF analysis should include the following:

- **CSF-VDRL:** This test is specific but not very sensitive; a positive result is diagnostic but a negative result does not rule out neurosyphilis.
- **Leukocytes:** Elevated white blood cell count (>10 cells/ μ L) is suggestive but not specific. Note that mononuclear pleocytosis (up to

5-20 cells/ μ L) is not uncommon in patients with HIV infection, particularly those with higher CD4 cell counts; a threshold of >20 cells/ μ L may improve the specificity of the neurosyphilis diagnosis.

- Some recommend checking CSF FTA-ABS. This is very sensitive but not very specific; a negative result indicates that neurosyphilis is highly unlikely.

Other testing

All patients who test positive for syphilis should be tested for gonorrhea and chlamydia, with sampling sites based on sexual practices and exposures (oropharyngeal, urethral, cervical or vaginal, or anorectal testing). Patients not known to be HIV infected also should be tested for HIV.

Treatment

Treatment of syphilis in HIV-infected individuals essentially is the same as in HIV-uninfected individuals, and depends on stage and the presence or absence of neurosyphilis. It is important to follow patients closely to assure the success of treatment. For further information, see the Centers for Disease Control and Prevention (CDC) STD treatment guidelines or the CDC/NIH/IDSA opportunistic infection (OI) guidelines (see “References,” below).

An RPR or VDRL test should be sent on the day of treatment; the titer will be the reference point for assessing treatment efficacy (see “Follow-Up,” below).

Early syphilis

(<1 year in duration [i.e., primary, secondary, and early latent]; no neurologic signs or symptoms)

- **Preferred therapy:** benzathine penicillin G, 2.4 million units IM (single dose)

- **Alternative therapy:** (for patients with penicillin allergy) note that penicillin is strongly preferred; consider allergy testing and desensitization to penicillin; alternative therapies are not as well proven in HIV-infected individuals; close monitoring for treatment response is recommended

- Doxycycline 100 mg PO BID for 14 days
- Tetracycline, 500 mg PO QID for 14 days*
- Ceftriaxone, 1 g IM or IV QD for 10-14 days

* Proposed in the STD guidelines; not mentioned in the OI guidelines

Treatment failures and resistance have been reported in patients treated with azithromycin (2 g, single dose); the STD and OI guidelines state that this regimen should not be used to treat MSM or pregnant women. For other patients, both guidelines state that azithromycin should be considered only when treatment with penicillin or doxycycline is not feasible, and with close follow-up.

Late latent syphilis

(>1 year in duration or of unknown duration; no neurologic signs or symptoms)

- **Preferred therapy:** Benzathine penicillin G, 2.4 million units IM weekly for 3 consecutive weeks (7.2 million units in total)
- **Alternative therapy:** For penicillin-allergic patients, refer for desensitization to penicillin. As an alternative, some specialists consider doxycycline 100 mg PO BID for 28 days, although efficacy in HIV-infected individuals is not proven. Referral to infectious disease specialist and close clinical monitoring are required.

Tertiary syphilis

Consult with specialists.

Neurosyphilis

(syphilis at any stage with neurologic or ocular symptoms, or CSF abnormalities consistent with neurosyphilis in patients who fail treatment)

Ideally, patients should be hospitalized and given 2 weeks of penicillin IV under close observation. Penicillin-allergic patients should be referred for desensitization, if possible.

- **Preferred therapy:** aqueous crystalline penicillin G, 18-24 million units IV per day (3-4 million units Q4H [or continuous infusion] for 10-14 days).
- **Alternative therapy (requires strict adherence with therapy):**
 - Procaine penicillin 2.4 million units IM per day, plus probenecid 500 mg PO QID, both for 10-14 days
 - Some experts consider use of ceftriaxone 2 g IM or IV QD for 10-14 days with close clinical monitoring
- Most experts recommend administration of benzathine penicillin, 2.4 million units IM weekly for 3 weeks, after completion of the standard 10- to 14-day course of therapy for neurosyphilis.
- Recheck CSF leukocyte count every 6 months until the cell count normalizes (if CSF pleocytosis was present at initial evaluation). If the leukocyte count is not lower at 6 months, consider retreatment (consult with a specialist). Normalization of serum RPR may predict normalization of CSF parameters.

Note: A **Jarisch-Herxheimer reaction** may occur after initial syphilis treatment, especially in primary, secondary, or even latent syphilis. This self-limited treatment effect should not be confused with an allergic reaction to penicillin. It usually begins 2-8 hours after the first dose of penicillin and consists of fever, chills, arthralgias, malaise, tender lymphadenopathy, and intensification of rash. It resolves within 24 hours and is best treated

with rest and acetaminophen. Patients should be warned about the possibility of a Jarisch-Herxheimer reaction.

Pregnancy

Pregnant women should be treated with penicillin, using a regimen appropriate for the stage of infection (see above). Additional treatment may be indicated in early syphilis; consult with a specialist. Penicillin-allergic pregnant women should be referred for desensitization to penicillin. Doxycycline and tetracycline may cause fetal toxicity and should not be used during pregnancy. Azithromycin and erythromycin do not have adequate efficacy in treating pregnant women or their fetuses and should not be used. The efficacy of ceftriaxone during pregnancy has not been studied adequately.

Women treated during the second half of pregnancy are at risk of contractions, early labor, and fetal distress if they develop a Jarisch-Herxheimer reaction; thus, they should be advised to seek obstetric attention if they develop fever or contractions, or note a decrease in fetal movement.

Sex partners

Syphilis is transmitted sexually only when mucocutaneous lesions of syphilis are present; this is uncommon after the first year of infection. Nevertheless, sex partners of a patient who has syphilis in any stage should be evaluated. For patients with primary syphilis, that means partners within the previous 3 months plus the duration of the lesion; for patients with secondary syphilis, partners within the previous 6 months plus the duration of signs; for patients with early latent syphilis, partners within the past 1 year.

- Persons exposed within 90 days preceding the diagnosis of primary, secondary, or early latent syphilis should be treated presumptively, as they may be infected with syphilis even if they are seronegative.
- Persons exposed more than 90 days before the diagnosis of primary, secondary, or early latent syphilis should be treated presumptively if serologic test results are not available immediately and their follow-up is in doubt. Otherwise, they should receive serologic testing and be treated appropriately if the test result is positive.

Follow-Up

All HIV-infected patients treated for early syphilis should be evaluated clinically and serologically at 3, 6, 9, 12, and 24 months (at 6, 12, 18, and 24 months for latent syphilis) to rule out treatment failure. Treatment success is determined by a fourfold decrease (equivalent to two dilutions) in RPR or VDRL titer by 6-12 months (for primary and secondary syphilis) or 12-24 months (for latent syphilis) of treatment. Patients whose titers do not decrease appropriately could have experienced treatment failure or may have been reinfected. Any patient with apparent treatment failure should undergo an LP for CSF analysis and be re-treated as appropriate.

For patients with neurosyphilis, current guidelines recommend that, if a CSF pleocytosis was present initially, the CSF cell count should be checked every 6 months until it decreases. If the CSF cell count is not normal after 2 years, retreatment for neurosyphilis should be considered.

After syphilis treatment that results in at least a fourfold decrease in RPR or VDRL titer, a sustained fourfold increase in titer most commonly reflects reinfection; the patient should be evaluated carefully for possible reexposure and treated for new infection if appropriate. If reinfection is unlikely, CSF testing should be done and appropriate treatment should be given. For patients with persistently high or fluctuating titers after CSF examination and appropriate re-treatment, consult with a specialist.

Some patients retain reactive (usually at low titer) nontreponemal test results after successful treatment for syphilis. In these “serofast” individuals, reinfection with syphilis is indicated by a rise in test titer of at least fourfold.

Risk-reduction counseling

All patients with syphilis should receive risk evaluation and risk-reduction counseling. Evaluate each patient’s sexual practices with

regard to risk of acquiring STDs and of transmitting HIV. Work with the patient to reduce sexual risks.

Patient Education

- Instruct patients to go to clinic for treatment at the intervals recommended. If patients are given oral antibiotics (penicillin-allergic individuals), instruct them to take their medications exactly as prescribed.
- Warn patients about the possibility of a Jarisch-Herxheimer reaction after an initial dose of penicillin and advise them about self-management of associated symptoms (e.g., acetaminophen or aspirin at usual doses, fluids, and rest).
- Instruct patients about the required follow-up laboratory and clinical evaluations necessary to document adequate treatment. Emphasize the need for regular evaluation of treatment efficacy.
- Sex partners from the previous 3-6 months (sometimes longer, depending on the stage of syphilis) need to be evaluated and treated as soon as possible, even if they have no symptoms. Advise patients to inform their partners that they need to be tested and treated. Ask patients whether they would like assistance with partner notification and refer to the local health department for partner services, if available.
- Syphilis is a reportable communicable disease in the United States. Inform patients that they may be contacted to verify adequate treatment and assist with partner notification and treatment.
- Provide education about sexual risk reduction. Review sexual practices and support patients in using condoms with every sexual contact to prevent becoming reinfected with syphilis or infected with other STDs, and to prevent passing HIV to sex partners.

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Toxoplasmosis

Background

Toxoplasma gondii is a common intracellular protozoan that preferentially infects the central nervous system (CNS). In immunodeficient patients it may cause encephalitis; it also can cause local disease such as chorioretinitis and pneumonia. Clinical disease usually occurs through reactivation of latent infection in patients who have CD4 counts of <100 cells/ μ L. *Toxoplasma* seroprevalence varies widely, from 11% in the United States to 75% in some European countries, and even higher in certain resource-limited countries. In the absence of prophylaxis, toxoplasmic encephalitis occurs in more than 30% of patients with advanced HIV infection who are seropositive for *T. gondii*. There have been case reports of CNS toxoplasmosis in the setting of immune reconstitution on antiretroviral therapy (ART); see chapter *Immune Reconstitution Inflammatory Syndrome*.

Toxoplasma has an infectious reservoir in almost all animals; humans acquire infection either through ingestion of tissue cysts contained in undercooked meat (usually pork, lamb, or beef) or oocysts on contaminated vegetables or through exposure to cat feces containing oocysts. There is no transmission by person-to-person contact.

CNS toxoplasmosis is an AIDS-defining condition that can be progressive and fatal. However, antimicrobial therapy, especially if given in conjunction with ART that results in immune reconstitution, can be successful in treating toxoplasmosis. Specific prophylaxis and effective ART also may be used to prevent toxoplasmosis in patients with advanced AIDS who have latent *T. gondii* infection (as demonstrated by the presence of anti-*Toxoplasma* immunoglobulin G [IgG] antibodies; see chapter *Preventing Exposure to Opportunistic and Other Infections*).

S: Subjective

The patient may complain of subacute onset of dull, constant headache, fever, visual changes or other focal neurologic symptoms, confusion, or disorientation. Seizures may occur. Caregivers may report subtle alterations in mental status or mood.

Take a careful history from the patient and caregivers about the symptoms listed above and their duration, progression, and severity. Inquire about other related symptoms. Ask whether the patient is taking *Toxoplasma* prophylaxis or ART.

O: Objective

- Measure vital signs (temperature, heart rate, blood pressure, respiratory rate).

- Perform a full physical examination including a thorough neurologic examination, looking for focal or nonfocal neurologic deficits, particularly weakness, cranial nerve abnormalities, visual field defects, gait disturbances, and abnormalities in speech, cognitive, or affective functions.
- Review previous laboratory values, particularly the following:
 - CD4 count (usually <50 - 100 cells/ μ L in patients with toxoplasmosis)
 - *Toxoplasma* IgG ($>95\%$ of patients with toxoplasmosis have positive IgG)

A: Assessment

Rule out other infectious or neoplastic causes of headache, fever, and neurologic changes.

A partial differential diagnosis includes the following:

- CNS lymphoma
- Cryptococcal meningitis
- Progressive multifocal leukoencephalopathy (PML)
- Tuberculous meningitis
- Brain abscesses of bacterial, fungal, or mycobacterial etiologies
- Herpes simplex virus or cytomegalovirus (CMV) encephalitis
- Primary HIV encephalopathy
- AIDS dementia complex
- Cerebrovascular accident secondary to hemorrhage, hypoxia, or emboli from vegetative endocarditis
- Neurosyphilis
- Other causes of chorioretinitis such as CMV, HIV, and cryptosporidiosis

P: Plan

Diagnostic Evaluation

Definitive diagnosis requires identification of *T. gondii* in tissue biopsy or body fluid samples from a patient with a compatible clinical presentation. Brain biopsy usually is not performed if toxoplasmosis is strongly suspected; instead, presumptive diagnosis is made on the basis of clinical presentation, laboratory and imaging tests, and response to therapy. Brain biopsy should be considered for patients who do not respond to therapy and for those whose diagnosis is unclear.

- Serum *Toxoplasma* IgG antibody test results are positive in nearly all patients with toxoplasmic encephalitis. A negative IgG test result makes the diagnosis very unlikely but does not rule it out. (Antibody titer changes are uncommon in reactivation disease and are not useful in making a diagnosis.)

- CNS imaging with computed tomography (CT) typically shows multiple contrast-enhancing mass lesions, but may show a single lesion or no lesions. Magnetic resonance imaging (MRI) is more sensitive than CT for CNS toxoplasmosis. Other imaging studies, such as single photon emission CT (SPECT), may be useful in distinguishing toxoplasmic lesions from CNS lymphoma.
- If possible, cerebrospinal fluid should be checked for *T. gondii* by polymerase chain reaction (PCR).
- Other diagnostic tests should be performed as indicated to rule out other potential causes of the patient's symptoms.
- Patients with toxoplasmic encephalitis typically respond quickly to treatment. If clinical improvement is not seen after 10-14 days of appropriate treatment, or if clinical worsening is seen in the first week, consider brain biopsy for alternative diagnoses.

Treatment

Treatment consists of two phases: acute therapy and chronic maintenance therapy. If possible, consult with an expert on the management of toxoplasmosis.

Presumptive treatment often is begun on the basis of clinical presentation, positive *Toxoplasma* IgG, and results of brain imaging studies. If patients do not respond quickly to treatment, other diagnoses should be considered. The following recommendations are based on treatment guidelines published by the Centers for Disease Control and Prevention, National Institutes of Health, and HIV Medicine Association/Infectious Diseases Society of America (see "References," below).

Acute Therapy

Acute therapy should be given for at least 6 weeks, and until the patient has shown improvement by clinical and radiographic measures.

Preferred

- Pyrimethamine 200 mg PO as a single loading dose, then 50 mg (<60 kg body weight) or 75 mg (>60 kg body weight) QD + sulfadiazine 1,000 mg (<60 kg body weight) or 1,500 mg (>60 kg body weight) PO Q6H + folinic acid (leucovorin) 10-25 mg QD

Dosage adjustments to the lower end of therapeutic range of pyrimethamine and sulfadiazine may be considered for patients who have significant bone marrow suppression despite folinic acid supplementation. Monitor patients carefully for cytopenias, especially if they are taking other agents that cause bone marrow suppression, such as zidovudine, valganciclovir, and ganciclovir.

Note: Patients at risk of G6PD deficiency should be checked for G6PD deficiency before starting pyrimethamine.

Alternative

- Pyrimethamine + folinic acid (administered as described above) + clindamycin 600 mg PO or IV Q6H; recommended for patients with significant allergic reactions to sulfa medications
- Trimethoprim-sulfamethoxazole (TMP-SMX) 5 mg/kg TMP and 25 mg/kg SMX PO or IV BID. TMP-SMX can be considered when the availability of other regimens is limited or when patients need IV therapy
- Atovaquone 1,500 mg PO BID + pyrimethamine + folinic acid (pyrimethamine and folinic acid as described above)
- Atovaquone 1,500 mg PO BID + sulfadiazine 1,000-1,500 mg PO Q6H (sulfadiazine dosing as above)
- Atovaquone 1,500 mg PO BID
- Pyrimethamine + leucovorin (dosing as above) + azithromycin 900-1,200 mg PO QD

Note: The regimens that contain sulfadiazine, TMP-SMX, or atovaquone also are effective in

preventing *Pneumocystis jiroveci* pneumonia (PCP), so patients on these regimens do not need additional PCP prophylaxis.

Adjunctive corticosteroids (e.g., dexamethasone 4 mg PO or IV Q6H) may be indicated for patients with CNS mass effect or edema. Use is based on clinical judgment and should be discontinued as soon as it is feasible to do so.

Anticonvulsant therapy should be given to patients with a history of seizures (but not to those who have not had seizures).

Ventilatory support may be necessary if severe CNS symptomatology is present.

Chronic Maintenance Therapy

After at least 6 weeks of initial therapy and significant clinical and radiologic improvement, chronic maintenance therapy can be considered.

Preferred

- Pyrimethamine 25-50 mg PO QD + sulfadiazine 2,000-4,000 mg PO daily in 2-4 divided doses + folinic acid 10-25 mg PO QD (also effective as PCP prophylaxis)

Alternative

- Pyrimethamine 25-50 mg PO QD + clindamycin 600 mg PO Q8H + folinic acid 10-25 mg PO QD
- TMP-SMX double-strength 1 tablet PO BID
- Atovaquone 750-1,500 mg PO BID + pyrimethamine 25-50 mg PO QD (+ folinic acid 10-25 mg PO QD)
- Atovaquone 750-1,500 mg PO BID + sulfadiazine 2,000-4,000 mg PO daily in 2-4 divided doses (also effective as PCP prophylaxis)
- Atovaquone 750-1,500 mg PO BID

For patients who complete acute therapy successfully, have resolution of signs and symptoms of toxoplasmosis, and have immune

reconstitution (with CD4 counts >200 cells/ μ L) for more than 6 months on ART, it is reasonable to consider discontinuing maintenance therapy. Some specialists would require resolution of CNS lesions on radiologic studies before discontinuation of therapy. Patients must be observed for recurrence of symptoms, and treatment should be restarted if the CD4 count decreases to <200 cells/ μ L.

Considerations During Pregnancy

All pregnant women should be tested for *T. gondii*. If the result is positive, evaluate the pregnant woman for signs or symptoms of toxoplasmosis and the neonate for evidence of congenital infection. Perinatal transmission usually occurs only with acute maternal infection, but in advanced HIV, it may occur with reactivation of chronic infection. If *T. gondii* infection occurs during pregnancy, consult with maternal-fetal and infectious disease specialists. Treatment for pregnant women is the same as for nonpregnant adults (see above). Note that sulfadiazine taken at the time of delivery may increase the risk of neonatal hyperbilirubinemia and kernicterus.

Patient Education

- Advise patients that antimicrobial therapy alone will not eradicate toxoplasmosis, but should decrease symptoms and improve quality of life. If medications are discontinued, the disease is likely to recur, unless the CD4 count increases to >100-200 cells/ μ L in response to ART.
- Inform patients that suppressive therapy must be continued to prevent recurrence. The duration of this therapy may be lifelong.
- It is essential for patients to take all medicines exactly as prescribed. If doses are missed, or if the medications are stopped and restarted, *Toxoplasma* can develop resistance to the medications. If patients are having trouble taking the medication on schedule, they should contact their health care provider immediately.
- Educate patients about the benefits of ART in strengthening the immune system and preventing opportunistic infections such as toxoplasmosis.
- Advise patients to contact the clinic promptly if symptoms worsen or if new symptoms develop.
- Toxoplasmosis is a late-stage HIV opportunistic infection that indicates profound immune suppression. Some patients may not respond to treatment or to ART. As with any patient who is at risk of a life-threatening HIV-related disease, clinicians should discuss advance directives and durable power of attorney with patients. Referral to a social worker, mental health clinician, or chaplain experienced in such issues may facilitate this discussion.

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Adverse Reactions to HIV Medications

Kirsten Balano, PharmD

Background

Clinicians and patients face many challenges associated with antiretroviral therapy (ART). These include making decisions about when to start therapy, what regimen to start, when to change medications, and how to switch if a regimen is failing. Although clinical research guides the selection of antiretroviral (ARV) regimens, it is important to remember that the best regimen for any patient is the regimen that individual is willing and able to take. No regimen, no matter how potent, will be effective if the patient does not take it properly. Adherence to ART is one of the most important predictors of treatment efficacy. Although many factors may interfere with proper adherence to ART, adverse reactions to the medications are among the most important. In one trial, patients experiencing adverse events were 13 times less likely than those not experiencing adverse events to have the highest levels (95-100%) of adherence. Monitoring and managing adverse reactions to ARVs are crucial to establishing a successful HIV regimen.

Although adverse reactions are common and often predictable, their management must be individualized. Several factors will affect the management of adverse reactions, including comorbid conditions, the patient's other current medications, the availability of alternative medications, and the patient's history of medication intolerance. In some cases, the patient's report of the severity of adverse effects can be inconsistent with the clinical interpretation (i.e., some patients may overemphasize symptoms, whereas others underemphasize them), and this must be considered when determining the management of adverse reactions.

Using a case-based approach, this chapter suggests strategies for the evaluation and management of adverse effects, and it reviews several of the most commonly noted adverse effects in patients starting an ARV regimen. It is not intended as a comprehensive guide to adverse effects. For detailed information regarding assessment of symptoms, see the complaint-specific chapters found in section *Common Complaints* of this manual. For information on common adverse reactions to ARV agents and to medications used to prevent and treat opportunistic infections, see chapter *Antiretroviral Therapy* and the Antiretroviral Reference Tables in this manual. In each case of suspected medication adverse effects, the patient should be evaluated for other possible causes of the symptoms. Consultation with an HIV expert can help in determining the best management strategy when symptoms may have multiple and overlapping causes.

S: Subjective

A pregnant woman presents 3 weeks after starting a new ARV regimen. She complains of fatigue, nausea, and rash. Her current ARV medications are nevirapine (NVP) plus a fixed-dose combination of zidovudine (ZDV) and lamivudine (3TC) (i.e., Combivir). This was selected on the basis of her pregnancy, her preferences, and her past treatment history. She also is taking trimethoprim-sulfamethoxazole

(TMP-SMX) as prophylaxis against PCP.

Although she reports that she had not missed any doses of her medications and she likes the low pill burden of this regimen, she does not want to continue because she has been feeling so sick that she cannot adequately care for her children. She is asking to stop her ARV therapy because of "too many side effects."

The patient should be evaluated in the clinic for her complaints about adverse effects.

O: Objective

The following are suggestions for this evaluation; they are not intended to be a complete review of the workup and management of each symptom or objective finding. For more-detailed information, refer to the complaint-specific chapters of this manual, as noted above.

Vital signs: Fever may indicate a hypersensitivity reaction (HSR) or acute hepatitis attributable to medications, or an immune reconstitution inflammatory syndrome in relation to an opportunistic infection in the setting of early ART therapy. See chapter *Fever* for a more complete discussion about fever workup and considerations. Tachycardia or hypotension may suggest anemia, HSR, dehydration, infection, or another illness.

Physical examination: Pay special attention to the skin (rash, pallor), mucous membranes, and liver (enlargement or tenderness). Positive physical examination findings should be evaluated for severity and extent of involvement.

Laboratory tests: Check the complete blood count when monitoring drugs that may cause bone marrow toxicity (e.g., anemia, neutropenia). Perform a complete metabolic panel including electrolytes and liver function tests (LFTs). If the history suggests pancreatitis, evaluate amylase and lipase.

Other studies: Perform as indicated by symptoms and examination (e.g., chest X-ray if respiratory symptoms are present).

A: Assessment

Step 1: Clarify the patient's reports of adverse reactions by requesting the following information for each symptom the patient describes:

- Characterize the symptoms by asking about severity, onset, timing, and frequency. It is

helpful to have the patient describe whether the symptoms have been improving or worsening over time.

- Ask whether the patient has tried any remedies to alleviate the symptoms and whether they were helpful.
- Explore how the patient is currently taking the regimen. Closed-end questions (e.g., "What are your current medications?" "How often do you take them?" "How many pills of each medicine do you take?" and "Do you take your medicines with or without food?") can be helpful in determining whether the patient has been taking medications correctly. Incorrect administration of medications (e.g., taking higher dosages than recommended) can lead to adverse effects and often is overlooked by providers.

Step 2: Assess the severity of the reaction against the need to continue the current regimen. For this assessment, it is important to have an understanding of the relative availability of alternative ARV regimens. Also try to determine the patient's risks of adverse reactions to specific medications. A review of the patient's clinical status, treatment history, resistance tests, and other testing is important.

- Most adverse effects are self-limited and mild-to-moderate in severity. With supportive care, patients often are able to continue their current medications. This is particularly true with regard to gastrointestinal symptoms (e.g., nausea, vomiting, bloating, diarrhea). Supportive care for gastrointestinal adverse effects includes reminding the patient to take medications with food (if appropriate), suggesting the use of symptomatic remedies (e.g., ginger-containing beverages or foods to relieve nausea [see "Nausea," below]), and prescribing medications such as antiemetics or antidiarrheals if needed. Other symptoms that can be monitored carefully with supportive care include fatigue, malaise, mild rashes, abdominal pain, and bloating.

- More severe reactions often require discontinuation of the offending medication. These include fever, liver function abnormalities, rash with mucous membrane involvement, or severe systemic symptoms.
- Determining which medication in a multidrug regimen is causing the reaction is often challenging because it is common for patients to concurrently take several medications with overlapping toxicities.
- Some patient factors affect the risk of particular adverse drug effects. For example, patients with higher CD4 cell counts at the time that nevirapine is initiated have a greater risk of hepatotoxicity (specifically, women with CD4 counts of >250 cells/μL or men with CD4 counts of >400 cells/μL), and patients with the HLA-B*5701 allele have higher rates of abacavir HSR. In patients with these risk factors, these drugs should be avoided.
- It is important to consider the possibility that non-ARV medications in the patient's regimen could be causing the adverse effects. This could include medications given as prophylaxis (or treatment) for opportunistic infections (e.g., TMP-SMX), or medications to treat other comorbidities. Even with patients who have been on other non-ARV medications for months or years, initiation of a new ARV regimen (e.g., one with potent hepatic CYP 450 inhibition or induction effects) may alter serum levels of these other medications (see chapter *Drug-Drug Interactions with HIV-Related Medications*). For example, an increase in anxiety symptoms after starting a new ARV regimen could be attributable to altered drug concentrations of a chronic antidepressant or antianxiety medicine caused by an ARV, not to the new ARV medications themselves.
- The threshold for stopping a medication depends in part on the availability of alternative agents for the individual patient. Some patients have limited alternatives

because their virus is resistant to other ARVs or because they have not tolerated certain ARVs in the past. For patients who develop significant adverse effects when starting their first ARV regimen, consider substituting alternative ARV medications (chosen with efficacy considerations in mind) that are better tolerated as early as possible to prevent nonadherence arising from a desire to avoid the adverse effects. For these situations, single-drug substitutions often improve tolerance and make it more likely that long-term viral suppression will be achieved.

- Some patients may refuse to attempt symptomatic treatment or to make substitutions in the ARV regimen. Although treatment interruptions generally should be avoided, in certain situations it may be best to discontinue all ARVs and return to an adherence-readiness assessment (see chapter *Adherence*) to determine when to restart ART and what medications to restart (see chapter *Antiretroviral Therapy*).

Gathering Additional Subjective and Objective Information

For the patient who reported nausea, fatigue, and rash 3 weeks after starting nevirapine and ZDV/3TC (Combivir) (see above), additional history, physical examination, and laboratory work yielded the following information:

- **Nausea:** This has been present since she started ART 3 weeks ago. She has had difficulty taking the ARVs with food, because of nausea. No actual vomiting or other abdominal pain has occurred. She has not tried any remedies. The nausea is not worsening and perhaps has improved slightly over the past few days.
- **Fatigue:** This has been present since she started ARVs 3 weeks ago. She is able to exercise and perform normal daily activities.
- **Vital signs:** Normal, with no fever or signs of hemodynamic changes.

- **Skin:** Skin and conjunctival pallor is noted, along with mild-to-moderate maculopapular rash on the trunk, back, and extremities. These are associated with slight itching, but no pain. No mucous membrane involvement is noted. The rash has been present for 6 days, with slight improvement over the past day.
- **Abdomen:** Nontender, with normal liver size.
- **Complete blood count:** Normal, except for a slight increase in mean corpuscular volume (MCV), probably from ZDV therapy and not indicating macrocytic anemia.
- **LFTs:** Normal.
- **Pretreatment laboratory results:** CD4 count of 190 cells/ μ L, HLA-B*5701 negative.

Assessing Availability of Alternative Regimens

A clarified ARV history yielded the following information. The patient took ZDV for 5 months during another pregnancy a few years ago, and she recalls similar feelings of nausea and fatigue that caused her distress at the time. She was able to continue ZDV through the end of her pregnancy. She has taken several ritonavir-boosted protease inhibitors briefly in the past; she did not tolerate these and subsequently has refused treatment with protease inhibitors. The resistance test done prior to initiation of ART shows no significant ARV resistance. She has no comorbidities. The patient has a number of treatment options, but these may be limited by tolerance issues (e.g., protease inhibitor intolerance).

Summary Assessment

The patient's symptoms are mild and are most likely related to starting ARV therapy, although pregnancy also can have associated nausea and fatigue. The laboratory evaluation does not reveal significant abnormalities (e.g., anemia, transaminitis). In particular, the symptoms, signs, and laboratory work

are not consistent with HSR, hepatotoxicity, or other serious adverse effects. Thus, no additional workup is needed at this time. Careful monitoring is important because, if symptoms do not improve over the next few days, the patient should have a more extensive workup for other possible causes of the symptoms. If other causes of her symptoms are ruled out and she is unable to tolerate supportive care, alternative ARV medications (e.g., tenofovir, abacavir, an integrase inhibitor, or perhaps an unboosted protease inhibitor) could be substituted for medications in her current regimen, keeping in mind the need to maintain efficacy of the overall regimen and the recommendations for ART in pregnancy (see chapter *Reducing Perinatal HIV Transmission*).

P: Plan

A suggested treatment plan for the mild adverse effects exhibited by the patient described above is as follows:

Fatigue

Fatigue is a common adverse effect among patients who are starting ART. It is usually self-limited, and, with reassurance that symptoms should improve over a few weeks, most patients are able to continue their regimens without any changes. If fatigue does not resolve within the first weeks of treatment, it is important to rule out other causes of fatigue, including depression. For ZDV-containing regimens, clinicians should rule out ZDV-induced anemia, especially when patients are taking other medications that can cause bone marrow toxicity (e.g., TMP-SMX). Some patients experience fatigue from ZDV even without anemia. If fatigue persists for several weeks or becomes debilitating, and other causes are ruled out, consider replacing ZDV in this regimen. Patients taking regimens containing efavirenz also may complain of fatigue. With efavirenz, the fatigue often is related to sleep disturbances and other

central nervous system (CNS) effects of this medication. Efavirenz-related CNS adverse effects, including fatigue, are likely to resolve over a period of days to weeks. Toxicities can be minimized by ensuring that patients take efavirenz on an empty stomach (1 hour before or 2 hours after eating). (See chapter *Fatigue*.)

Nausea

Nausea is another common adverse effect described by patients starting a new ARV regimen. As with fatigue, it usually is self-limited, and patients without other systemic symptoms, acute hepatitis, HSR, or pancreatitis usually can continue their regimens. Supportive care often helps patients to continue their regimens. For example, patients should take their medications with food, unless contraindicated for the ARV. Small, frequent snacks may be helpful for patients with significant nausea. Clinical trials have suggested that ginger extract may relieve nausea symptoms. Patients can take ginger (available in a variety of forms, including ginger ale, tea, cookies, and candies) or antiemetics.

Among the medications that the patient described above is taking, ZDV is the most likely culprit to cause persistent nausea. If nausea symptoms continue for several weeks despite taking the ARVs with food, using ginger, or taking other antiemetics, and if other underlying causes are ruled out, consider replacing ZDV in this regimen. (See chapter *Nausea and Vomiting*.)

Rash

Rash is a common adverse effect of certain ARVs and many other medications. It may present with a wide range of severity, as follows:

- Mild rash with no other related symptoms, resolving over the course of days or weeks
- Moderate rash, may be accompanied by

systemic symptoms (e.g., fever, liver function abnormalities, myalgias)

- Life-threatening rashes (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis) associated with pain, mucous membrane involvement, fever, liver function changes, and myalgias

If a patient is taking two or more medications that have rash as a possible adverse effect, it may be difficult to determine which medicine is the most likely cause of the rash. In the case of the patient described above, the rash most likely is related to one of two medications.

Her rash currently is mild, but drug rash can range from mild to severe and life-threatening (including Stevens-Johnson syndrome).

- Nevirapine
 - Mild nevirapine rash: usually a self-limited reaction that can be treated symptomatically
 - Moderate to severe nevirapine rash, with or without hepatitis: requires discontinuation of nevirapine
- TMP-SMX reaction: may be mild or severe, and onset may be delayed
- Other reactions: can be caused by other medications, by immune reconstitution inflammatory effects, contact dermatitis, folliculitis, and other causes

If the clinician discontinues all of the suspect medications and the rash resolves, the patient will be relieved, but the clinician will not be able to determine which medication caused the rash. In cases of mild rash, it is reasonable to try to identify the offending agent by discontinuing one medication at a time (a substitution should be made for a discontinued ARV, to maintain regimen potency). This situation would require careful clinical judgment or consultation with an expert regarding the advantages or disadvantages of discontinuing each of the suspect medications.

Other Adverse Reactions

Patients may describe any number of adverse effects after starting new medications.

Although some adverse effects are caused directly by the medications themselves, some symptoms may occur simply in the process of starting ART. The start of ART may precipitate a significant psychological shift in a patient's perception of self, in living with HIV infection, and in daily routine. In particular, patients who have kept their HIV infection distant from their "everyday" lives may notice significant psychological changes as they take medications every day, go to the pharmacy to pick up medications, and make frequent visits to the clinic for evaluation and laboratory work. Some patients become depressed upon realizing that the severity of their illness now requires them to be on treatment. These psychological adjustments can cause significant symptoms that should be assessed and managed in a manner similar to the way in which pharmacologic adverse reactions are managed.

These psychological effects can be considered "process" effects from starting ART rather than adverse effects of the ARV medications themselves. As with the self-limited adverse effects of early-stage ARV therapy, process effects should become more tolerable over time as the medication regimen becomes routine for the patient. One of the most common process effects is fatigue. Many patients hope that their ARV regimen will give them increased energy and health, and they become frustrated when they notice increasing fatigue after starting the regimen. These patients must

be evaluated to rule out common adverse effects that contribute to fatigue (e.g., anemia, hepatitis, lactic acidosis). Equally important, especially for patients beginning a new regimen, symptoms of fatigue could indicate depression or signal that the "process" of taking medications is emotionally difficult. Counseling, peer support, and antidepressant medications can be used to treat this type of fatigue. Often, once patients realize that some of the goals of treatment are being achieved (e.g., the CD4 cell count increases, the HIV viral load becomes undetectable, or symptoms of HIV infection resolve), they recognize the benefits of ARV medications, and their fatigue or other adverse symptoms associated with the process of starting the regimen may lessen.

This discussion has focused on the adverse reactions to ARV medications that patients are most likely to describe as they start a new regimen. Patients and providers also need to consider counseling about and management of long-term toxicities such as lipodystrophy, renal dysfunction, peripheral neuropathy, cardiac disease, diabetes, and dyslipidemia. As these long-term toxicities continue to challenge providers and patients alike, clinical trials and expert guidelines will provide support and information.

Clinicians are encouraged to report adverse reactions to medications to the U.S. Food and Drug Administration (FDA) MedWatch program by telephone at 800-FDA-1088, via fax at 800-FDA-0178, via the Internet at www.fda.gov/Safety/MedWatch/HowToReport/, or by mail at MedWatch HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857.

Patient Education

- All medications have potential to cause adverse reactions, which are defined as negative, unintended effects of medication use.
- Advise patients to report any adverse reaction to their medical care provider as soon as possible.
- Before starting a new medication, medical care providers or pharmacists should counsel patients about the most common adverse effects and about any remedies that are available to minimize the severity of those effects.
- Advise patients to talk to their provider or pharmacist before starting any new medications (including over-the-counter medications and herbs) because some drugs may interact with ARVs or other medications and can increase side effects or cause unwanted reactions.
- Nausea is one of the most common adverse effects. Counsel patients that nausea can be minimized by taking medications with food (if indicated, as some medications should be taken on an empty stomach) or by using ginger-based food or beverages (e.g., ginger ale, tea, cookies). If these measures do not work, patients should talk with their medical care provider; they may need medications to treat the symptoms.
- Counsel patients that they should not stop taking any medications unless instructed to do so by their medical care provider.

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Drug-Drug Interactions with HIV-Related Medications

Kirsten Balano, PharmD

Background

Drug-drug interactions are common concerns of patients with HIV and their health care providers. The issues involved in evaluating drug interactions are complex. Although many questions can be articulated simply (e.g., “What antidepressant is least likely to have drug interactions with antiretroviral medications?”), the responses to these questions involve more complex concerns (e.g., “In choosing an antidepressant for my patient with HIV, I must consider efficacy, adverse effects, and tolerability as well as drug interactions.”).

This complexity is increased because antiretroviral (ARV) agents, particularly protease inhibitors (PIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), the pharmacokinetic booster cobicistat, and the CCR5 antagonist maraviroc, can cause or be affected by alterations in the activity of the cytochrome (CYP) P450 enzyme system in the liver, as well as by other mechanisms of drug metabolism. Interactions between an ARV and another drug (whether another ARV or a different type of medication) may result in an increase or a decrease in the serum levels of either the ARV or the interacting drug, potentially changing the effectiveness or the toxicity risk of substrate drugs. Understanding drug-drug interactions is challenging because of several factors, including the following:

- Different drugs affect different P450 enzymes.
- Some medications have dosage-related responses that influence their effects on P450 enzymes.
- Formal pharmacokinetic studies on drug combinations are limited.
- Even when pharmacokinetic data exist for specific drug combinations, the clinical significance of any changes in pharmacokinetic parameters may not be clear.
- Patients taking ARVs often have complex drug regimens. Patients typically are taking three or more medications that could influence interactions. Pharmacokinetic studies that evaluate the clinical significance of drug interactions involving more than two medications are less likely to be available.
- Other metabolic pathways of medications such as P-glycoprotein (P-gp) and UDP-glucuronosyltransferase (UGT)-1A1, can be altered by drug interactions. The integrase inhibitors dolutegravir and raltegravir, for example, are metabolized by UGT-1A1.
- Some drug interactions involve effects on absorption or drug availability rather than metabolism. For example, the PI atazanavir and the NNRTI rilpivirine require gastric acidity for absorption; integrase inhibitor activity is impaired by polyvalent cations (e.g., iron, aluminum, calcium, and magnesium, and antacids, laxatives, supplements, and other preparations that contain them).
- Other influences on medication activity include food-drug interactions, protein binding, and altered intercellular activation of medications.

Information on various drug-drug interactions is available in guidelines and via the Internet (see “Resources,” below). Such resources can provide data regarding two-drug combinations, but rarely consider all the complexities outlined above. What follows, therefore, is a suggested approach to considering drug-drug interactions in managing HIV-infected patients and making patient-specific decisions, illustrated by a case study.

S: Subjective

A new patient arrives for a clinic intake appointment. The patient receives medical care from a local infectious disease physician who treats only a handful of HIV-infected patients. The patient was recently released from hospital with a discharge diagnosis of pneumonia and *Mycobacterium avium* complex (MAC). The patient is not yet taking ARVs, but needs to start ART promptly, along with an adherence support program. The patient has other medical problems, including hyperlipidemia, erectile dysfunction, diabetes, depression, gastroesophageal reflux disease (GERD), and herpes. The clinician wants to review the patient’s medication list to check for any potential drug-drug interactions.

O: Objective

Review the patient’s pharmacy records for current medications, and ask about use of over-the-counter (OTC), herbal or natural products, and dietary supplements. As requested, the patient has brought in all medications from home for review. The current medication list includes the following:

- Clarithromycin 500 mg BID
- Ethambutol 1,000 mg QD
- Rifabutin 300 mg QD
- Trimethoprim-sulfamethoxazole (TMP-SMX) (Septra, Bactrim) double-strength, 1 tablet QD
- Lovastatin 20 mg QD

- Metformin 500 mg BID
- Bupropion 150 mg QD
- Acyclovir 400 mg BID
- Omeprazole 20 mg QD (patient buys OTC for heartburn)
- Milk thistle (silymarin) (patient takes as needed for energy and liver health)

A: Assessment

Step 1: Identify interactions and classify them as follows:

- Definite interactions
- Probable interactions
- Possible interactions

Definite Drug Interactions

A drug interaction is definite if a high level of evidence is available regarding the drug combination, the clinical significance of the interaction is well understood, and consensus exists regarding the management strategy (e.g., whether dosage adjustments are required, or concurrent use is contraindicated). Common definite interactions for HIV patients include the following:

- Certain combinations of HIV agents (e.g., certain PIs or integrase inhibitors with NNRTIs, maraviroc with PIs or NNRTIs, tenofovir with atazanavir)
- Rifamycins and PIs, NNRTIs, cobicistat, or maraviroc
- Statins with PIs or cobicistat
- Erectile dysfunction agents and PIs or cobicistat
- Methadone and certain PIs or NNRTIs
- Fluticasone and PIs or cobicistat

Probable Drug Interactions

A drug interaction is probable if the limited available evidence suggests that an interaction may occur, even if the clinical outcome or significance may not be clearly established. Effective management of a probable interaction

is based on assessment and clinical judgment about the risks and benefits of a particular combination for each patient. Examples of probable interactions with HIV-related medications include the following:

- Antidepressants and PIs or NNRTIs
- Oral contraceptives and PIs or cobicistat
- Warfarin and PIs, NNRTIs, or cobicistat
- Proton pump inhibitors (PPIs) or H-2 blockers and atazanavir or rilpivirine
- Polyvalent cations (e.g., calcium, iron, cation-containing antacids) and integrase inhibitors
- Certain antifungal agents and PIs, NNRTIs, or cobicistat (except in the case of voriconazole, for which definite information on interactions is available)
- Certain antiepileptic medications and PIs, NNRTIs, or cobicistat

Possible Drug Interactions

Possible drug interactions may be difficult to distinguish from probable drug interactions, but in these cases, only theoretical evidence is available. The proper management of such interactions requires weighing the risks and benefits of the combination and making sound clinical judgments. Examples of possible drug interactions with HIV medications include the following:

- Herbal products and PIs, NNRTIs, or cobicistat (except in the case of St. John's wort, for which definite information on interactions is available)
- Antidiabetic medications and PIs or NNRTIs
- Antipsychotic agents and PIs, NNRTIs, or cobicistat

Memorizing all the potential drug interactions is impossible. It is possible, however, to remember a few commonly encountered drug combinations that have the potential for clinically significant interactions. It is also

important to recognize that PIs (particularly ritonavir), NNRTIs, and cobicistat very commonly interact with other medications. The above examples of definite, probable, and possible interactions are reasonable “red flag” drug combinations that can be recalled easily. In addition, certain Internet resources allow providers to submit all of a patient's current medications and planned additions (e.g., atazanavir/ritonavir as part of a new ARV regimen) and receive information on potential interactions (see “Resources,” below). Finally, consultation with clinical pharmacists can aid in identifying and classifying potential interactions.

P: Plan

Step 2: The patient described above will start an ARV regimen of atazanavir/ritonavir + tenofovir + emtricitabine. The PI may cause problematic drug-drug interactions with some of the patient's preexisting medications, and tenofovir interacts with atazanavir. Develop a plan for management when these ARVs are added. For this patient, the following definite interactions should be of concern:

- Rifabutin and atazanavir/ritonavir
- Lovastatin and atazanavir/ritonavir
- Tenofovir and atazanavir
- Clarithromycin and atazanavir/ritonavir

Refer to available references for management suggestions. Such references include the following:

- U.S. Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* (aidsinfo.nih.gov/guidelines), relevant tables
- HIV InSite Database of Antiretroviral Drug Interactions (hivinsite.ucsf.edu/interactions)
- University of Liverpool HIV Drug Interaction Charts (www.hiv-druginteractions.org)

- Clinical Care Options (www.clinicaloptions.com/HIV.aspx)

Most of these resources include specific dosage adjustments or alternative agents to consider when managing these drug combinations. The suggestions for this patient are as follows:

- Rifabutin levels are increased by atazanavir/ritonavir. The rifabutin dosage should be decreased to 150 mg daily with standard atazanavir/ritonavir dosing. Alternatively, discuss with the patient's primary care provider whether rifabutin is important to the current MAC regimen or whether the patient could be treated adequately with just clarithromycin + ethambutol to avoid the above-cited interactions.
- Lovastatin levels are increased substantially by atazanavir/ritonavir; concurrent use with a PI can lead to potentially fatal rhabdomyolysis. Lovastatin should be discontinued when atazanavir/ritonavir is initiated. To manage hyperlipidemia, the patient should be switched to a statin whose metabolism is less affected by these PIs, such as pravastatin or low-dose atorvastatin (simvastatin, also is contraindicated for use by patients who take a PI).
- Tenofovir can decrease plasma concentrations of unboosted atazanavir, but can be administered safely with ritonavir-boosted atazanavir.
- Clarithromycin levels are increased by atazanavir/ritonavir; concurrent use can lead to QTc prolongation. If clarithromycin is co-administered with atazanavir/ritonavir, its dosage should be reduced by 50%.

Although this patient's current medication list does not contain an erectile dysfunction agent, the patient should be educated about the definite interactions and dosage adjustments recommended for patients using those agents with PIs. Some patients may obtain erectile dysfunction agents outside the care of their physician and, if unaware of the interactions

and suggested dosage adjustments, may be at risk of life-threatening consequences.

The following probable or possible interactions should be considered if PIs are begun, including:

- Omeprazole with atazanavir/ritonavir
- Bupropion with atazanavir/ritonavir
- Milk thistle with atazanavir/ritonavir

The web-based resources and other references listed above include some information about these potential interactions. The following are suggestions:

- **Omeprazole:** PPIs and H2-blockers decrease serum levels of atazanavir, even when boosted with ritonavir, but the clinical significance of this interaction has not been demonstrated. In general, it may be best to avoid concomitant use of these acid-blocking medications with atazanavir by either discontinuing the GERD medication or switching to another ARV. Unboosted atazanavir should not be used with PPIs. For patients without evidence of ARV resistance in whom coadministration of these medications is judged unavoidable, atazanavir/ritonavir may be used, but doses of omeprazole should not exceed 20 mg and must be taken at least 12 hours prior to taking atazanavir/ritonavir. Note that tenofovir also can lower atazanavir levels, so increasing atazanavir to 400 mg/day with ritonavir 100 mg/day could be considered.
- **Bupropion and milk thistle:** Specific management or dosage adjustments based on data are not available. This patient should be monitored for increased or decreased effects of bupropion and educated about potential interactions with milk thistle. Clinical judgment and decision making with the primary care provider and other specialists (e.g., psychiatrists) may be required.

Consultation with clinical pharmacy services may assist in evaluating the potential significance of drug interactions and developing management strategies.

Patient Education

- Instruct patients that HIV medications, in particular PIs, NNRTIs, cobicistat, and maraviroc, have a high potential for significant drug interactions.
- Tell patients to bring all their medicines, including any herbal, nutritional, and dietary supplements and OTC remedies, with them to all medical appointments. If they cannot bring the actual containers with them, they should bring a list of current prescribed medications, supplements, and OTC medications.
- Patients should have their primary care provider or pharmacist review any newly prescribed medications along with their current list of medicines. This is especially important if another physician prescribes a new medication.
- Patients should not “borrow” medications from friends or family. Assure patients that if they have a problem that needs medical treatment, their primary care provider will discuss it and choose the safest treatments for them.
- Tell patients that, if they are considering buying a new nutritional or herbal supplement or an OTC product, they should consult their pharmacist or primary care provider about interactions with drugs on their current medication list.
- Not all drug interactions are cause for alarm. Some drug combinations are safe for certain people, but less safe for others. Warn patients not to stop taking any medicines without the advice of their primary care provider.

Resources

- HIV InSite Database of Antiretroviral Drug Interactions (hivinsite.ucsf.edu/interactions)
- University of Liverpool HIV Drug Interaction Charts (www.hiv-druginteractions.org/)
- Clinical Care Options (www.clinicaloptions.com/HIV.aspx)

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Antiretroviral Medications and Hormonal Contraceptive Agents

Background

Few pharmacokinetic or clinical studies have examined interactions between antiretroviral (ARV) medications and hormonal contraceptives, but it is known that certain protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors (NNRTIs), as well as the boosted integrase inhibitor combination elvitegravir/cobicistat, do interact with hormonal contraceptives. These interactions may increase the risk of medication failure or medication adverse effects of either the ARV or the contraceptive. There are no known interactions between hormonal contraceptives and nucleoside analogues or the CCR5 antagonist.

Oral Contraceptives

All oral contraceptives currently marketed in the United States, with the exception of progestin-only pills (which contain norethindrone), contain both ethinyl estradiol and a progestin (desogestrel, drospirenone, ethynodiol diacetate, levonorgestrel, norethindrone, norethindrone acetate, norgestimate, or norgestrel). The oral contraceptives ethinyl estradiol and norethindrone may interact in complex ways with PIs and NNRTIs. The mechanism of these interactions may be multifactorial and includes the activity of these agents on cytochrome P450 enzymes. Pharmacokinetic studies have shown changes (either increases or decreases) in levels of ethinyl estradiol and norethindrone in women who are taking certain PIs, NNRTIs, or elvitegravir/cobicistat. Other studies have shown decreases in levels of amprenavir (the active agent of fosamprenavir) in women taking oral contraceptives.

The clinical significance of these drug interactions has not been evaluated thoroughly, but may cause oral contraceptive failure, ARV failure, or medication toxicity, depending on whether drug levels are lowered or raised by the interacting drug. The consequences of decreased hormone levels may include an increased risk of pregnancy, so an alternative or additional method of contraception is commonly recommended. The consequences of decreased ARV levels may include virologic failure and development of resistance mutations. The consequences of a higher level of hormones may include risk of thromboembolism, breast tenderness, headache, nausea, and acne.

The available pharmacokinetic data are summarized in Table 1. For further discussion of oral and non-oral contraceptives for HIV-infected women, see chapter *Health Care of HIV-Infected Women Through the Life Cycle*.

Table 1. Interactions Between Antiretroviral Agents and Oral Contraceptives**Key to symbols:**

- ☐ Use alternative/additional method or do not administer together
 ! Use with caution
 ✓ Safe to use in combination or no dosage adjustment necessary

Antiretroviral Agent	Pharmacokinetic Changes with Oral Contraceptives		Comments
Protease Inhibitors			
Atazanavir (ATV, Reyataz) (unboosted)	- EE AUC ↑ 48% - NE AUC ↑ 110%	!	OC should contain ≤30 mcg EE. Monitor for side effects, or use alternative method.
ATV/r	- EE AUC ↓ 19% 17-deacetyl norgestimate (active metabolite of NG) AUC ↑ 85%	!	- OC should contain ≥35 mcg EE. - OCs containing progestins other than norethindrone or norgestimate have not been studied.
Darunavir (DRV, Prezista) DRV/r	- EE AUC ↓ 44% - NE AUC ↓ 14%	⊗	Use alternative or additional method of contraception.
Fosamprenavir (FPV, Lexiva)	- EE C_{min} ↑ 32% - NE C_{min} ↑ 45%; AUC ↑ 18% - Amprenavir AUC ↓ 22% - Amprenavir C_{min} ↓ 20%	⊗	- Data are derived from studies with amprenavir (the active metabolite of FPV). - Risk of ARV failure and of EE or NE adverse effects: do not coadminister fosamprenavir with OCs. - Use alternative method of contraception.
FPV/r	- EE AUC ↓ 37% - NE AUC ↓ 34%	⊗	- Risk of contraceptive failure and of ritonavir adverse effects. - Use alternative method of contraception.
Indinavir (IDV, Crixivan)	- EE AUC ↑ 24% - NE AUC ↑ 26%	✓	- No dosage adjustment is recommended. - Monitor for EE or NE adverse effects.
IDV/r	No data	⊗	Risk of contraceptive failure; use alternative or additional method of contraception.
Lopinavir/r (LPV/r, Kaletra)	- EE AUC ↓ 42% - NE AUC ↓ 17%	⊗	Risk of contraceptive failure; use alternative or additional method of contraception.
Nelfinavir (NFV, Viracept)	- EE AUC ↓ 47% - NE AUC ↓ 18%	⊗	Risk of contraceptive failure; use alternative or additional method of contraception.
Ritonavir (RTV, Norvir)	EE AUC ↓ 40%	⊗	Risk of contraceptive failure; use alternative method of contraception.
Saquinavir (SQV, Invirase)/r	- No data; theoretic EE ↓ - SQV kinetics not affected by OC	⊗	Risk of contraceptive failure; use alternative or additional method of contraception.
Tipranavir (TPV, Aptivus)/r	- EE AUC ↓ 48% - NE no significant change	⊗	Risk of contraceptive failure; use alternative or additional method of contraception.

Antiretroviral Agent	Pharmacokinetic Changes with Oral Contraceptives		Comments
Nonnucleoside Reverse Transcriptase Inhibitors			
Efavirenz (EFV, Sustiva)	• EE AUC no significant change • 17-deacetyl norgestimate (active metabolite of NG) AUC ↓ 64% • LN AUC ↓ 58-83% • NE: AUC ↓ predicted	☒	• Decrease in progestin levels: risk of contraceptive failure (including failure of emergency contraception (Plan B)); use alternative or additional method of contraception.
Etravirine (ETR, Intelence)	• EE AUC ↑ 22% • NE AUC ↓ 5%	✓	• No dosage adjustment is necessary.
Nevirapine (NVP, Viramune)	• EE AUC ↓ 20% • NE AUC ↓ 19%	☒	• Risk of contraceptive failure; use alternative or additional method of contraception.
Rilpivirine (RPV, Edurant)	• EE AUC ↑ 14% • NE no significant change	✓	• No dosage adjustment is necessary.
CCR5 Antagonist			
Maraviroc (MVC, Selzentry)	• No significant effect on EE or LN	✓	• No dosage adjustment is necessary.
Integrase Inhibitor			
Dolutegravir (DTG, Tivicay)	• No significant change in EE AUC or NG AUC	✓	• No dosage adjustment is necessary
Elvitegravir (EVG, Stribild)	• NE AUC ↓ 25%, C_{min} ↓ 44% • NG AUC, C_{max}, C_{min} ↑ >2-fold	!	• Risk of NG adverse effects (not fully known; may include venous thrombosis); consider alternative method of contraception.
Raltegravir (RAL, Isentress)	• No significant change in EE AUC or NG AUC	✓	• No dosage adjustment is necessary.

Abbreviations: AUC = area under the time-concentration curve (drug exposure); C max = maximum concentration; C min = minimum concentration; EE = ethinyl estradiol; LN = levonorgestrel; NE = norethindrone; NG = norgestimate; OC = oral contraceptive; RTV = ritonavir; /r = low-dose ritonavir

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines.

Non-Oral Hormonal Contraceptives

Hormonal contraceptives using delivery methods other than oral include the following:

- Products containing both progestin and estrogen components: transdermal patch, vaginal ring
- Products containing a progestin alone (medroxyprogesterone acetate, levonorgestrel, norelgestromin, or

etonogestrel): subcutaneous or IM injection, intrauterine system, implantable device

There has been little research on the interactions between ARVs and most of these agents. Theoretically, interactions with ARVs would be less likely with contraceptive methods that have primarily local action and minimal systemic absorption, and for injection or transdermal delivery systems, since first-pass metabolism is avoided. However, caution is still warranted, as this assumption has not been proven.

Because the transdermal patch and vaginal ring contain ethinyl estradiol, women who take ARVs that increase or decrease serum estradiol levels (see Table 1) are advised to use an alternative (or additional) contraceptive method. Small studies of depo-medroxyprogesterone acetate (DMPA, or Depo-Provera) have shown no significant interactions between DMPA and nelfinavir, efavirenz, or nevirapine. Interactions between DMPA and other ARVs have not been studied, but DMPA's interactions with PIs and NNRTIs would be expected to be similar to those of norethindrone (see Table 1). For other non-oral hormones, pending further study, an alternative (or additional) method of contraception should be considered.

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Pain Syndrome and Peripheral Neuropathy

Background

The International Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.” Pain is subjective, it is whatever the patient says it is, and it exists whenever the patient says it does. Pain is a common symptom in people with HIV infection, especially those with advanced disease. It occurs in 30-60% of HIV/AIDS patients and can diminish their quality of life significantly. Like cancer patients, HIV patients experience an average of 2.5 to 3 types of pain at once. Pain in HIV-infected patients may have many causes (as discussed below).

Pain is significantly undertreated, especially among HIV-infected women, because of factors ranging from providers’ lack of knowledge about the diagnosis and treatment of pain to patients’ fear of addiction to analgesic medications. Pain, as the so-called fifth vital sign, should be assessed at every patient visit.

Peripheral Neuropathy

Pain from HIV-associated peripheral neuropathy is particularly common, and may be debilitating. Peripheral neuropathy is clinically present in approximately 30% of HIV-infected individuals and typically presents as distal sensory polyneuropathy (DSP). It may be related to HIV itself (especially at CD4 counts of <200 cells/ μ L), to medication toxicity (e.g., from certain nucleoside analogues such as stavudine or didanosine), or to the effects of chronic illnesses (e.g., diabetes mellitus). Patients with peripheral neuropathy may complain of numbness or burning, a pins-and-needles sensation, shooting or lancinating pain, and a sensation that their shoes are too tight or their feet are swollen. These symptoms typically begin in the feet and progress upward; the hands also may be affected. Patients may develop difficulty walking because of discomfort, or because they have difficulty feeling their feet on the ground. Factors associated with increased risk of peripheral neuropathy include the following:

- Previous peripheral neuropathy
- Low CD4 count (<200 cells/ μ L)
- Previous AIDS-defining opportunistic infection or neoplasm
- Vitamin B12 deficiency
- Exposure to stavudine or didanosine
- Use of other drugs associated with peripheral neuropathy (e.g., isoniazid, dapsone, metronidazole, hydroxyurea, thalidomide, linezolid, ribavirin, vincristine)
- Use of other neurotoxic agents (e.g., alcohol)
- Diabetes mellitus

Patients should be assessed carefully before the introduction of a potentially neurotoxic medication (including stavudine or didanosine), and the use of these medications for patients at high risk of developing peripheral neuropathy should be avoided.

S: Subjective

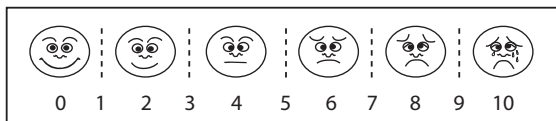
Self-report is the most reliable method to assess pain.

The patient complains of pain. The site and character of the pain will vary with the underlying cause. Ascertain the following from the patient:

- Duration, onset, progression
- Distribution, symmetry
- Character or quality (e.g., burning, sharp, dull)
- Intensity
- Severity (using the 0-10 scale; see Figure 1)
- Neurologic symptoms (e.g., weakness, cranial nerve abnormalities, bowel or bladder abnormalities)
- Exacerbating or relieving factors
- Response to current or past pain management strategies
- Past medical history (e.g., AIDS, diabetes mellitus)
- Psychosocial history
- Substance abuse and alcohol use history (amount, duration)
- Medications, current and recent (particularly zalcitabine, didanosine, stavudine, and isoniazid)
- Nutrition (vitamin deficiencies)
- Meaning of the pain to the patient

Measuring the severity of the pain: Have the patient rate the pain severity on a numeric scale of 0-10 (0 = no pain; 10 = worst imaginable pain), a verbal scale (none, small, mild, moderate, or severe), or a pediatric faces pain scale (when verbal or language abilities are absent). Note that pain ratings >3 usually indicate pain that interferes with daily activities. Use the same scale for evaluation of treatment response.

Figure 1. Faces Pain Rating Scale (0-10)



Quick screen for peripheral neuropathy: Ask about distal numbness and check Achilles tendon reflexes. Screening for numbness and delayed or absent ankle reflexes has the highest sensitivity and specificity among the clinical evaluation tools for primary care providers. For a validated screening tool, use the ACTG Brief Peripheral Neuropathy Scale (BPNS) to scale and track the degree of peripheral neuropathy (see www.hiv.va.gov/provider/manual-primary-care/peripheral-neuropathy.asp#S4.2X).

O: Objective

Measure vital signs (increases in blood pressure, respiratory rate, and heart rate can correlate with pain). Perform a symptom-directed physical examination, including a thorough neurologic and musculoskeletal examination. Look for masses, lesions, and localizing signs. Pay special attention to sensory deficits (check for focality, symmetry, and distribution [such as “stocking-glove”]), muscular weakness, reflexes, and gait. Patients with significant motor weakness or paralysis, especially if progressive over days to weeks, should be evaluated emergently.

To evaluate peripheral neuropathy: Check ankle Achilles tendon reflexes and look for delayed or absent reflexes as signs of peripheral neuropathy. Distal sensory loss often starts with loss of vibratory sensation, followed by loss of temperature sensation, followed by onset of pain. Findings are usually bilateral and symmetric.

A: Assessment

Pain assessment includes determining the type of pain, for example, nociceptive, neuropathic, or muscle spasm pain.

Nociceptive pain occurs as a result of tissue injury (somatic) or activation of nociceptors resulting from stretching, distention, or inflammation of the internal organs of the body. It usually is well localized; may be described as sharp, dull, aching, throbbing, or gnawing in nature; and typically involves bones, joints, and soft tissue.

Neuropathic pain occurs from injury to peripheral nerves or central nervous system structures. Neuropathic pain may be described as burning, shooting, tingling, stabbing, or like a vise or electric shock; it involves the brain, central nervous system, nerve plexuses, nerve roots, or peripheral nerves. It is associated with decreased sensation and hypersensitivity.

Muscle spasm pain can accompany spinal or joint injuries, surgeries, and bedbound patients. It is described as tight, cramping, pulling, and squeezing sensations.

Although pain in HIV-infected patients can result from opportunistic infections, neoplasms, or medication-related neuropathy, it is important to include non-HIV-related causes of pain in a differential diagnosis. Some of these other causes may be more frequent in HIV-infected individuals. A partial list for the differential diagnosis includes:

- Anorectal carcinoma
- Aphthous ulcers
- Appendicitis
- Arthritis, myalgias
- Candidiasis, oral or esophageal
- Cholecystitis
- Cryptococcal disease
- Cytomegalovirus colitis
- Dental abscesses
- Gastroesophageal reflux disease (GERD)
- Ectopic pregnancy
- Herpes simplex
- Herpes zoster
- Kaposi sarcoma
- Lymphoma
- Medication-induced pain syndromes (e.g., owing to growth hormone, granulocyte colony-stimulating factor)
- Medication-induced peripheral neuropathy (e.g., owing to didanosine, stavudine, isoniazid, vincristine)
- Other causes of peripheral neuropathy: diabetes, hypothyroidism, B12 deficiency, syphilis, cryoglobulinemia (especially in patients with hepatitis C coinfection)
- *Mycobacterium avium* complex
- Myopathy
- Pancreatitis
- Pelvic inflammatory disease
- Toxoplasmosis

P: Plan

Perform a diagnostic evaluation based on the suspected causes of pain.

Treatment

Treatment should be aimed at eliminating the source of pain, if possible. If symptomatic treatment of pain is needed, begin treatment based on the patient's pain rating scale, using the least invasive route. The goal is to achieve optimal patient comfort and functioning (not necessarily zero pain) with minimal medication adverse effects. Use the three-step pain analgesic ladder originally devised by the World Health Organization (WHO); see Figure 2.

Nonpharmacologic interventions

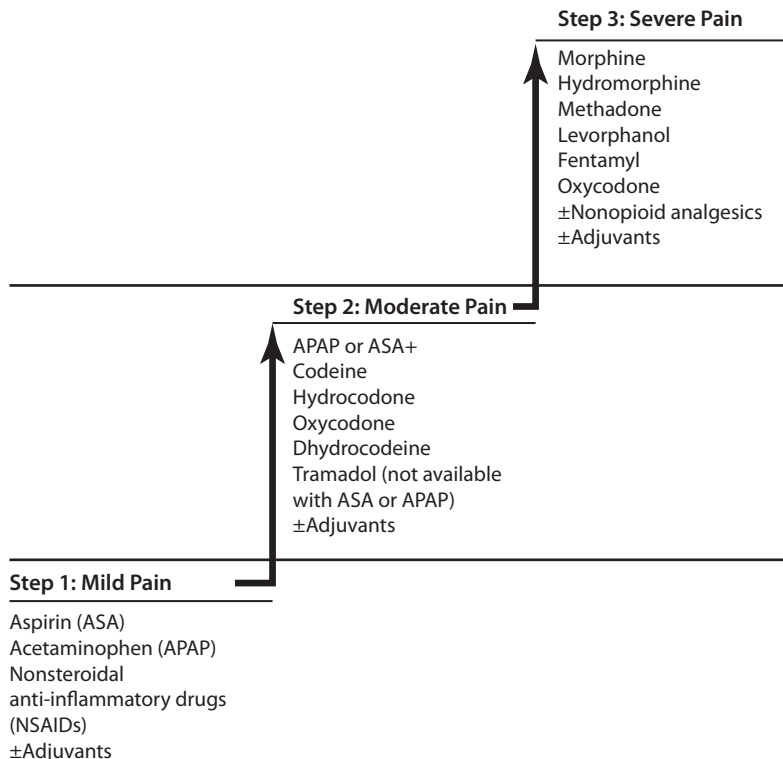
The following interventions can be used at any step in the treatment plan:

- A therapeutic provider-patient relationship
- Physical therapy
- Exercise
- Relaxation techniques
- Guided imagery
- Massage
- Biofeedback
- Reflexology
- Acupuncture
- Thermal modalities (hot and cold compresses or baths)
- Transcutaneous electrical nerve stimulation (TENS)
- Spiritual exploration
- Prayer
- Deep breathing
- Meditation
- Enhancement of coping skills
- Self-hypnosis
- Humor
- Distraction
- Hobbies

Pharmacologic interventions**Principles of pharmacologic pain treatment**

- The dosage of the analgesic is adjusted to give the patient adequate pain control.
- The interval between doses is adjusted so that the pain control is uninterrupted. It can take 4-5 half-lives before the maximum effect of an analgesic is realized.
- Chronic pain is more likely to be controlled when analgesics are dosed on a continuous schedule rather than “as needed.” Sustained-release formulations of opioids should be used whenever possible.
- For breakthrough pain, use “as needed” medications in addition to scheduled-dosage analgesics. When using opiates for both scheduled analgesia and breakthrough pain, a good rule of thumb is to use 10% of the total daily dosage of opiates as the “as needed” opiate dose for breakthrough pain.
- Oral administration has an onset of analgesia of about 20-60 minutes, tends to produce more stable blood levels, and is cheaper.
- Beware of the risk of prolonged analgesic half-lives in patients with renal or hepatic dysfunction.
- Caution when using combination analgesics that are coformulated with ingredients such as acetaminophen, aspirin, or ibuprofen. Determine the maximum daily dosage of all agents.

The following three steps are adapted from the WHO analgesic ladder. Agents on higher steps are progressively stronger pain relievers but tend to have more adverse effects.

Figure 2. Pharmacologic Approaches to Pain Management: WHO Three-Step Ladder

Adapted from World Health Organization. *Cancer Pain Relief and Palliative Care, Report of a WHO Expert Committee*. Geneva: World Health Organization; 1990.

Note: "Adjuvants" refers either to medications that are coadministered to manage an adverse effect of an opioid or to so-called adjuvant analgesics that are added to enhance analgesia.

Step 1: Nonopioids for mild pain (pain scale 1-3)

- The most common agents in this step include acetaminophen (650-1,000 mg PO Q6H as needed) and nonsteroidal antiinflammatory drugs (NSAIDs) such as ibuprofen 600-800 mg PO TID with food, and cyclooxygenase-2 (COX-2) inhibitors such as celecoxib and rofecoxib.
- A proton-pump inhibitor (such as omeprazole) can decrease the risk of gastrointestinal bleeding when using NSAIDs.

- Acetaminophen has no effect on platelets and no antiinflammatory properties; avoid use in patients with hepatic insufficiency, and in general limit to 4 g per day in acute use (or 2 g per day for patients with liver disease). Monitor liver function tests in chronic use.
- NSAIDs and acetaminophen can be used together for synergism.
- Note that COX-2 inhibitors have been associated with an increased risk of cardiovascular events and should be used with caution.

Step 2: Mild opiates with or without nonopiates for moderate pain (pain scale 4-6)

- Most agents used to treat moderate pain are combinations of opioids and Step 1 agents. The most common agents are acetaminophen combined with codeine, oxycodone, or hydrocodone. Codeine can be dosed as codeine sulfate, separately from acetaminophen. Beware of acetaminophen toxicity in these combination drugs.
- Other agents include buprenorphine (partial opiate agonist).
- Tramadol (Ultram) is a centrally acting nonopiate that can be combined with NSAIDs. As with opiates, it is prone to abuse. Tramadol lowers the seizure threshold; avoid use for patients with a seizure history. Avoid coadministration with selective serotonin reuptake inhibitors (SSRIs) and monoamine oxidase inhibitors (MAOIs) because of the risk of serotonin syndrome.

Step 3: Opioid agonist drugs for severe pain (pain scale 7-10)

- Morphine is the drug of choice in this step. Start with short-acting morphine and titrate the dosage to adequate pain control, then divide the 24-hour total in half to determine the dosing for the sustained-release morphine, given Q12H. When converting from IV to PO morphine, PO dosage is about two to three times the parenteral dosage.
- Other agents used are oxycodone, hydromorphone, fentanyl, levorphanol, methadone, codeine, hydrocodone, oxycodone, and buprenorphine.
- Avoid meperidine because of the increased risk of delirium and seizures.
- Around-the-clock, sustained-release PO dosing will achieve optimum pain relief.

- Patients unable to take PO therapy may use transdermal fentanyl patches or do rectal administration of sustained-release tablets such as long-acting morphine. Note that the onset of analgesia with fentanyl patches can take more than 12 hours, and the analgesic effect can last more than 18 hours after the patch is removed.
- Anticipate and treat complications and adverse effects of opioid therapy, such as nausea, vomiting, and constipation. Constipation often leads to nausea and can be prevented with prophylactic stool softeners (such as docusate) and stimulant laxatives (such as senna).

Adjunctive treatments

The addition of antidepressant medications can improve pain management, especially for chronic pain syndromes. These agents, and anticonvulsants, usually are used to treat neuropathic pain (discussed in more detail below), but should be considered for treatment of other chronic pain syndromes as well.

Treatment of neuropathic pain

Assess the underlying etiology, as discussed above, and treat the cause as appropriate. Review the patient's medication list for medications that can cause neuropathic pain. Discontinue the offending agents, if possible. For patients on stavudine or didanosine, in particular, switch to another nucleoside analogue if suitable alternatives exist, or at least consider dosage reduction of stavudine to 30 mg BID (consult with an HIV expert). For patients on isoniazid, ensure that they are taking vitamin B6 (pyridoxine) regularly to avoid isoniazid-related neuropathy.

Nonpharmacologic interventions for neuropathic pain

The nonpharmacologic interventions described above can be useful in treating neuropathic pain.

Pharmacologic interventions for neuropathic pain

Follow the WHO ladder of pain management described above. If Step 1 medications are ineffective, consider adding antidepressants, anticonvulsants, or both before moving on to opioid treatments.

Antidepressants

Antidepressant medications often exert analgesic effects at dosages that are lower than those required for antidepressant effects. As with antidepressant effects, optimum analgesic effects may not be achieved until several weeks after starting therapy.

- **Tricyclic antidepressants (TCAs):** Note that ritonavir and other protease inhibitors, and the pharmacokinetic booster cobicistat, may increase the level of TCAs, so start at the lowest dosage and titrate up slowly. Dosages may be titrated upward every 3-5 days, as tolerated. In general, TCAs are best avoided in elderly patients.
- **Nortriptyline (Pamelor):** Starting dosage is 10-25 mg QHS. Usual maintenance dosage is 20-150 mg QHS.
- **Desipramine (Norpramin):** Starting dosage is 25 mg QHS. Usual maintenance dosage is 25-250 mg QHS.
- **Imipramine:** Starting dosage is 25 mg QHS. Usual maintenance dosage is 25-300 mg QHS.
- **Amitriptyline (Elavil):** Starting dosage is 10-25 mg QHS. Usual maintenance dosage is 25-150 mg QHS. Amitriptyline has the highest rate of adverse effects among the TCAs, so other agents typically are preferred.

Adverse effects include sedation, anticholinergic effects (e.g., dry mouth, urinary retention), altered mental status, QT prolongation, arrhythmias, and orthostatic hypotension. Monitor TCA levels and EKG at higher dosage levels. There is a significant risk of overdose if taken in excess.

- **SSRIs:** See chapter *Major Depression and Other Depressive Disorders* for dosing, side effects, and drug interactions associated with this class of agents. SSRIs are less effective than TCAs in treating chronic pain.
- **Venlafaxine (Effexor):** Starting dosage is 37.5 mg daily. Usual maintenance dosage is 75-300 mg daily in divided doses or by extended-release formulation (Effexor XR). Note that there are limited data on using venlafaxine for patients with HIV infection.
- **Duloxetine (Cymbalta):** Starting dosage is 30-60 mg daily. Dosages of >60 mg per day are rarely more effective for either depression or pain treatment. Note that there are limited data on using duloxetine for patients with HIV infection.

Anticonvulsants

The following agents may be effective for neuropathic pain:

- **Gabapentin (Neurontin):** Considered first-line for HIV sensory neuropathy for its tolerability. Starting dosage is 100-300 mg QHS; may be increased every 3-5 days to BID or TID to achieve symptom relief. Monitor response and increase the dosage every 1-2 weeks by 300-600 mg/day. Usual maintenance dosage is 1,200-3,600 mg/day in divided doses. Adverse effects include somnolence, dizziness, fatigue, weight gain, and nausea. To discontinue, taper over the course of 7 or more days.
- **Pregabalin (Lyrica):** Starting dosage is 25-50 mg TID; may be increased by 25-50 mg per dose every 3-5 days as tolerated to achieve symptom relief. Maximum dosage is 200 mg TID. Adverse effects are similar to those of gabapentin. To discontinue, taper over the course of 7 or more days.
- **Lamotrigine (Lamictal):** Starting dosage is 25 mg QOD; titrate slowly to 200 mg BID over the course of 6-8 weeks to reduce the risk of rash (including Stevens-Johnson syndrome). Adverse effects include sedation,

dizziness, ataxia, confusion, nausea, blurred vision, and rash. Note that lopinavir/ritonavir (Kaletra) may decrease lamotrigine levels; higher dosages may be needed. To discontinue, taper over the course of 7 or more days.

- Although phenytoin and carbamazepine have some effectiveness in treating neuropathy, they have significant drug interactions with protease inhibitors and nonnucleoside reverse transcriptase inhibitors, and their use with HIV-infected patients is limited. Topiramate and valproic acid have been used for migraine prophylaxis and anecdotally may be useful for treating peripheral neuropathy, but have not been well-studied in HIV-related neuropathies.

Topical therapy

- **Capsaicin cream** (0.075%, 0.1%): Capsaicin inhibits the secretion of substance P and has been found to be effective for the management of pain associated with arthritis and neuropathy. It may be applied BID or TID. Patients must be instructed to wash their hands well after applying to avoid spreading the residual cream to sensitive areas such as the nose or eyes. It may cause burning.

Treatment of Muscle Spasm Pain

Stretching, heat, and massage may help the pain of muscle spasm. This pain also can respond to muscle relaxants such as baclofen, cyclobenzaprine, tizanidine, benzodiazepines, as well as intraspinal infusion of local anesthetics for spinal injuries.

Substance Abuse, HIV, and Pain

Some health care providers hesitate to treat pain in patients with current or past substance abuse because of concern about worsening these patients' dependence on opioids or suspicion that such patients are seeking pain medications for illicit purposes. However, the following points should be considered:

- Many patients with current or past substance abuse do experience pain, and this pain should be evaluated by care providers and treated appropriately.
- Failure to distinguish among addiction, tolerance, and dependence can lead to undertreatment of chronic pain by health care providers.
- Addiction (substance abuse) is a complex behavioral syndrome characterized by compulsive drug use for the secondary gain of euphoria.
- Pharmacologic tolerance refers to the reduction of effectiveness, over time, of a given dosage of medication.
- Physical dependence is the consequence of neurophysiologic changes that take place in the presence of exogenous opioids.
- Aberrant use of pain medications, if it develops, is best managed by an interdisciplinary team of providers from HIV clinical care, psychiatry, psychology, pharmacy, social services, and drug addiction management.
- Drug-drug interactions between certain antiretroviral medications and methadone can decrease methadone serum concentrations (see chapter *Drug-Drug Interactions with HIV-Related Medications*). If this occurs, methadone dosages may need to be increased to prevent opiate withdrawal.
- As part of chronic pain management in patients with substance abuse, consider establishing a written pain-management

contract to be signed by the clinician and the patient. The contract should:

- Clearly state limits and expectations for both the patient and provider.
- Identify a single clinician responsible for managing the pain regimen.
- Tell the patient what to do if the pain regimen is not working.
- Describe the procedure for providing prescriptions (e.g., one prescription given to the patient, in person, for a limited period of time, such as 1 month).
- List the rules for dealing with lost medications or prescriptions.

Patient Education

- Pain management is part of HIV treatment, and patients should give feedback to allow the best treatment decisions. If pain persists for more than 24 hours at a level that interferes with daily life, patients should inform their health care provider so that the plan can be changed and additional measures, if needed, can be tried.
- Patients should not expect full pain relief in most cases, but enough relief that they can perform their daily activities.
- “Mild” pain medications (e.g., NSAIDs, aspirin, acetaminophen) usually are continued even after “stronger” medications are started because their mechanism of action is different from that of opiates. This combination of pain medication has additive effects, so that pain may be controllable with a lower narcotic dosage.
- Patients taking “around-the-clock” medications should take them on schedule. Those taking “as needed” medications should take them between doses only if they have breakthrough pain.
- Patients who are prescribed opiates should be advised to take no more than the prescribed dosages. Misuse or inappropriate use can result in overdose.
- Opiates may cause severe constipation. Patients must remain hydrated and will likely need stool softeners, laxatives, or other measures. They should contact their health care provider promptly if constipation occurs.
- Patients taking opiates should avoid driving and operating machinery.

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HIV-Associated Neurocognitive Disorders

Background

HIV is a neurotropic virus that directly invades the brain shortly after infection. HIV replicates in brain macrophages and microglia, causing inflammatory and neurotoxic host responses. HIV may cause cognitive, behavioral, and motor difficulties. These difficulties may range in severity from very mild to severe and disabling.

The American Academy of Neurology (AAN) recognizes three categories of HIV-associated neurocognitive disorder (HAND) (see Table 1, below).

- **Asymptomatic neurocognitive impairment (ANI)** is determined by neurocognitive testing and is not apparent clinically.
- **Mild neurocognitive disorder (MND)** is a diagnosis of exclusion; it may be made clinically if neurocognitive testing is not available, and it involves mild functional impairment.
- **HIV-associated dementia (HAD)** involves moderate to severe functional impairment.

[In the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) section on cognitive disorders, MND correlates with mild neurocognitive disorder, and HAD with major neurocognitive disorder.]

Both MND and HAD are AIDS-defining conditions (listed as “Encephalopathy, HIV Related” in the classification system used by the U.S. Centers for Disease Control and Prevention), and they are risk factors for death. Neurocognitive disorders associated with HIV are among the most common and clinically important complications of HIV infection. However, they are diagnoses of exclusion, and other medical causes must be ruled out.

Risk factors for developing an HIV-associated neurocognitive disorder include the following:

- Older age
- Female gender
- More advanced HIV disease (including CD4 count of <100 cells/μL, wasting)
- High plasma HIV RNA (viral load)
- Comorbid conditions (especially anemia and infection with cytomegalovirus, human herpesvirus 6, and JC virus)
- History of injection drug use (especially with cocaine)
- History of delirium

With the advent of ART, HAD prevalence has declined and MND prevalence has increased.

As people with HIV live longer and become older, the risk of developing cognitive impairment increases. The use of effective antiretroviral therapy (ART) that maintains the plasma HIV RNA at undetectable or low values is important for preventing and treating HIV-related neurocognitive disorders. In people with neurocognitive impairment, however, there may be some benefit in using antiretroviral (ARV) agents that penetrate the CNS. However, recent research suggests that neuroinflammation rather than the HIV viral load in the CNS is primarily responsible for cognitive impairment in HIV-infected individuals. In choosing an ART regimen, it is important to take into consideration resistance testing, CNS penetration, and adherence issues.

Minor Neurocognitive Disorder

MND is characterized by mild impairment in functioning and may escape diagnosis by the clinician. The onset and course of MND can vary dramatically. The more demanding the activities of a particular individual, the more likely that person would be to notice the difficulties in functioning.

HIV-Associated Dementia

HAD is characterized by symptoms of cognitive, motor, and behavioral disturbances. There is often a progressive slowing of cognitive functions, including concentration and attention, memory, new learning, sequencing and problem solving, and executive control. HAD also can present with behavioral changes, which mainly take the form of apathy, loss of motivation, poor energy, fatigue, and social withdrawal. Motor changes, including slowing, clumsiness, unsteadiness, increased tendon reflexes, and deterioration of handwriting may occur.

S: Subjective

If a neurocognitive disorder is suspected, obtain a history of the patient's symptoms (see below). Whenever possible, obtain a parallel history of the patient's past history and recent mental status changes from significant others or caretakers.

Patient self-reports of cognitive problems and bedside cognitive status tests may be insensitive, particularly to subtler forms of impairment. Often, other people may observe changes in the person's behavior or mood that indicate some change in cognitive functioning.

To help clarify factors that may be causing the changes in mental status, inquire about the following:

- Acuity of onset
- Recent changes or events
- Medications, particularly new medications
- Drug and alcohol use
- Symptoms of opportunistic illnesses, other infections
- HIV history, including duration, CD4 cell count, HIV viral load, history of ART
- History of other medical and psychiatric disorders

Table 1. AAN Criteria for HIV-Associated Neurocognitive Disorder

HIV-Associated Asymptomatic Neurocognitive Impairment (ANI)
• Acquired impairment in cognitive functioning, involving at least two ability domains, documented by performance of at least 1 SD below the mean for age-education-appropriate norms on standardized neuropsychological tests. The neuropsychological assessment must survey at least the following abilities: verbal/language; attention/working memory; abstraction/executive; memory (learning; recall); speed of information processing; sensory-perceptual, motor skills. • The cognitive impairment does not interfere with everyday functioning. • The cognitive impairment does not meet criteria for delirium or dementia. • There is no evidence of another preexisting cause for the ANI.
Mild Neurocognitive Disorder (MND)
• Acquired impairment in cognitive functioning, involving at least two ability domains, documented by performance of at least 1 SD below the mean for age/education-appropriate norms on standardized neuropsychological tests. The neuropsychological assessment must survey at least the following abilities: verbal/language, attention/working memory, abstraction/executive, memory (learning and recall), speed of information processing, sensory-perceptual and motor skills. • The cognitive impairment produces at least mild interference in daily functioning (at least one of the following): • Self-report of reduced mental acuity, inefficiency in work, homemaking or social functioning • Observation by knowledgeable others that the individual has undergone at least mild decline in mental acuity with resultant inefficiency in work, homemaking, or social functioning • The cognitive impairment does not meet criteria for delirium or dementia. • There is no evidence of another pre-existing cause for the mild neurocognitive disorder. If the individual with suspected mild neurocognitive disorder also satisfies criteria for a severe episode of major depression with significant functional limitations or psychotic features, or substance dependence, the diagnosis of mild neurocognitive disorder should be deferred to a subsequent examination conducted at a time when the major depression has remitted or at least 1 month after cessation of substance use.
HIV-Associated Dementia (HAD)
• Marked acquired impairment in cognitive functioning, involving at least two ability domains; typically the impairment is in multiple domains, especially in the learning of new information, slowed information processing and defective attention/concentration. The cognitive impairment must be ascertained by neuropsychological testing with at least two domains being 2 standard deviations or greater below that of demographically corrected means. • The cognitive impairment produces marked interference with day-to-day functioning (work, home life and social activities). • The pattern of cognitive impairment does not meet criteria for delirium. • There is no evidence of another, pre-existing cause for the dementia (e.g., other CNS infection, CNS neoplasm, cerebrovascular disease, pre-existing neurologic disease or severe substance abuse compatible with CNS disorder).

Adapted from Antinori A, Arendt G, Becker JT, et al. *Updated research nosology for HIV-associated neurocognitive disorders. Neurology.* 2007 Oct 30;69(18):1789-99.

Additionally, the AAN specifies that, for patients with severe depression or substance dependence who are suspected of having HAD, the neurocognitive assessment should be deferred until the depression or substance use is in remission.

Although the AAN criteria include assessment via neuropsychological testing, in the absence of such testing, it is acceptable to make a presumptive diagnosis of MND or HAD on the basis of clinical signs and symptoms once all other possible causes of changes in mental function have been ruled out.

O: Objective

- Check temperature and other vital signs (MND and HAD are not associated with fever).
- Perform a complete physical examination with special attention to signs of opportunistic illnesses.
- Perform a thorough neurological examination, including funduscopy. Rule out focal neurologic deficits.
- Perform Mini-Mental State Examination (note that this is not sensitive for HIV-associated neurocognitive disorders; negative results do not rule out these conditions).

Consider a neuropsychological screening test such as the Modified HIV Dementia Scale (see Figure 1), International HIV Dementia Scale, or the Montreal Cognitive Assessment. Others are noted in “Laboratory and Diagnostic Evaluation,” below.

A: Assessment

A differential diagnosis includes the following medical conditions, which may present with cognitive changes or delirium:

- Substance use: intoxication or withdrawal from alcohol, opioids, stimulants, etc.
- Psychiatric disorders, especially major depression
- Metabolic or systemic disorders, including hepatic encephalopathy, vitamin B12 or folate deficiency, uremia, endocrine disorders (e.g., hypogonadism)
- Central nervous system (CNS) opportunistic infections, such as cytomegalovirus encephalitis, cryptococcal meningitis, tuberculous meningitis, CNS toxoplasmosis, and progressive multifocal leukoencephalopathy (PML)
- Systemic infections
- Brain tumors, including CNS lymphoma and metastatic disease
- Other causes of cognitive impairment and dementia (e.g., neurosyphilis, substance-induced dementia, vascular dementia, brain injury, Alzheimer disease, and hydrocephalus)
- Medication adverse effects: ARV medications (especially efavirenz), psychotropic medications, interferon, anticholinergics, and others
- Poisoning with toxic substances

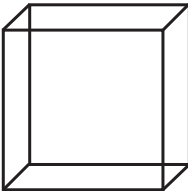
P: Plan**Laboratory and Diagnostic Evaluation**

A change in the mental status of an HIV-infected person should prompt a thorough search for underlying biological causes. As noted above, HIV-related neurocognitive disorders are diagnoses of exclusion, and other causes of the patient’s symptoms should be ruled out.

Perform the following tests:

- Laboratory tests: Complete blood count, electrolytes and creatinine, liver function, thyroid function, vitamin B12, rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL).
- Toxicology tests if substance use is suspected (e.g., opioids, ethanol, amphetamines).
- Brain imaging studies (computed tomography [CT] scan or magnetic resonance imaging [MRI]); rule out space-occupying masses and other lesions; cortical atrophy may be seen in advanced HAD; this finding is not specific.
- Cerebral spinal fluid (CSF) tests if CNS infection is suspected.
- Consider tests for neurocognitive impairment as noted in the table below; most of these can be found on the website of the New York State Department of Health AIDS Institute at www.hivguidelines.org/clinical-guidelines/hiv-and-mental-health.
- Refer to an HIV-experienced neuropsychologist, neurologist, or psychiatrist, if available.

Figure 1. Modified HIV Dementia Scale

Maximum Score	Score	Exercise
N/A	N/A	Memory/Registration: State four words for the patient to recall (dog, hat, green, peach), pausing 1 second between each. Then ask the patient to restate all four.
6	(__)	Psychomotor Speed: Ask the patient to write the alphabet in upper case letters horizontally across the page; record time: ____seconds. ≤ 21 sec = 6 21.1 - 24 sec = 5 24.1 - 27 sec = 4 27.1 - 30 sec = 3 30.1 - 33 sec = 2 33.1 - 36 sec = 1 > 36 sec = 0
4	(__)	Memory Recall: Ask the patient to restate the four words from Memory/Registration above. Give one point for each correct response. For words not recalled, prompt with a "semantic" clue, as follows: animal (dog); piece of clothing (hat), color (green), fruit (peach). Give 1/2 point for each correct after prompting.
2	(__)	Construction: Copy the cube below; record time: ____seconds. (< 25 sec = 2; 25 - 35 sec = 1; > 35 sec = 0) 

Maximum score: 12 points; a score of < 7.5 points suggests possible HAD (note, this test is not specific)

Adapted from McArthur JC. *Minor cognitive motor disorder: Does it really exist?* Hopkins HIV Rep. Nov 1996;8(4):8.

Table 2. Tests for Identifying and Staging HIV-Related Neurocognitive Impairment

HIV Dementia Scale	• Screens for the memory and attention deficits and psychomotor slowing that are typical of HAD • Requires training to administer and, therefore, may not be ideal for a clinic setting
Modified HIV Dementia Scale	• Designed specifically for use by non-neurologists and, therefore, may be more useful than the HIV Dementia Scale for a primary care setting • Requires approximately 5 minutes to administer • See Figure 1, above
Mental Alternation Test	• Useful for assessing patients with early dementia, who will show impairments in timed trials
Memorial Sloan-Kettering (MSK) Scale	• Can be used for assessing severity • Combines the functional impact of both cerebral dysfunction (dementia) and spinal cord dysfunction (myelopathy); the two entities can be separated and staged independently
Trail Making Test, Parts A and B (from the Halstead-Reitan Neuropsychological Battery)	• May be used as a screening tool, but results require interpretation by a neuropsychologist • May be used at the bedside to track a patient's response to ART over time
Grooved Pegboard (dominant and nondominant hand)	• May be used as a screening tool and does not require literacy

Treatment

There are no specific treatments for HIV-associated neurocognitive disorders, but ART may reverse the disease process, and a number of therapies may be helpful. The treatment of MND and HAD ideally utilizes a multidisciplinary approach that may involve HIV specialists, neurologists, psychiatrists, psychologists, nurse practitioners, social workers, substance-use counselors, case managers, and others.

Neurocognitive impairment in patients with HIV infection often is multifactorial. In addition to treating HIV-associated neurocognitive disorders themselves, it is important to correct, as much as possible, all medical conditions that may adversely affect the brain (e.g., psychiatric comorbidities, endocrinologic abnormalities, adverse medication effects). For patients using alcohol or illicit or nonprescribed drugs, implement strategies to reduce their use; these agents can further impair cognition.

Pharmacologic Management of HIV-Associated Neurocognitive Disorders

- **ART:** Maximal suppression of HIV replication via ART may partially or fully reverse HIV-associated neurocognitive disorders, and ART is the treatment of choice for both treatment and prevention of HIV-associated neurocognitive disorders, including dementia. In general, ART regimens that effectively suppress HIV RNA in the serum also suppress HIV in the CNS. However, ARV medications vary in their ability to penetrate the blood-brain barrier and, therefore, in their ability to act directly on the HIV in the CNS. Limited data suggest that using ARVs with good CNS penetration may be important in treating or preventing neurocognitive disorders, and some experts recommend the use of these ARVs, if otherwise appropriate, for patients with HIV dementia. ARVs with the best CNS penetration include the nucleoside reverse transcriptase inhibitors (NRTIs)

abacavir, emtricitabine, and zidovudine (AZT, ZDV); the nonnucleoside reverse transcriptase inhibitor (NNRTI) nevirapine; the protease inhibitors (PIs) indinavir/ritonavir and lopinavir/ritonavir; and the CCR5 antagonist maraviroc. The integrase inhibitor raltegravir has reasonably good CNS penetration. There currently is no role for testing levels of HIV RNA in the CSF outside research settings.

- **Stimulants:** Stimulant medications (e.g., methylphenidate, dextroamphetamine) have been used as palliative agents to help manage symptoms of fatigue, decreased concentration, and memory deficits among patients with MND and HAD. Starting dosages of both is 5 mg/day; maximum dosage is 60 mg/day. The response to stimulants is idiosyncratic and varies from patient to patient; begin with the lowest dose of 5 mg QAM and titrate upward as needed. If BID dosing is required as a result of afternoon fatigue, the afternoon dose should be taken before 2 p.m. to prevent interference with sleep. Consider referral to a psychiatrist or neurologist for evaluation and initiation of treatment; after a stable dosage is achieved, treatment may be continued. These medications should be used with caution for patients who have a history of stimulant abuse.
- For comorbid depression, consider prescribing antidepressant medications as for other medically ill HIV-infected patients (see chapter *Major Depression and Other Depressive Disorders*).
- Antipsychotic medications may be useful in treating agitation and hallucinations but should be used for patients with dementia only when nonpharmacologic measures are insufficient for patient management; consult with a psychiatrist. All antipsychotic medications increase the risk of death in elderly patients with dementia. Start antipsychotic medications at the lowest possible dosage and increase slowly as needed.

- Many agents are being studied for either their neuroprotective effects or their therapeutic effects on HIV-associated neurocognitive disorders. The data are not sufficient at present to make specific recommendations. Patients with dementia often are sensitive to medication side effects; follow closely.
- Benzodiazepines have been shown to increase confusion and decrease concentration, and generally should be avoided.

Nonpharmacologic Management of MND and Mild HAD

- Encourage patients to remain appropriately active
- Explain the benefits of structured routines
- Encourage good nutrition
- Use strategies to minimize use of alcohol and illicit drugs
- Use memory aids such as lists
- Simplify complex tasks, especially drug regimens
- When giving instructions, do the following:
 - Repeat information
 - Write instructions to provide structure for patients and caregivers
 - Ask patients to express the information and instructions in their own words
- Adherence to medical regimens, including ART, often is particularly difficult for patients with neurocognitive disorders. Encourage use of medication adherence tools such as pill boxes, alarms, and, if available, packaged medications (e.g., blister packs) or prefilled medi-sets. Encourage patients to enlist adherence support from family members and friends.
- Cognitive skills building can be helpful (e.g., reading, solving puzzles, intellectual conversation).

Nonpharmacologic Management of Moderate to Severe HAD

The strategies noted above should be utilized, but additional measures are needed.

Management of patients with severe or late-stage HAD requires an evaluation of their safety and a determination of the environment and level of supervision that are needed. The clinician should attend to the following:

- Help determine whether patients can be left alone at home or whether doing so would present the risk of them wandering away or sustaining an injury in the home (e.g., from the use of an appliance such as the oven).
- For patients who cannot be left alone at home, assess options for support (e.g., help from family members or paid home attendants).
- Utilize fall prevention strategies.
- For patients who smoke, decide whether smoking can be done safely; if smoking is deemed unsafe, consider smoking cessation programs or supervision.
- If lesser measures fail, explore options for placement in a skilled nursing facility.

Additional helpful strategies for managing patients who are confused, agitated, or challenged by their experience include the following:

- Keep their environments familiar to the extent possible (e.g., in terms of objects, people, locations).
- Redirect or distract patients from inappropriate behavior.
- Remain calm when patients become confused or agitated; refrain from confronting an agitated patient; reorient confused or agitated patients.
- Provide a clock and calendar in the room to help keep patients oriented to time and to day of the week.

- Provide lighting that corresponds with day and night.
- Emphasize routines.
- Ensure that patients who require eyeglasses or hearing aids wear them to help lessen confusion and disorientation.
- Prepare patients for any planned changes.
- Ensure that patients are receiving their prescribed medications.
- Protect wandering patients.
- Supervise any cigarette smoking.
- Offer activities that keep patients' minds alert.
- Educate family members about the nature of dementia and methods for helping patients maintain activities of daily living.
- Suggest that patients or their family members make arrangements for financial, health, and other matters in the event they become unable to make decisions about their affairs (e.g., advance health care directives, durable powers of attorney, wills).

Patient Education

- Advise patients that ART can be effective in preventing and treating HIV-related neurocognitive impairment.
- Inform patients and family members of the many other strategies that may aid in managing neurocognitive impairment. Such strategies may help patients maintain the highest possible level of skills and independence.
- Family members and significant others can be important sources of support (e.g., by providing assistance with medication adherence).
- Advise patients with advanced HAD that placement in a residential facility may be the best option for ensuring their safety.

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Major Depression and Other Depressive Disorders

Background

Major depression is the most prevalent psychiatric comorbidity among people with HIV infection and commonly has a significant impact on health. The etiology may be multifactorial, as with depression in HIV-uninfected persons, but HIV infection may bring additional complexity. A diagnosis of HIV may cause a psychological crisis, but also may complicate underlying psychological or psychiatric problems (e.g., preexisting depression, anxiety, or substance abuse). Direct viral infection of the central nervous system (CNS) can cause several neuropsychiatric syndromes. In addition, both HIV-related medical conditions and HIV medications can cause or contribute to depression.

Patients with untreated depression experience substantial morbidity and may become self-destructive or suicidal. They are at continuing risk of engaging in unsafe behaviors that may lead to HIV transmission and poor adherence to care and treatment.

Major depression in persons with comorbid medical illness, including HIV infection, has been associated with the following:

- Decreased survival
- Impaired quality of life
- Decreased adherence to antiretroviral therapy (ART)
- Increased risk behaviors
- Suicide
- Longer hospital stays and more frequent medical visits (e.g., emergency room, medical clinics)
- Higher treatment costs

Stress and depressive symptoms, especially when they occur jointly, are associated with diminished immune defenses in HIV-infected individuals, and severe depression is associated with higher mortality rates. Anxiety symptoms are common among people with major depression (see chapter *Anxiety Disorders*). Psychotic symptoms may occur as a component of major depression and are associated with an increased risk of suicide. Even one or two symptoms of depression

HRSA HAB Performance Measures

Percentage of patients aged 12 years and older **screened for clinical depression** on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen

(Adult and Adolescent measure)

increase the risk of an episode of major depression.

All clinicians should do the following:

- Maintain a high index of suspicion for depression and screen frequently for mood disorders.
- Elicit any history of psychiatric diagnoses or treatment.

Rule out medical conditions that may cause mood or functional alterations.

Refer for psychiatric evaluation and psychosocial support, including, as appropriate, to substance abuse counselors and domestic violence service providers.

A screening test for depression such as the Patient Health Questionnaire-2 (PHQ-2) should be administered yearly or whenever a patient's complaints or symptoms suggest depressive disorders.

Patient Health Questionnaire-2 (PHQ-2)

Over the past 2 weeks, how often have you been having little interest or pleasure in doing things?

0 = Not at all

1 = Several days

2 = More than half the days

3 = Nearly every day

Over the past 2 weeks, how often have you been feeling down, depressed, or hopeless?

0 = Not at all

1 = Several days

2 = More than half the days

3 = Nearly every day

Calculate the total point score: ____

Score interpretation: Patient Health Questionnaire-2 (PHQ-2)

Score	Probability of major depressive disorder (%)	Probability of any depressive disorder (%)
1	15.4	36.9
2	21.1	48.3
3	38.4	75.0
4	45.5	81.2
5	56.4	84.6
6	78.6	92.9

Depression is diagnosed, as in HIV-uninfected individuals, according to the criteria of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM)-5.

Major Depression

The patient may complain of either or both of two cardinal symptoms:

- Diminished interest or pleasure in activities
- Depressed mood, sadness

If either or both of these are present, other complaints may be used to diagnose major depression, including the following:

- Decreased ability to concentrate
- Appetite changes with weight changes (increase or decrease)
- Fatigue or loss of energy
- Feelings of worthlessness or guilt
- Insomnia or hypersomnia
- Psychomotor agitation or retardation
- Recurrent thoughts of death or suicide

The diagnosis of major depression is made if five of the above symptoms occur on most days for at least 2 weeks. Depressed mood or diminished interest or pleasure must be one of the five symptoms present.

Other subjective symptoms of depression may include the following:

- Hopelessness
- Helplessness
- Irritability or anger
- Somatic complaints in addition to those noted above

Other Depressive Disorders

- **Persistent depressive disorder:** A new DSM category that subsumes dysthymia and chronic major depressive disorder. This is another very common depressive disorder found among HIV-infected patients. Treatments for major depression and persistent depressive disorder are similar.

Dysthymia has been characterized by more chronic but less severe symptoms than those

found in major depression. The diagnosis is made when a person has had a depressed mood for most of the day, for more days than not, for at least 2 years. While depressed, the patient exhibits two or more of the following symptoms:

- Poor appetite or overeating
- Insomnia or hypersomnia
- Low energy or fatigue
- Low self-esteem
- Poor concentration or difficulty making decisions
- Feelings of hopelessness

In addition, the symptoms must cause clinically significant distress or impairment in functioning, and there can have been no major depressive episode during the first two years of the disturbance.

- **Bipolar disorder:** Major depression may be a manifestation of bipolar disorder. Bipolar disorder should be ruled out before giving an antidepressant to a patient with major depression, as bipolar disorder usually requires the use of mood stabilizers before, or instead of, beginning antidepressant medications (antidepressant therapy may precipitate a manic episode). Bipolar disorder should be suspected if a patient has a history of episodes of high energy and activity with little need for sleep, has engaged in risky activities such as buying sprees and increased levels of risky sexual behavior, or has a history of taking mood stabilizers (lithium and others) in the past. If bipolar disorder is suspected, refer the patient to a psychiatrist for further evaluation and treatment.
- **Other forms of depression** include adjustment disorder with depressed mood (acute reaction to a life crisis, such as the loss of a job), premenstrual dysphoric disorder, disruptive mood dysregulation disorder, and depressive disorder not otherwise specified.

S: Subjective

- Inquire about the symptoms listed above, and about associated symptoms.
- Take a careful history of the timing and duration of symptoms, their relationship to life events (e.g., HIV testing, loss of a friend, onset of physical symptoms), and any other physical changes noted along with the mood changes.
- Elicit personal and family histories of depression, bipolar disorder, or suicidal behavior.
- Probe for suicidal thoughts, plans, and materials to execute the plans (see chapter *Suicide Risk*).
- Inquire about hallucinations, paranoia, and other symptoms.
- Ask about current and past medication use and substance abuse.

O: Objective

Perform mental status examination, including evaluation of affect, mood, orientation, appearance, agitation, or psychomotor slowing; perform thyroid examination, inspection for signs of self-injury, and neurologic examination if appropriate.

A: Assessment

Partial Differential Diagnosis

Rule out nonpsychiatric causes of symptoms, which may include the following:

- Hypothyroidism or hyperthyroidism
- Hypotestosteronism (hypogonadism) – very common with HIV disease in both men and women
- Other endocrine disorders such as Addison disease
- Substance-induced mood disorder (intoxication or withdrawal)
- Medication adverse effects (e.g., from steroids, efavirenz, isoniazid, or interferon-alfa)

- HIV dementia or minor cognitive motor disorder
- HIV encephalopathy
- Neurosyphilis
- Opportunistic illnesses affecting the CNS (e.g., toxoplasmosis, cryptococcal disease, CNS cytomegalovirus, progressive multifocal leukoencephalopathy)
- Vitamin B12, folate (B6), zinc, vitamin A, or vitamin D deficiency

P: Plan

Evaluation

The diagnosis is based on clinical criteria as indicated above. Rule out medical and other causes. An initial screening includes the following:

- Complete blood count, electrolytes, creatinine, blood urea nitrogen (BUN), glucose
- Thyroid function tests (thyroid stimulating hormone [TSH], T4)
- Vitamin B12, vitamin D, and folate levels
- Testosterone (both in men and women)
- Other tests as suggested by history and physical examination

Treatment

Refer immediately for psychiatric evaluation or treatment if the patient is:

- Hopeless
- Suicidal (see chapter *Suicide Risk*)
- Displaying psychotic symptoms
- Debilitated or functionally impaired by severe symptoms
- Not responding to treatment

The combination of psychotherapy and antidepressant medication is more effective than either treatment modality alone. Social

support interventions (e.g., community-based HIV support groups) also can help; refer to available resources. Patients should be encouraged to discontinue alcohol or substance use, and should be referred for treatment as indicated.

Psychotherapy

Individual psychotherapy with a skilled, HIV-experienced mental health professional can be very effective in treating depression. Several specific types of individual and group psychotherapies for depression (e.g., interpersonal therapy, cognitive-behavioral therapy, behavioral activation, supportive psychotherapy, coping effectiveness) have been shown to be effective for HIV-infected individuals.

Pharmacotherapy

For most patients, a selective serotonin reuptake inhibitor (SSRI) or a serotonin-norepinephrine reuptake inhibitor (SNRI) is the most appropriate initial treatment for depression. For patients who experience treatment failure with these agents (or have an incomplete response) at a customary therapeutic dosage, consultation with a psychiatrist is recommended.

When selecting antidepressant medications, consider their side effect profiles as a means to manage other symptoms the patient may be experiencing. For example, activating antidepressants (taken in the morning) may help patients who complain of low energy; antidepressants that increase appetite may be useful for patients with wasting syndrome; sedating antidepressants (taken at bedtime) may help patients with insomnia. Medications that may be lethal if overdosed (e.g., tricyclic antidepressants) should not be prescribed to patients for whom suicidality may be a concern.

The information below describes specific antidepressant medications, with information on dosage and possible adverse effects.

Most antidepressants should be started at low dosages and gradually titrated upward to avoid unpleasant side effects that might lead to nonadherence. Antidepressant effect usually is not noticed until 2-4 weeks after starting a medication. If there is no improvement in symptoms in 2-4 weeks, and there are no significant adverse effects, the dosage may be increased.

A therapeutic trial consists of treatment for 4-6 weeks at a therapeutic dosage. If the patient's symptoms have not improved, an increase in dosage or a switch to another medication should be considered. Patients who remain depressed should be referred to a psychiatrist.

Monitor all patients closely after starting them on antidepressant medications. Depressive symptoms may continue to worsen while on medication; improved energy is the initial effect of antidepressants, whereas hopelessness and sadness improve later. In addition, some young persons are at risk of worsening depression caused by antidepressants. Black-box warnings advise that antidepressants may cause increased risk of suicidality in children, adolescents, and young adults (<24 years of age) with major depressive or other psychiatric disorders, especially during the first month of treatment.

Medications should be continued for 6-9 months beyond the resolution of symptoms, to reduce the risk of recurrence. After this time, treatment may be tapered down gradually if the patient wishes, with careful monitoring for depressive symptoms. The risk of recurrence is higher if the first depressive episode is inadequately treated or if the patient has had multiple depressive episodes. For patients with recurrent depression, consider long-term maintenance antidepressant treatment. See "Discontinuing antidepressant medication," below.

Potential ARV Interactions

Interactions may occur between certain ARVs and agents used to treat depression. Some combinations may be contraindicated and others may require dosage adjustment. Refer to medication interaction resources or consult with an HIV expert, psychiatrist, or clinical pharmacist before prescribing.

Some ARV medications (particularly protease inhibitors [PIs]) and the pharmacokinetic booster cobicistat may affect the metabolism of some antidepressants via cytochrome P450 interactions. For example, ritonavir can significantly increase serum levels of tricyclic antidepressants, increasing the risk of tricyclic toxicity. In the case of most other antidepressants, interactions with ARVs generally are not clinically significant, but most antidepressants used concomitantly with PIs or cobicistat should be started at low dosages and titrated cautiously to prevent antidepressant adverse effects and toxicity. On the other hand, some PIs may decrease levels of paroxetine, sertraline, and bupropion, and efavirenz also lowers sertraline and bupropion levels; these antidepressants may require upward titration if used concurrently with interacting ARVs. Further information is presented under individual agents and classes, below.

For patients who are starting ARV medications (particularly PIs) or cobicistat and are on a stable antidepressant regimen, monitor carefully for adverse effects and for efficacy of the antidepressant; dosage adjustments may be required.

The available antidepressant medications (SSRIs and SNRIs), including therapeutic dosages and possible positive and negative effects, are listed in Table 1.

Table 1. SSRI and SNRI Antidepressant Medications and Possible Positive and Negative Effects

Medication/Usual Dosage	Possible Positive Effects	Possible Negative Effects
SSRIs	No anticholinergic or cardiovascular effects, nonfatal in overdose; may help treat anxiety	- Sexual dysfunction (men and women) - Serotonin withdrawal syndrome if discontinued abruptly
Citalopram (Celexa): 10-60 mg QD	May have lower risk of significant drug-drug interactions than other SSRIs	Mild nausea, possible sedation
Escitalopram (Lexapro): 10-20 mg QD	May have lower risk of significant drug-drug interactions than other SSRIs	Mild nausea, possible sedation
Fluoxetine (Prozac): 10-40 mg QD	Rarely sedating, often energizing, lower risk of SSRI withdrawal syndrome if discontinued abruptly	Insomnia, agitation, nausea, headache, sexual dysfunction in men and women, long half-life
Paroxetine (Paxil): 10-40 mg QD	May be sedating (for patients experiencing sedation with paroxetine, dose at bedtime; can be useful with depression-associated insomnia)	Insomnia, agitation (for patients experiencing these effects, administer dose in mornings), nausea, headache, higher risk of SSRI withdrawal syndrome, weight gain
Sertraline (Zoloft): 50-200 mg QD	May have lower incidence of significant drug-drug interactions compared with fluoxetine and paroxetine	Insomnia, agitation, nausea, headache
SNRIs		- Nausea, headache, nervousness, sexual dysfunction (men and women) - Serotonin withdrawal syndrome if discontinued abruptly
Duloxetine (Cymbalta): 30-60 mg QD	May be used also for pain management and neuropathy; may have lower risk of significant drug-drug interactions compared with SSRIs	Nausea, somnolence
Venlafaxine (Effexor): 37.5-75 mg BID or TID OR Venlafaxine XR (Effexor XR): 75-375 mg QD	May have lower risk of significant drug-drug interactions compared with SSRIs	Hypertension (monitor blood pressure at higher dosages) Higher risk of SSRI/SNRI withdrawal syndrome
Desvenlafaxine (Pristiq): 50 mg QD	May have lower risk of significant drug-drug interactions compared with SSRIs	Higher risk of SSRI/SNRI withdrawal syndrome

Other agents

- **Bupropion (Wellbutrin and others):** Bupropion is available in immediate-release form (requires TID dosing), sustained-release (SR) (requires BID dosing), or extended-release (XL) (QD dosing) formulations. At higher bupropion dosages, there is an increased risk of seizures, and this drug is contraindicated in patients who have risk factors for seizures. For patients taking PIs, caution should be used as the dosage approaches 300-400 mg per day because of possible increases in levels of bupropion (however, tipranavir and efavirenz may decrease bupropion levels). Bupropion may have an activating effect, which some patients may experience as agitation, insomnia, or both, and also may have an appetite suppressant effect. It usually does not cause sexual dysfunction, and therefore may be helpful for individuals with depression who experience adverse sexual effects with other antidepressants.
- **Mirtazapine (Remeron):** (15-45 mg QPM) May have lower risk of significant drug-drug interactions compared with SSRIs; can be useful when weight gain and sleep induction are needed. Potential adverse effects include sedation, increased appetite, weight gain, constipation, and dry mouth. Note that the higher dosages may result in increased activation owing to increased norepinephrine (NE) receptor antagonism.
- **Tricyclics:** Tricyclic antidepressants may be effective, but generally are not recommended for treatment of depression because they have a higher risk of adverse effects than do SSRIs and SNRIs. They also are more dangerous (potentially fatal) in overdose. Adverse effects include anticholinergic effects, sedation, and cardiac conduction abnormalities. Levels of tricyclics are increased by ritonavir, so lower dosages may be needed for patients taking ritonavir or ritonavir-boosted PIs.

Routine monitoring of blood levels of tricyclics should be performed on patients receiving higher doses (e.g., 100 mg per day; 50 mg for nortriptyline), those on concurrently on ritonavir, and those with risk factors for cardiac conduction abnormalities. A routine electrocardiogram should be performed before prescribing tricyclics, and this class of drugs should not be prescribed to patients with cardiac conduction problems.

The adverse effects of tricyclics can be used to treat insomnia or diarrhea, for example, and tricyclics can be effective for neuropathic pain.

- **Imipramine (Tofranil):** FDA indications for depression and chronic pain. The full recommended dosage for either problem is 150-300 mg QHS. Starting dosage: 25-75 mg PO QHS.
- **Doxepin (Sinequan):** FDA indications for depression and anxiety at adult dosages of 150-300 mg QHS. Starting dosage: 25-75 mg PO QHS.
- Three other available tricyclics have an FDA indication for depression only: **nortriptyline (Pamelor)** at dosages of 50-150 mg QHS; **desipramine (Norpramin)** at dosages of 50-200 mg a day; and **protriptyline (Vivactil)** at dosages of 5-10 mg, either TID or QID.
- **Tricyclics need to be started at low dosages and titrated gradually.** Lower dosages (or alternative agents) often are more appropriate for patients who are elderly, medically ill, or taking ritonavir or a ritonavir-boosted PI.

- **Trazodone:** a highly sedating antidepressant that is rarely used at an antidepressant dosage. Rather, it is often given at lower dosage for insomnia associated with depression, at a dosage of 25-50 mg 1-2 hours before bedtime. Ritonavir and other PIs can increase trazodone levels significantly; start at low dosage and use the lowest effective dosage; monitor for adverse effects.
- **Nefazodone (Serzone):** an antidepressant that usually should be avoided in people with HIV infection. Little information on interactions with ARVs is available, but it appears that nefazodone may increase levels of maraviroc and saquinavir, and that ritonavir may increase nefazodone levels. It has a black-box warning for severe liver toxicity. If the patient has ever had liver toxicity from the drug, restarting it is contraindicated.
- **St. John's wort:** an herbal antidepressant that can significantly decrease serum concentrations of PIs, NNRTIs, and maraviroc; it is contraindicated for use by patients taking those ARVs.

Treatment may involve antidepressant combinations, including psychostimulants; consult with a psychiatrist.

Discontinuing antidepressant medication

Antidepressant medication generally should be continued for at least 6 months following resolution of a first episode of major depression. Longer term, and even indefinite, maintenance treatment may be necessary for people with recurrent major depression. When discontinuing antidepressants, it is important to taper them gradually to avoid withdrawal symptoms or rebound depression. Abrupt discontinuation of SSRI and SNRI antidepressants often precipitates unpleasant withdrawal symptoms such as confusion, agitation, irritability, sensory disturbances, and insomnia. This is particularly true for paroxetine and venlafaxine. Fluoxetine, because of its long half-life, is uncommonly associated with withdrawal symptoms.

Brain stimulation treatments

There are a variety of brain stimulation treatments that usually are reserved for patients who have inadequate responses to medication. Electroconvulsive therapy (ECT) is the best known of these treatments and, despite the stigma associated with it, is more effective than antidepressant medication. Newer brain stimulation treatments also are available. These treatments require referral to the specialty care locations that offer them. Antidepressant medication often is used for maintenance after stabilization with ECT, but for some people, maintenance ECT is needed to prevent the relapse of depression.

Patient Education

- Providers should explain to patients that illness (physical or emotional) is not a character flaw or a moral or spiritual weakness. It is a common aspect of HIV infection. Sadness is a normal part of life, but major depression always is abnormal and often can be alleviated with medication, psychotherapy, or both.
- Providers should help patients identify the symptoms of depression and the factors that led them to seek treatment. Patients will need to monitor themselves for recurrences or exacerbations and get help if the symptoms recur. Patients should be told to contact providers if they notice changes in their sleep, appetite, mood, activity level, or concentration, or if they notice fatigue, isolation, sadness, or feelings of helplessness.
- When starting an antidepressant medication, patients should expect that it will take 2-4 weeks for them to notice any improvement. Their symptoms should continue to decrease over the following weeks. If they do not have much improvement in symptoms, providers may choose to adjust the dosage of the medication or to change medications. Patients must continue taking their medications so that the symptoms of depression do not return.
- Providers should let patients know that St. John's wort can lower levels of ARVs and cannot be taken if they are on ART.
- Antidepressants typically are given for a long time, usually for a year or longer, to help patients with the chemical imbalances associated with major depression. Patients should be told that they should not suddenly stop antidepressants they have been taking for a long time, and that these medications need to be discontinued gradually.
- Some patients develop problems with sexual function while they are taking antidepressants. They should report any problems to their prescribers. (Note: Providers should let patients know that sexual well-being is fundamental to quality of life and can be talked about and addressed in the clinical setting.)

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Suicide Risk

Background

Transient suicidal thoughts are common for some people throughout the course of HIV disease and often do not indicate significant risk of suicide. However, persistent suicidal thoughts with associated feelings of hopelessness and intent to die are very serious and must be assessed promptly and carefully. Compared with people at high risk of suicide who are not HIV infected, people living with HIV have significantly increased frequency and severity of both suicidal ideation and thoughts of death. The risk of suicide is especially high for patients who are depressed and for those at pivotal points in the course of HIV infection. Stigma, quality of life concerns, and issues regarding disclosure may be contributing factors.

Suicidality may be the direct physiological result of HIV (e.g., owing to the impact of HIV in the brain), a reaction to chronic pain, or an emotional reaction to having a chronic and life-threatening illness (e.g., major depression as a result of physical illness or psychiatric side effects caused by medications used to treat HIV infection and associated comorbidities). Many events may trigger suicidal thoughts among people with HIV. Such events include learning of their positive HIV status, disclosing to family and friends, starting antiretroviral therapy (ART), noticing the first symptoms of infection, having a decrease in CD4 cell count, undergoing a major illness or hospitalization, receiving an AIDS diagnosis, losing a job, experiencing major changes in lifestyle, requiring evaluation for dementia, and losing a significant relationship.

Evaluation of suicide risk must be included as part of a comprehensive mental health evaluation for HIV-infected patients. Note that asking patients about suicidal thoughts does not increase their risk of suicide.

HRSA HAB Performance Measures

Percentage of patients aged 12 years and older **screened for clinical depression** on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen

(Adult and Adolescent measure)

Risk factors for suicide attempts include the following:

- Previous suicide attempts
- Abandonment by or isolation from, family, friends, or significant others
- Age >45 for men, >55 for women; or teen years
- Male gender
- Gay sexual orientation
- Transgender
- Any acute change in health status; worsening of HIV-related illness or other physical illnesses
- Family history of completed suicide
- Alcohol and other substance misuse, abuse, or dependence
- Relapse into drug use after significant recovery
- Severe anxiety, depression, psychotic disorder, or other mental health disorder
- Domestic violence
- Social isolation (e.g., being single, divorced, or alone, or experiencing the death of a spouse)
- Multiple losses or recent stressors
- Financial difficulty, unemployment

- Hopelessness and lack of pleasure
- Impulsivity
- Pain
- Perception of poor prognosis
- Perception of poor social support
- Planning for death
- Stigmatization associated with illness, sexual orientation, substance use history, or other factors
- Fear of HIV-associated dementia

Protective factors include the following:

- Strong psychosocial support
- Evidence of good coping mechanisms
- Cultural and religious beliefs against suicide
- Reasons for living
- No specific plan for suicide

S: Subjective

The patient expresses or exhibits, or a personal care giver discloses, the following:

- Active suicidal ideation with intent and plan, such as giving away significant personal belongings, saying goodbye, acquiring the means (e.g., gun, pills), writing a suicide note
- Depressed mood, hopelessness, agitation, intoxication with alcohol or other drugs
- Passive withdrawal from therapy or medical care or decreased adherence (e.g., stopping medications, missing appointments)
- A desire for HIV disease to progress more rapidly

Inquire about the following during the history (*again, note that asking patients about suicidal thoughts does not increase their risk of suicide*):

- Previous suicide attempt(s) – one of the best predictors of eventual death by suicide
- Friend or family member who has committed suicide
- Personal or family history of depression
- Previous episode of psychosis
- Presence of risk factors described above

Probe for other depressive symptoms and the immediacy of potential suicidal intent. Sample questions may include the following:

- “It sounds as if you’re in great pain. Have you ever thought that life is not worth living?”
- “Do you often think of death?”
- “Do you think about hurting yourself?”
- “How might you do that?”
- “Do you have a plan?” Ask whether the patient has access to the components of the plan (e.g., gun, pills)
- “Is this something you feel you might do?”
- “What would prevent you from doing this?”
- “Have you ever attempted suicide? What did you do?”

O: Objective

- Perform a mental status examination and suicide assessment.
- Look for signs of self-inflicted injuries such as wrist lacerations or neck burns.
- Look for signs of depression, agitation, or intoxication.

A: Assessment

See chapter *Major Depression and Other Depressive Disorders* for differential diagnosis of possible causes of depression and suicidality.

P: Plan**Evaluation**

Evaluate the patient for depression, risk factors for suicide, and contributing psychiatric illnesses or situational stressors. Determine the immediacy of potential suicidal intent. If a mental health professional is available on site or can be summoned, an urgent consultation often is helpful in making these determinations.

Treatment

- If the patient exhibits active suicidal ideation with a plan, hospitalize the patient immediately, preferably in a psychiatric facility.
- If suicidal thoughts are passive, refer for evaluation for specific psychiatric disorders and refer for psychotherapy with an HIV-experienced mental health provider.
- Encourage the patient to contact you or another specified clinician for help, or to go to a hospital if suicidal ideation worsens or patient worries about acting upon suicidal thoughts.
- Note that making a contract with a patient against suicide is not recommended; research shows it is not effective, and it can provide a false sense of security.

- Inform patients about local suicide prevention resources, including suicide hotlines, emergency response (e.g., 911), and local emergency departments.
- Contact the patient between appointments. Enlist the help of significant others (if the patient agrees); invite them to accompany the patient on the next visit and see all of them together. Consider a support group or peer referral, if available.
- Consider dispensing medications on a weekly basis for the following purposes:
 - Monitoring emotional status and treatment adherence
 - Preventing the availability of lethal doses of medications
- Perform appropriate follow-up. In consultation with a skilled mental health provider, be sure that the patient is receiving appropriate ongoing treatment for underlying or persisting psychiatric illness. Assess at each visit for adherence to mental health care and for recurrence of symptoms.

Patient Education

- Suicidal ideation and severe depression are not normal aspects of HIV infection, and usually can be treated effectively.
- Patients should report suicidal thoughts to their health care provider.
- Inform patients about local suicide prevention resources, including suicide hotlines, emergency response (e.g., 911), and local emergency departments.

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Anxiety Disorders

Background

Anxiety symptoms are common and can develop or recur for many reasons, including a patient's worries about HIV infection and treatment, or issues unrelated to HIV. Symptoms can range from mild distress to full-blown anxiety disorders. Symptoms of anxiety can mimic symptoms of physical illness, and an appropriate workup should be performed to rule out other illnesses. Use of illicit drugs (e.g., amphetamines, cocaine) or alcohol can cause or substantially worsen anxiety symptoms; all patients should be screened for substance use.

Anxiety disorders include generalized anxiety disorder, specific phobia, and social phobia; related disorders include posttraumatic stress disorder (PTSD) and panic disorder. This chapter focuses primarily on anxiety symptoms and generalized anxiety disorder. See chapters *Panic Disorder* and *Posttraumatic Stress Disorder* for further information about these conditions.

HRSA HAB Performance Measures

Percentage of patients aged 12 years and older **screened for clinical depression** on the date of the encounter using an age-appropriate standardized depression screening tool AND, if positive, a follow-up plan is documented on the date of the positive screen

(Adult and Adolescent measure)

S: Subjective

The criteria for a diagnosis of generalized anxiety disorder include unrealistic or excessive worry about two or more life circumstances for ≥ 6 months, and at least three of the following subjective complaints:

- Restlessness or feeling keyed-up or on edge
- Difficulty concentrating or mind going blank
- Irritability
- Muscle tension
- Being easily fatigued
- Sleep disturbance (difficulty falling or staying asleep, or restless, unsatisfying sleep)

Other subjective complaints may include the following:

- Shortness of breath or smothering sensations
- Palpitations or accelerated heart rate
- Dizziness or lightheadedness
- Exaggerated startle response

- Trembling, twitching, or feeling shaky
- Dry mouth
- Flushes or chills
- Frequent urination
- Muscle aches or soreness
- Nausea, diarrhea, or other abdominal distress
- Skin rashes
- Sweating or cold, clammy hands
- Trouble swallowing or "lump in the throat"

Ask about the symptoms indicated above, and about the following:

- Anxiety patterns (e.g., constant or intermittent; timing, duration, precipitants)
- Onset: sudden or gradual
- Caffeine intake
- Recreational drug or alcohol use (current or recent)
- Concomitant illnesses (e.g., cardiac, pulmonary, endocrine)

- Family history of similar problems
- Medications, supplements, and herbal preparations
- History of previous episodes
- Recent stressors
- Sleep disturbances
- Other physical symptoms

O: Objective

Measure vital signs, with particular attention to heart rate (tachycardia) and respiratory rate (shortness of breath, hyperventilation).

Perform a physical examination, including mental status and neurologic, cardiopulmonary, and thyroid examinations.

A: Assessment

A differential diagnosis may include the following medical conditions:

- Substance use (e.g., amphetamines, cocaine)
- Substance or medication withdrawal (e.g., alcohol, benzodiazepines)
- Excessive caffeine intake
- Electrolyte imbalances
- Heart disease, arrhythmias
- Hyperthyroidism
- Hypoglycemia
- Immune disorders
- Respiratory disease, hypoxia
- Medication adverse effects (e.g., with efavirenz, isoniazid, corticosteroids, theophylline, or stimulants)
- Sleep disturbances or sleep deprivation
- Allergic reactions
- Anemia
- Central nervous system (CNS) or opportunistic infections or malignancies

- Systemic or other infections
- Vitamin B12 deficiency

P: Plan

Diagnostic Evaluation

Perform the following tests:

- Blood glucose, electrolytes
- Thyroid function tests (TSH, T4)
- Electrocardiogram (EKG) if patient has shortness of breath or palpitations
- Arterial blood gases (if difficulty breathing is not self-limited)
- Other tests as indicated by symptoms and physical examination

Treatment

Once medical disorders have been ruled out, and the diagnosis of an anxiety disorder is established, several options are available:

Psychotherapy

Options include cognitive-behavioral therapy, interpersonal therapy, exposure therapy, a stress-management group, relaxation therapy, visualization, guided imagery, supportive psychotherapy, and psychodynamic psychotherapy. Long-term psychotherapy may be indicated if experienced professionals are available and the patient is capable of forming an ongoing relationship. If possible, refer to an HIV-experienced therapist. The type of psychotherapy available to the patient often depends on the skills and training of the practitioners in a given health care system or region. In addition, the patient may be referred to available community-based support.

Pharmacotherapy

Medications, with or without psychotherapy, may alleviate symptoms of anxiety. Patients with advanced HIV disease, like geriatric patients, may be more vulnerable to the CNS effects of certain medications. Medications that affect the CNS should be started at low

dosage and titrated slowly. Similar precautions should apply to patients with liver dysfunction.

Antidepressants

Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) are effective in treating patients with anxiety. They are favored for long-term use when a specific anxiety disorder is present and persistent. These medications do not cause tolerance or pose a risk of addiction. Below is a list of antidepressants approved by the U.S. Food and Drug Administration (FDA) for specific anxiety disorders, and their usual recommended dosages. FDA recommendations are based on availability of specific study data, but all SSRIs (regardless of whether they have an FDA indication for anxiety) may be helpful for a broad range of anxiety disorders.

Common adverse effects of SSRIs and SNRIs include sexual dysfunction, sleep disturbance, and nausea. For patients who are medically ill, these medications should be started at low dosage and titrated up slowly; a low dosage may be effective. These medications also should be down-tapered slowly; SSRI/SNRI discontinuation syndrome may occur if they are discontinued abruptly.

See chapter *Major Depression and Other Depressive Disorders* for further information about antidepressant medications, including adverse effects.

SSRI antidepressants:

- Fluoxetine (Prozac): FDA indication for panic disorder with a recommended dosage of 20 mg QD. Also recommended for obsessive-compulsive disorder, but higher dosages are needed, sometimes up to 80 mg daily.
- Escitalopram (Lexapro): FDA indication for generalized anxiety disorder at a dosage of 10 mg QD.
- Citalopram (Celexa): Does not have specific FDA indications for anxiety

disorders. Suggested dosage: start at 10 mg QD and titrate as needed; maximum dosage: 60 mg daily.

- Paroxetine (Paxil): FDA indications for obsessive-compulsive disorder and panic disorder both at a recommended dosage of 40 mg QD. Also indicated for social anxiety disorder at a dosage of 20-40 mg daily. Usual starting dosage: 10 mg daily.
- Sertraline (Zoloft): FDA indications for panic disorder and PTSD at dosages of 50-200 mg QD. Usual starting dosage: 25 mg daily.

SNRI antidepressants:

- Venlafaxine timed-release formulation (Effexor XR): FDA indication for generalized anxiety disorder, at recommended dosages of 75-225 mg per day. Note: There is a risk of hypertension at the higher dosages of venlafaxine; monitor blood pressure.
- Duloxetine (Cymbalta): FDA indication for generalized anxiety disorder at a recommended dosage of 60 mg QD.

Other antidepressants:

- Some sedating antidepressants are effective, nonaddictive agents that are helpful when taken at bedtime for both insomnia and anxiety symptoms. These include trazodone 25-100 mg QHS or imipramine (Tofranil) 25 mg QHS. Note that imipramine and other tricyclics must be used with caution but are not contraindicated for use by patients taking ritonavir (including ritonavir-boosted protease inhibitors [PIs]).
- Gabapentin (Neurontin), which sometimes is used as a mood stabilizer, may be given at dosages of 200-400 mg BID to QID and may help to diminish anxiety.

Anxiolytics

Short-term use of benzodiazepines sometimes is appropriate for mild and brief situational anxiety symptoms, even without the presence of a specific anxiety disorder. For longer-term use, non-benzodiazepines (e.g., buspirone [see below], SSRIs, or SNRIs) are preferred.

- Buspirone (BuSpar) is a nonaddictive anxiolytic. Start at 5 mg PO TID. If symptoms persist, the dosage can be increased by 5 mg per dose each week to a maximum of 10-15 mg TID (for a total daily dosage of 30-45 mg). It will take several weeks for patients to notice a decrease in anxiety; low-dose benzodiazepines may be used during this interval. The major potential adverse effects of buspirone are dizziness and lightheadedness.
- Consider intermediate half-life benzodiazepines such as lorazepam (Ativan) 0.5 mg PO Q8H or oxazepam (Serax) 10 mg PO Q6H if buspirone is not tolerated or to alleviate anxiety symptoms until buspirone takes effect. Longer-acting benzodiazepines such as clonazepam (Klonopin) also may be useful at dosages of 0.25-0.5 mg PO BID.
- Benzodiazepines generally should be used only for acute, short-term management because of the risk of tolerance and physiologic dependence. These risks are even more problematic for patients with a history of addiction.

Potential ARV Interactions

Interactions may occur between certain ARVs and agents used to treat anxiety. Some combinations may be contraindicated and others may require dosage adjustment. Refer to medication interaction resources or consult with an HIV clinical pharmacist, HIV specialist, or psychiatrist before prescribing.

Antidepressants

- Some ARV medications (particularly PIs) and the pharmacokinetic booster cobicistat may affect the metabolism of some antidepressants via cytochrome P450 interactions. For most SSRIs and SNRIs, interactions with ARVs generally are not clinically significant; in the case of tricyclics, their levels may be significantly increased by ritonavir. On the other hand, some PIs may decrease levels of paroxetine and sertraline, and efavirenz also lowers sertraline levels. See chapter *Major Depression and Other Depressive Disorders* for further information.

Anxiolytics

- PIs, nonnucleoside reverse transcriptase inhibitors (NNRTIs), and cobicistat may raise blood concentrations of many benzodiazepines. Consider using a benzodiazepine metabolized by glucuronidation (e.g., lorazepam, oxazepam), particularly in patients with liver disease. For benzodiazepines metabolized by the CYP system (e.g., clonazepam), start at low dosages and titrate slowly. Given the very long half-life of both the parent drug and its metabolites, diazepam is best avoided in patients receiving ART. Other CNS depressants and alcohol should be avoided in patients taking these benzodiazepines.
 - Midazolam (Versed) and triazolam (Halcion) are contraindicated for use with all PIs and with cobicistat, delavirdine, and efavirenz.
- Buspirone levels may be increased by ritonavir-boosted PIs and cobicistat, and may be decreased by CYP inducers. Monitor patients for adverse effects and for efficacy.

Patient Education

- Behavioral interventions can help to reduce anxiety, but may take practice. Patients should seek help from a therapist or another experienced source.
- Advise patients that misuse of alcohol or illicit drugs can cause or substantially worsen anxiety symptoms; advise patients to decrease or eliminate use. Refer for substance abuse treatment if indicated.
- Inform patients that they may develop problems with sexual function because of antianxiety medications. Patients should report any problems to their prescribers. (Note: Providers should let patients know that sexual well-being is fundamental to quality of life and can be talked about and addressed in the clinical setting.)

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- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing; 2013.
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Panic Disorder

Background

Panic disorder is an anxiety disorder whose essential feature is the presence of recurrent, unexpected panic attacks. Panic attacks are discrete, sudden-onset episodes of intense fear or apprehension accompanied by specific somatic or psychiatric symptoms (e.g., palpitations, shortness of breath, fear of losing control). A patient is diagnosed as having panic disorder when he or she has experienced such attacks, and at least one of the attacks has been followed by ≥ 1 month of persistent concern about additional attacks, worry about the implications or consequences of the attack, or a significant change in behavior related to the attack.

The symptoms of panic disorder usually begin in late adolescence to the mid-30s and may coincide with the presentation of major depressive disorder, social phobia, or generalized anxiety disorder. Panic disorder can interfere with the ability to conduct activities of daily living. Patients with panic disorder have an increased incidence of suicide.

Symptoms may mimic those of various physical illnesses or be caused by other medical conditions (e.g., hyperthyroidism, brain tumors, adrenal tumors, heart arrhythmias, hypoglycemia, anemia). Substance or alcohol intoxication or withdrawal also may cause panic symptoms. Patients with panic symptoms should be evaluated for other causative conditions.

Major depressive disorder occurs in 50-65% of people with panic disorder. Major depression may precede or follow the onset of panic disorder. Patients with panic disorder therefore should be screened for depression initially and periodically thereafter (see chapter *Major Depression and Other Depressive Disorders*). Anxiety also commonly is experienced by persons with panic disorder; see chapter *Anxiety Disorders* for further information about this condition.

S: Subjective

The patient complains of discrete periods of intense fear or discomfort in which four or more of the following symptoms developed abruptly and reached a peak within 10 minutes:

- Shortness of breath or smothering sensation
- Sweating
- Trembling or shaking
- Dizziness, lightheadedness, faintness, or feeling of unsteadiness
- Numbness or tingling sensations
- Chest pain or discomfort
- Palpitations or accelerated heart rate
- Hot flashes or chills
- Sensation of choking

- Depersonalization or derealization
- Fear of dying
- Fear of going crazy or losing control
- Nausea or abdominal distress

Other subjective complaints may include the following:

- Apprehension about the outcome of routine activities and experiences
- Anticipation of a catastrophic outcome from a mild physical symptom or from medication side effects
- Discouragement and demoralization

Panic attacks are, by definition, self-limited and they peak quickly. Symptoms that persist continuously for longer periods suggest other causes.

Ask about the symptoms indicated above and about the following:

- Frequency, duration, and onset of panic episodes
- Possible precipitants, (e.g., settings in which attacks occur), situations (e.g., being alone outdoors), relationship to food or hunger
- Current medications, herbal products, and supplements; recent medication changes
- Multiple visits to health care providers with complaints suggesting panic attacks
- Family history of mood and psychiatric illnesses, particularly anxiety and panic
- Use of recreational drugs (especially stimulants such as cocaine or amphetamines), alcohol (current and recent), and caffeine
- Sleep disturbances
- Concomitant illnesses (e.g., endocrine, cardiac, pulmonary)
- Any associated or concurrent symptoms that could suggest a medical etiology
- Screen for depression (see chapter *Major Depression and Other Depressive Disorders*)

O: Objective

Measure vital signs, with particular attention to heart rate (tachycardia) and respiratory rate (shortness of breath, hyperventilation). Perform a complete physical examination, including thyroid, cardiac, pulmonary, and neurologic evaluation.

During actual panic attacks, patients may have increases in heart rate, respiratory rate, or systolic blood pressure.

A: Assessment

A differential diagnosis may include the following conditions:

- Congestive heart failure, myocardial ischemia, arrhythmias
- Hyperthyroidism
- Intoxication with or withdrawal from psychoactive substances (e.g., amphetamines, cocaine, hallucinogens, caffeine, medications)
- Hypoglycemia
- Hypoxia
- Hyperparathyroidism
- Medication side effects
- Pheochromocytoma
- Adrenal disorders, Cushing syndrome, electrolyte abnormalities
- Respiratory infection
- Seizure disorder
- Vestibular dysfunction
- Allergic reactions
- Posttraumatic stress disorder
- Social phobia or specific phobia (specific phobia is a response to a specific stimulus, whereas a patient with panic attacks is unsure when they will recur and what will trigger them)
- Agoraphobia
- Obsessive-compulsive disorder
- Separation anxiety disorder

P: Plan

Diagnostic Evaluation

Perform the following tests:

- Electrolytes, blood glucose
- Thyroid function tests (thyroid stimulating hormone [TSH], T4)
- Arterial blood gases if the patient has persistent shortness of breath
- Electrocardiogram if chest pain or other cardiac symptoms are present
- Other tests as indicated by symptoms and physical examination

Treatment

Once other diagnoses have been ruled out, consider the following treatments:

Psychotherapy

Options include cognitive-behavioral therapy, interpersonal therapy, exposure therapy, a stress-management group, relaxation therapy, visualization, guided imagery, supportive psychotherapy, and psychodynamic psychotherapy. Long-term psychotherapy may be indicated if experienced professionals are available and the patient is capable of forming an ongoing relationship. If possible, refer to an HIV-experienced therapist. The type of psychotherapy selected often will depend on the skills and training of the practitioners available in a given health care system or region. In addition, refer the patient to available community-based support. Emergency referrals may be needed for the most anxious patients and those with comorbid depression.

Pharmacotherapy

Patients with advanced HIV disease and geriatric patients may be more vulnerable to the central nervous system (CNS) effects of certain medications. Medications that affect the CNS should be started at low dosage and titrated slowly. Similar precautions should apply to patients with liver dysfunction.

Options

A number of medications have an approved indication by the U.S. Food and Drug Administration (FDA) for panic disorder. These include the serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitor (SNRI) venlafaxine extended-release, and benzodiazepines listed below. For most patients, SSRIs are preferable to benzodiazepines for the treatment of panic disorder because they do not have the potential for addiction and they do not pose the same level of risk if drug interactions cause an elevation of their levels. Other medications used to treat anxiety disorders, such as SNRIs may be considered, and some of them are less likely to interact with ARV medications. See chapter *Anxiety Disorders* for descriptions of these medications.

SSRI antidepressants approved for panic disorder include the following:

- Fluoxetine (Prozac), recommended dosage 20 mg PO QD (usual starting dosage 10 mg daily)
- Paroxetine (Paxil), recommended dosage 40 mg PO QD (usual starting dosage 10 mg daily)
- Sertraline (Zoloft), recommended dosage 50-200 mg PO QD (usual starting dosage 25 mg daily)

SNRI antidepressant approved for panic disorder:

- Venlafaxine (Effexor XR), recommended dosage 75-225 mg PO QD (usual starting dosage 37.5 mg daily)

Benzodiazepines approved for panic disorder include the following:

- Clonazepam (Klonopin), recommended dosage 0.5-2 mg PO BID
- Alprazolam (Xanax), recommended dosage 0.5-3 mg PO TID or Xanax XR at a recommended dosage of 3-6 mg PO QD; start at low dosage, may increase every 3-4 days in increments of ≤ 1 mg/day if tolerated

Potential ARV Interactions

Interactions may occur between certain ARVs and agents used to treat panic. Some combinations may be contraindicated and others may require dosage adjustment. Refer to medication interaction resources or consult with an HIV expert or clinical pharmacist before prescribing.

Some ARV medications (particularly protease inhibitors [PIs]) and the pharmacokinetic booster cobicistat may affect the metabolism of some SSRIs via cytochrome P450 interactions. These generally are not clinically significant, but SSRIs used concomitantly with PIs or cobicistat should be started at low dosages and titrated cautiously to prevent antidepressant adverse effects and toxicity. On the other hand, some PIs may decrease levels of paroxetine and sertraline, and efavirenz also lowers sertraline levels; these antidepressants may require upward titration if used concurrently with interacting ARVs.

PIs and cobicistat can significantly elevate the levels of clonazepam and alprazolam, resulting in the potential for severe sedation or respiratory depression. For patients receiving clonazepam or alprazolam, it is recommended that these medications be used at the lowest dosages for the shortest duration possible.

Patient Education

- Inform patients that behavioral interventions can help to reduce the frequency and severity of panic attacks.
- Some antidepressants and anti-anxiety medications can prevent or reduce the severity of panic attacks.
- Advise patients that they may develop problems with sexual function because of the medications. Patients should report any problems to their prescribers. (Note: Providers should let the patient know that sexual well-being is fundamental to quality of life and can be talked about and addressed in the clinical setting.)

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Posttraumatic Stress Disorder

Francine Cournois, MD; and Milton Wainberg, MD

Background

Symptoms of posttraumatic stress disorder (PTSD) can develop after exposure to a traumatic event. A traumatic event may be a single instance, such as a car accident or experience of a natural disaster, or an ongoing pattern of events, such as continuous neglect, physical or sexual abuse, or chronic exposure to war or violent conflict. PTSD causes intrusive memories, hyperarousal, and psychological numbing or avoidance, among other symptoms. It may impair an individual's psychological and physical functioning, decreasing immune system function and increasing susceptibility to illness. Untreated PTSD can increase the risk of HIV transmission or acquisition and worsen the course of HIV treatment.

Individuals with PTSD may experience depression, anxiety, social isolation, impairments in trust and attachments, and feelings of anger, and PTSD often coexists with depression, anxiety, or other psychiatric illnesses. PTSD may be associated with increased risk-taking behavior (e.g., substance abuse, unsafe sex).

The rate of PTSD among individuals with HIV infection (in whom the lifetime prevalence is possibly as high as 42%) is higher than that of the general population (1.3%-7.8%). Women experience PTSD at a higher rate than men. The likelihood of developing PTSD increases in relation to the severity of or proximity to the traumatic event. A history of traumatic experiences may increase an individual's risk of developing PTSD after a new trauma. Although a diagnosis of HIV may trigger PTSD symptoms, a history of trauma or abuse often is present as well. A personal or family psychiatric history may increase the likelihood of developing PTSD.

PTSD is diagnosed, as in HIV-uninfected individuals, according to the criteria of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM)-5 (see "References," below). It is treatable through diverse therapies and psychopharmacology.

S: Subjective

The following reflect DSM-5 diagnostic criteria; include them in the history.

- The person experienced, witnessed, or was confronted with an event or events that involved actual or threatened death, serious injury, or sexual violence, or a threat to the physical integrity of self or others.
- The person's response involved intense fear, helplessness, or horror.
- The person complains of persistently reexperiencing the event in one or more of the following ways:
 - Recurrent and intrusive distressing recollections of the event, including

images, thoughts or perceptions

- Recurring distressing dreams of the event
- Acting or feeling as if the traumatic event were recurring (includes a sense of reliving the experience, illusions, hallucinations and dissociative flashback episodes, including those that occur when awakening or intoxicated)
- Intense psychological distress at exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event
- Physiological reactivity on exposure to internal or external cues that symbolize or resemble an aspect of the traumatic event

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- The person makes efforts to avoid thoughts or reminders of the trauma.
- The person has disturbances in mood or cognition that began or worsened after the traumatic event.

Other complaints may include the following:

- Overwhelming emotions caused by memories of the event
- Emotional numbness
- Disruptions in consciousness, memory, or identity
- Depersonalization (i.e., a feeling of watching oneself act, while having no control over a situation)
- Derealization (i.e., alteration in the perception or experience of the external world so that it seems strange or unreal)
- Feelings of estrangement from others
- Episodes of lost time

The patient may experience the following:

- Recurrent distressing recollections of the event
- Recurrent distressing dreams of the event
- Illusions/hallucinations of the event actually occurring
- Psychological distress triggered by cues reminiscent of the event
- Avoidance of thoughts, feelings, or conversation associated with the event
- Avoidance of activities, places, or people associated with the event
- Inability to recall important aspects of the event
- Diminished interest in significant activities
- Detachment
- Restricted range of affect
- Difficulty falling or staying asleep
- Irritability or outbursts of anger

- Difficulty concentrating
- Hypervigilance

Ask about the duration of symptoms (PTSD is characterized by symptoms that last for more than 1 month).

Also screen for the following:

- Clinical depression
- Anxiety disorders
- Alcohol or other substance-use disorders

O: Objective

- Check vital signs, with particular attention to heart rate (tachycardia) and respiratory rate (shortness of breath, hyperventilation).
- Perform a physical examination, including mental status and neurologic examination (tremor, hyperreflexia, focal abnormalities).
- Look for signs of physical trauma or sexual assault.

A: Assessment

A differential diagnosis may include the following:

- Substance use (e.g., amphetamines, cocaine)
- Substance withdrawal (e.g., alcohol, benzodiazepines)
- Electrolyte imbalances
- Excessive caffeine intake
- Hyperthyroidism
- Medications effects (e.g., efavirenz, isoniazid, steroids, theophylline)
- Allergic reactions
- Head trauma
- Hypoglycemia
- Sleep disturbances or sleep deprivation
- Central nervous system (CNS) or opportunistic infections or malignancies

- Systemic or other infections
- Respiratory disease
- Heart disease, arrhythmias
- Anemia
- Vitamin B12 deficiency

P: Plan

Evaluation

Perform the following tests:

- Complete blood count, electrolytes, creatinine, blood urea nitrogen, glucose
- Thyroid function tests (thyroid stimulating hormone [TSH], T4)
- Vitamin B12 levels
- Other tests as suggested by history and physical examination

Treatment

Once other diagnoses have been ruled out and the diagnosis of PTSD is established, several treatment options are available.

Psychotherapy

Options include individual cognitive-behavioral therapy, cognitive processing therapy, exposure therapy, eye movement desensitization and reprocessing, interpersonal therapy, a stress-management group, relaxation therapy, visualization, guided imagery, supportive psychotherapy, and other forms of therapy. Long-term psychotherapy may be indicated if experienced professionals are available and the patient is capable of forming an ongoing relationship. If possible, refer to an HIV-experienced therapist. The specific psychotherapy often depends on the skills and training of the practitioners available in a given health care system or region. In addition, refer the patient to available community-based support.

Pharmacotherapy

Antidepressants

Most antidepressants should be started at low dosages and gradually titrated upward to avoid unpleasant side effects. Therapeutic effects may not be noticed until 2-4 weeks after starting a medication. If there is no improvement in symptoms in 2-4 weeks, and there are no significant adverse effects, the dosage may be increased. Before prescribing a medication, always remember to check for drug-drug interactions, particularly with concurrent antiretrovirals (ARVs). See “Potential ARV Interactions,” below, and chapter *Major Depression and Other Depressive Disorders* for further information about antidepressants, including possible adverse effects and interactions with ARVs.

- **Selective serotonin reuptake inhibitors** (SSRIs) have the strongest evidence for efficacy and tolerability for PTSD and are first-line medication treatment. Two SSRI antidepressants have a specific indication for PTSD approved by the U.S. Food and Drug Administration (FDA): sertraline (Zoloft) at recommended dosages of 50-200 mg QD (usual starting dosage: 25 mg daily) and paroxetine (Paxil) at recommended dosages of 20-50 mg QD (usual starting dosage: 25 mg daily). Other SSRIs include fluoxetine (Prozac), citalopram (Celexa), and escitalopram (Lexapro).
- The **serotonin norepinephrine reuptake inhibitor** (SNRI) antidepressants such as venlafaxine (Effexor), desvenlafaxine (Pristiq), and duloxetine (Cymbalta), as well as the antidepressant mirtazapine (Remeron), are second-line treatments if SSRIs prove ineffective or are not well tolerated.
- **Tricyclic antidepressants** (TCAs) may be employed if the individual has had a good response to them in the past and they do not cause severe side effects, or if the individual

has failed to respond to or cannot tolerate SSRIs or SNRIs. TCAs in low dosages also may be used for sleep; see chapter *Insomnia*.

Anxiolytics

Antianxiety medications have not been shown to be effective treatments for PTSD when used alone but may be effective, as adjunctive therapy, in reducing anxiety symptoms. Benzodiazepines can reduce anxiety rapidly, often within hours, but may have counterbalancing side effects early in the course of their use that include sedation and incoordination. In addition, physical dependency may develop in patients who use them for more than a few weeks. Benzodiazepines are not recommended for people who have a history of alcohol abuse or dependence. Benzodiazepines ideally would be used only briefly and intermittently to quell acute and severe anxiety symptoms. Levels of many benzodiazepines may be increased by certain protease inhibitors and nonnucleoside reverse transcriptase inhibitors; see “Potential ARV Interactions,” below.

Buspirone (BuSpar) is a nonaddictive anxiolytic. It usually must be taken for at least 1-2 weeks before anxiety symptoms begin to lessen. Starting dosage is 5 mg PO TID. If symptoms persist, the dosage can be increased by 5 mg per dose each week to a maximum of 10-15 mg PO TID (for a total daily dosage of 30-45 mg). Low-dose benzodiazepines may be used during the initial weeks of buspirone therapy, until the effects of buspirone are felt. The major potential adverse effects of buspirone are dizziness and lightheadedness.

Anticonvulsants

Mood stabilizers such as valproate (Depakote), carbamazepine (Tegretol), lamotrigine (Lamictal), and topiramate (Topamax) may be added for patients with a partial response to an antidepressant. They may be helpful for those who have considerable irritability, anger, or hostility, as well as those with reexperiencing symptoms (e.g., flashbacks, intrusive memories). Gabapentin (Neurontin) 200-400 mg BID or QID sometimes helps to diminish anxiety. Treatment with these agents usually should be done by or in consultation with a psychiatrist.

Antipsychotics

Older and newer antipsychotics (aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone) may be suitable for individuals with psychotic features of PTSD or those who have a comorbid psychotic illness. These medications also may be helpful for some individuals who have not benefited from medications indicated for PTSD. Adverse effects may include dyslipidemia, hyperglycemia, weight gain, and sudden cardiac death. Consultation with a psychiatrist is recommended.

Other medications

A variety of other medications have been used as adjunctive treatment when insomnia and nightmares persist despite adequate use of psychotropic medications. Research is still quite limited, but suggests that the antihypertensive drugs clonidine (Catapres) and prazosin (Minipress) may help with the insomnia and nightmares of PTSD.

Patients with advanced HIV disease and geriatric patients may be particularly vulnerable to the CNS effects of certain medications. Medications that affect the CNS should be started at low dosage and titrated slowly. Similar precautions should apply to patients with liver dysfunction.

Potential ARV Interactions

Interactions may occur between certain antiretrovirals and agents used to treat PTSD. Some combinations may be contraindicated and others may require dosage adjustment. Refer to medication interaction resources or consult with an HIV expert or pharmacist before prescribing.

Antidepressants

- Levels of many SSRIs and SNRIs may be increased or decreased by certain protease inhibitors (PIs) or NNRTIs and by the pharmacokinetic booster cobicistat. These interactions generally are not clinically significant, but most agents should be started at low dosages and titrated cautiously while monitoring efficacy and adverse effects. See chapter *Major Depression and Other Depressive Disorders*.
- Tricyclic levels can be increased substantially by ritonavir and cobicistat. If they are used for patients taking ritonavir, ritonavir-boosted PIs or cobicistat, they should be started at low dosage, patients should be followed closely, and tricyclic levels should be monitored.

Anxiolytics

- PIs, cobicistat, and nonnucleoside reverse transcriptase inhibitors may raise blood concentrations of many benzodiazepines. If benzodiazepines are used, they should be started at low dosage, and other CNS depressants should be avoided. Consult with a clinical pharmacist before prescribing. See chapters *Anxiety Disorders* and *Insomnia* for additional information.
 - Midazolam (Versed) and triazolam (Halcion) are contraindicated for use with all PIs or cobicistat and with delavirdine and efavirenz.
- Buspirone levels may be increased by ritonavir-boosted PIs or cobicistat and may be decreased by CYP inducers. Monitor patients for adverse effects and for efficacy.

Anticonvulsants

- Most anticonvulsants may have significant interactions with certain ARVs and other medications; check for drug-drug interactions before prescribing.

Antipsychotics

- Potential interactions vary according to the specific medications used; consult with a pharmacist or psychiatrist.

Patient Education

- Explain to patients that illness (physical or emotional) is not a character flaw or a moral or spiritual weakness.
- Inform patients that both behavioral interventions and medication can be very helpful in treating PTSD. If one strategy is not successful, many others are available.
- Advise patients that psychiatric medications are often given for a long time, usually for a year or longer.
- Advise patients that, when they start taking an antidepressant medication for PTSD, they should expect that it will take 2-4 weeks for them to notice any improvement. Their symptoms should continue to decrease over the following weeks. If they do not have much improvement in symptoms, providers may choose to adjust the dosage of the medication or to change medications. Patients must continue taking their medications so that symptoms do not return.
- Advise patients that they may develop problems with sexual function because of psychiatric medications. They should report any problems to their prescribers.

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Insomnia

Background

Insomnia is a common accompaniment to HIV infection, especially as the disease progresses and complications worsen. Once present, insomnia tends to be chronic, unlike the transient disturbances of sleep that are a normal part of life. Most insomnia related to HIV can be characterized by the amount, quality, or timing of sleep. Insomnia may cause progressive fatigue and diminished functioning.

S: Subjective

The patient may complain of the following:

- Difficulty initiating sleep
- Early-morning awakening
- Mind-racing thoughts (e.g., “I can’t turn off my thoughts.”)
- Difficulty maintaining sleep
- Nonrestorative sleep (i.e., although the amount of sleep is adequate, the patient does not feel rested upon awakening)
- Nighttime restlessness

Ask about the symptoms above, and about the following:

- Determine the patient’s bedtime sleep habits; request additional history from a sleep partner, if possible
- Try to quantify how long the patient actually sleeps each night

Ask about the following:

- Alcohol and recreational drug use
- Caffeine intake (quantity, times of day)
- Nightmares, life stressors
- Concurrent medications that may cause insomnia as an adverse effect (e.g., efavirenz, corticosteroids, pseudoephedrine, and decongestants)
- Medications (prescription or over-the-counter) or supplements used to promote sleep

- Shift work, exercise, nighttime reflux or heartburn, snoring, and periods of apnea (not breathing)
- Collar size (size >16 more often associated with sleep apnea)

Screen for depression and anxiety.

O: Objective

Perform a general symptom-directed physical examination, including evaluation of body habitus, neurologic status, and mental status.

A: Assessment

A partial differential diagnosis includes the following:

- Alcohol intake (interferes with sleep 2-4 hours after ingestion, may cause nocturnal awakening)
- Caffeine intake
- Recreational drug use
- Anxiety disorder
- Major depression (insomnia is a primary symptom)
- Transient insomnia related to acute stress
- Cognitive impairment
- Disturbance of the sleep/wake cycle because of excessive time in bed or inadequate sleep hygiene (e.g., noise in the bedroom)
- Medication adverse effects (e.g., from steroids, efavirenz)

- Other identifiable sleep disorders (e.g., obstructive sleep apnea, periodic leg movements)
- Pain
- Underlying systemic medical conditions that can interfere with sleep, such as delirium, lung disease, congestive heart failure, renal failure, diarrhea, and incontinence

P: Plan

Evaluation

The diagnosis usually is based on history. A sleep evaluation (including polysomnography) may be indicated when a physiologic cause (e.g., obstructive sleep apnea) is suspected or insomnia is severe.

Treatment

Treat underlying illnesses that may be causing or contributing to insomnia.

- Manage correctible medical conditions that may interfere with sleep.
- Treat depression and anxiety disorders. These are very common contributors to insomnia among people with HIV infection. See chapters *Major Depression and Other Depressive Disorders*, *Anxiety Disorders*, and *Panic Disorder*.
- If the patient is suspected of having sleep apnea, periodic limb movements in sleep, or restless limb syndrome, refer to a specialist in sleep medicine for evaluation.

The following options are available for treatment:

Behavioral strategies

- To correct deleterious sleep habits, patients should do the following:
 - Establish a bedtime routine.
 - Avoid stimuli before bedtime.
 - Avoid vigorous exercise within 3-4 hours of bedtime.
 - Reduce or eliminate daytime napping.
 - Avoid eating, reading, watching TV, or working in bed.
 - Wake up at the same time each day regardless of total hours of sleep.
 - Have a dark, cool, quiet, comfortable environment conducive to sleep.
 - Place the bedroom clock out of sight.
- If unable to fall sleep after 15-20 minutes, the patient should get up, go into another room for nonstimulating activity in dim light (such as reading), and not go back to bed until sleepy.
- The patient should discontinue use of caffeine, central nervous system stimulants, alcohol, and tobacco, with tapering if necessary, to avoid withdrawal symptoms.
- Teach or refer the patient for relaxation techniques.

Pharmacotherapy

Choosing a pharmacologic agent for insomnia

A number of medications may be effective in treating insomnia. In selecting a medication for an individual patient, consider the following about a specific medication:

- Is it likely to improve symptoms that may be contributing to the patient's insomnia (e.g., depression, anxiety, psychosis, neuropathic pain)?
- Does it pose risks to the patient based on comorbid medical conditions (e.g., benzodiazepines should not be given to patients with sleep apnea, tricyclic antidepressants should not be given to patients with cardiac conduction problems)?
- Does it have adverse interactions with other medications (e.g., zolpidem [Ambien], zaleplon [Sonata], and eszopiclone [Lunesta] should be used with caution in patients taking protease inhibitors [PIs])?
- Is it the optimal agent for a patient with a current or past history of alcohol or sedative abuse/dependence?
- Is it affordable (e.g., formulary or co-pay issues)?

Treatment considerations

There are limited data to guide the frequency (nightly, intermittently, as needed) and duration (brief, intermediate, long-term) of hypnotic medications. Hypnotics should be prescribed at the lowest effective dosage for the shortest possible period. The greater the degree of physical illness, the more likely the patient will need a low dosage of a hypnotic agent. When long-term treatment is necessary, benzodiazepines pose the greatest risk of tolerance, abuse, and dependence.

Possible adverse effects of all hypnotics include excess sedation, daytime grogginess, impaired judgment, behavior changes, and disruption of the sleep architecture. In addition, persons taking hypnotics may engage in overnight activities or behaviors without being fully awake, and may not remember these activities afterwards (e.g., walking, driving, eating); they also may have impairment in cognition and motor skills the next morning.

Interactions may occur between certain antiretrovirals (ARVs) and agents used to treat insomnia. Some combinations may be contraindicated and others may require dosage adjustment. Refer to medication interaction resources or consult with an HIV expert, psychiatrist, or pharmacist before prescribing.

Agents with FDA-Approved Indications for Insomnia

Antihistamines

- The antihistamines diphenhydramine, doxylamine, and hydroxyzine, given at doses of 25-50 mg QHS, can be used for sleep. Adverse anticholinergic effects often interfere with long-term use.

Antidepressants

- Trazodone, 25-50 mg; maximum dose: 200 mg QHS.
 - Trazodone, a triazolopyridine derivative antidepressant and sedative, is the only antidepressant with a U.S. Food and Drug Administration (FDA) indication for insomnia, and it is widely used for this purpose. However, levels may be increased by ritonavir-boosted PIs and by the pharmacokinetic booster cobicistat. Do not use with saquinavir/ritonavir; use lower dosages for patients receiving other PIs or cobicistat. Trazodone may (rarely) cause priapism. Trazodone can be used for an indefinite period of time as it is not associated with tolerance or addiction.

Non-benzodiazepine hypnotics (agonists of the benzodiazepine receptor)

- Zolpidem (Ambien) 5 mg for women, 5-10 mg for men, 5 mg for geriatric patients; zolpidem-CR (Ambien-CR) 6.25 mg for women, 6.25-12.5 mg for men; zaleplon (Sonata) 5-10 mg; and eszopiclone (Lunesta) 2-3 mg QHS.
 - These newer hypnotic agents are benzodiazepine receptor agonists with shorter half-lives than benzodiazepines and may be less likely to result in day-after drowsiness. They may have decreased addiction potential compared with benzodiazepine hypnotics. Higher doses and extended-release formulations appear to increase the risk of next-morning impairment. Patients should be advised to use these hypnotics on an as-needed basis rather than nightly; it is easier for patients to discontinue a drug that they are not taking every day. The inhibition of CYP 3A4 enzyme activity by PIs or cobicistat may increase levels of these benzodiazepine receptor agonists, particularly eszopiclone; this may cause excessive sedation or respiratory depression.

Melatonin agonists

- Ramelteon (Rozerem), 8 mg QHS.
 - The first of a new class of melatonin agonists to receive FDA approval, ramelteon may have some advantages over sedative/hypnotic agents, such as reduced dependence and overuse. However, it may have severe adverse reactions, including hypersensitivity reactions such as anaphylaxis and angioedema. Long-term interactions with ARV agents are unknown.

Benzodiazepine hypnotics

- A number of benzodiazepines have FDA-approved indications for the short-term treatment of insomnia. They carry a risk of addiction and residual drowsiness the following day.
- Metabolized by glucuronidation; predicted to have few drug interactions with ARVs:
 - Temazepam (Restoril) 7.5-30 mg; intermediate half-life
 - Lorazepam (Ativan), 1-2 mg; intermediate half-life.
- Metabolized by CYP 3A4; PIs and cobicistat may prolong their duration, resulting in excessive daytime somnolence. These may be most beneficial for use with patients whose insomnia is associated with anxiety:
 - Flurazepam (Dalmane) 15-30 mg
 - Quazepam (Doral) 7.5-15 mg
 - Estazolam (ProSom) 1-2 mg
- Clonazepam (Klonopin) at a dose of 0.5-2 mg has been approved for treatment of periodic leg movements. PIs and cobicistat may prolong its duration and increase risk of adverse effects; start at low dosage and titrate slowly.
- Triazolam (Halcion), another approved agent for insomnia, is contraindicated for use with all PIs, some nonnucleoside reverse transcriptase inhibitors (NNRTIs) (delavirdine, efavirenz), and cobicistat because of potentially life-threatening reactions (e.g., respiratory depression)

Agents Used for Sedating Side Effects (no FDA indication for insomnia)

Antidepressants

- Tricyclic antidepressants at doses of 10-50 mg can be beneficial for sleep, but they have longer half-lives than short-acting hypnotic agents, and potential adverse effects include cardiac dysrhythmias and pulmonary complications. Tricyclics generally should be avoided for geriatric patients. Levels of tricyclics are elevated by ritonavir and by cobicistat, and lower dosages may be needed for patients taking ritonavir or ritonavir-boosted PIs or cobicistat. Routine testing of tricyclic blood levels should be performed on patients receiving higher doses (e.g., 100 mg per day; 50 mg for nortriptyline), those concurrently on ritonavir, and those with risk factors for cardiac conduction abnormalities. A routine electrocardiogram should be performed before prescribing tricyclics, and this class of drugs should not be prescribed to patients with cardiac conduction problems. However, tricyclic antidepressants also have characteristics that may benefit some patients, including treatment of chronic pain, promotion of weight gain, and reduction of diarrhea. Amitriptyline (Elavil) and doxepin (Sinequan) are the most sedating of the tricyclic antidepressants and therefore are the drugs in this class most often used for sleep.
- The tetracyclic antidepressant mirtazapine (Remeron) is sedating and has been effective in treating insomnia at low dosages (7.5-15 mg). Higher dosages may result in increased activation owing to increased norepinephrine (NE) receptor antagonism.
- The selective serotonin reuptake inhibitor (SSRI) antidepressants are not sufficiently sedating to be used as sleeping agents, but when insomnia is caused by depression, sleep will improve as the depression lifts.

Anticonvulsants

- Gabapentin (Neurontin) can be useful for patients with insomnia and has been demonstrated to be particularly beneficial for patients with alcohol and other substance-use disorders; it is widely prescribed for neuropathic pain.

Patient Education

- Instruct patients in behavioral interventions that can help to reduce insomnia.
- Additional interventions are available when behavioral interventions are not sufficient.
- Patients should be warned strongly about risks associated with medications used to treat insomnia, including the risk of sleepwalking and other overnight activities and next-morning impairment in cognition and coordination.
- Patients should report new or worsening symptoms to their health care provider. These may be not only signs of worsening insomnia, but also of symptoms of anxiety, depression, medications, or changes in medical conditions

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Oral Health

Background

Examination of the oral cavity should be included in both the initial and interim physical examination of all HIV-infected patients. Patients with lesions suspected to be oral manifestations of HIV disease should be referred to an oral health expert with experience in treating oral lesions associated with HIV/AIDS. Other oral lesions may be a sign of a systemic disease, a side effect of medications, or a result of poor oral hygiene.

The following is an overview of conditions commonly seen in patients with HIV infection. See chapters *Oral Hairy Leukoplakia*, *Oral Warts*, *Oral Ulceration*, and *Necrotizing Ulcerative Periodontitis and Gingivitis* for more information about those conditions.

HRSA HAB Performance Measures

Percentage of HIV-infected oral health patients who had a **dental and medical health history** (initial or updated) at least once in the measurement year

Percentage of HIV-infected oral health patients who had a **dental treatment plan** developed and/or updated at least once in the measurement year

Percentage of HIV-infected oral health patients who received **oral health education** at least once in the measurement year

Percentage of HIV-infected oral health patients who had a **periodontal screen or examination** at least once in the measurement year

Percentage of HIV-infected oral health patients with a **Phase 1 treatment plan** that is completed within 12 months

Xerostomia (Dry Mouth)

S: Subjective

The chief complaint may be a dry, “sticky,” or possibly a burning sensation in the mouth, or an inability to “taste” food. The patient may present with difficulty swallowing.

O: Objective

The oral mucosal tissues appear dry and sometimes “shiny” in appearance. The lips may be dry and cracked, and the tongue is dry. Dental decay may be present on the cervical portion of the teeth (near the gingival margin or “gumline”). Oral candidiasis (thrush) may or may not be present.

A: Assessment

The differential diagnosis for the cause of xerostomia includes but is not limited to medication side effects (e.g., from anticholinergics), systemic diseases (e.g., Sjögren syndrome), adverse effects of radiation therapy, and salivary gland diseases.

P: Plan

Identify the cause of xerostomia and modify, if possible. Treat with artificial saliva products or oral lubricant products (e.g., Salivart, Biotene Oral Balance Dry Mouth Relief Moisturizing Gel, TheraSpray). Discourage sucking on hard candies with sugar that can promote caries (dental decay). Encourage patients to use sugar-free gums and candies to help promote salivary function. Promote good oral hygiene with flossing and brushing with a fluoride

toothpaste, and encourage regular (every 3-4 months) dental recall visits. Severe cases of xerostomia may be treated by prescribing cholinergic stimulants such as pilocarpine (Salagen).

Burning Mouth Syndrome; Atrophic Glossitis

S: Subjective

The patient may complain of a constant burning sensation in the mouth or a numbness or tingling feeling of the tongue. Eating certain foods or spices may trigger the burning sensation. The patient also may complain of dry mouth or a metallic taste in the mouth.

O: Objective

The tongue and oral mucosal tissues may be normal in appearance or there may be a slight redness on the tip and lateral margins of the tongue. In other cases, the tongue may appear “bald,” owing to the loss of papillae on the dorsal surface, and it may be “beef red” in color.

A: Assessment

Possible systemic etiologies include nutritional and vitamin deficiencies (atrophic glossitis), chronic alcoholism, medication adverse effects, diabetes mellitus, and gastric reflux. Local etiologies include denture irritation, oral habits such as tongue or cheek biting, and excessive use of certain toothpastes or mouthwashes. Psychological factors and nerve damage also may cause burning mouth. Erythematous candidiasis also can present as a burning sensation.

P: Plan

Identify the cause of the burning sensation, if possible, by review of the medical history and by performing diagnostic tests as indicated (e.g., complete blood count, biopsy, or oral cytological smears). Once the underlying cause is identified, treatment may be as simple as changing a dentifrice or eliminating the identified irritant, or the condition may require systemic treatment.

Recurrent Aphthous Ulceration (RAU)

S: Subjective

The patient complains of a painful ulcer or ulcers in the mouth that recur.

O: Objective

The typical appearance of an aphthous ulcer is a “red raised border with a depressed, necrotic (white-to-yellow pseudomembrane) center.” Aphthous ulcers tend to present on nonkeratinized or nonfixed tissues such as the buccal mucosa or posterior oropharynx and may be small or large, solitary or in clusters, and can resemble intraoral herpetic lesions (although herpetic lesions tend to present on keratinized tissues such as the roof of the mouth and gingival tissues).

A: Assessment

The differential diagnosis includes traumatic ulcers and herpes simplex virus ulcers.

P: Plan

The diagnosis usually is based on appearance. For further information, see chapter *Oral Ulceration*.

Recurrent Herpes Simplex

S: Subjective

The patient complains of a locally painful ulcer or ulcers on the lips or intraoral areas.

O: Objective

Herpes lesions are located on the lips, gingival tissues, or the hard palate. They may appear as small vesicular lesions that rupture, forming small ulcers. They may rupture and coalesce into larger lesions.

A: Assessment

The differential diagnosis includes aphthous ulcer and traumatic ulcer.

P: Plan

The diagnosis usually is based on appearance. For further information, see chapters *Oral Ulceration* and *Herpes Simplex, Mucocutaneous*.

Periodontal Disease

The medical evaluation of patients with HIV infection should include assessment of periodontal health. Whereas the same type of plaque-induced periodontal diseases can be seen in both immunocompetent and immunosuppressed individuals, periodontal disease in HIV-infected patients can be a marker of HIV disease progression. In the HIV-infected patient with periodontal disease, it is important to distinguish whether the periodontitis represents an acute/aggressive or chronic presentation unique to those with HIV disease. In addition, it is important to determine whether the patient has an inflammatory oral disease process that may further compromise his or her health.

Various illnesses and systemic factors (e.g., diabetes mellitus, hormonal abnormalities, medications, and malnutrition) can complicate the clinical presentation of periodontal disease. If significant periodontal disease is suspected, refer to an experienced dentist for diagnosis and treatment. Gingivitis (gum disease), a milder form of periodontal disease, usually is reversible with proper professional and home oral health care. For further information on necrotizing ulcerative periodontitis or necrotizing ulcerative gingivitis, see chapter *Necrotizing Ulcerative Periodontitis and Gingivitis*.

S: Subjective

The patient may complain of red, swollen, or painful gums, which may bleed spontaneously or with brushing; chronic bad breath or bad taste in the mouth; loose teeth or teeth that are separating; or a “bite” that feels abnormal.

O: Objective

Examine the gingival tissues. Periodontitis appears as localized or generalized gingival inflammation. The gingivae appear bright red or reddish-purple, ulcerated, or necrotic. Spontaneous gingival hemorrhage and purulent discharge may be evident around the teeth, especially if pressure is applied to the gingivae. Gingiva may be pulling away from the teeth. Fetor oris may be present.

A: Assessment

The differential diagnosis includes gingivitis, periodontitis, trench mouth, and oral abscesses. Diagnosis usually is based on appearance. Patients with severe or recalcitrant disease should be referred to an oral health care provider for definitive diagnosis and treatment.

P: Plan

Treatment may include:

- Warm saline rinses
- Daily brushing and flossing
- Antimicrobial mouth rinse (e.g., Listerine, chlorhexidine)
- Antibiotic therapy

For further information, see chapter *Necrotizing Ulcerative Periodontitis and Gingivitis*.

Dental Caries Caused by Methamphetamine and Cocaine Use

Dental decay seen in individuals who smoke methamphetamine or crack cocaine, or use cocaine orally, often is referred to as “meth mouth.”

S: Subjective

The chief complaint may be pain in one or more teeth. However, if the condition is chronic, the patient may not complain of pain.

O: Objective

In meth mouth, the enamel on all teeth or multiple teeth is grayish-brown to black in color (owing to decay), and appears “soft” (this has been described as a “texture less like that of hard enamel and more like that of a piece of ripened fruit”). Oral mucosal tissues appear dry as a result of decreased salivary flow. The gingiva appears red or inflamed, and there may be spontaneous bleeding of the gingiva around the teeth.

Another pattern of dental decay can be seen in cocaine users who rub the drug along the gingiva in order to test its strength or purity. This can lead to localized dryness of the gingival tissues. Consequently, plaque sticks to the cervical portion of the teeth in the area where the cocaine is rubbed, resulting in dental caries along the cervical portion of the teeth.

A: Assessment

The differential diagnosis includes other causes of caries.

P: Plan

Refer to a dentist for appropriate care, which may involve restorative, endodontic therapy, periodontal care, and oral surgery. In severe cases, extraction of the involved teeth and replacement with a partial or complete denture may be necessary. Encourage proper oral hygiene; evaluate sucrose intake.

Oral Cancer

S: Subjective

Oral malignancies may be symptomatic or asymptomatic. Data suggest two distinct pathways for the development of oropharyngeal cancer: one driven predominantly by the carcinogenic effects of tobacco or alcohol (or both), the other by genomic instability induced by human papillomavirus.

The patient may complain of a mouth sore that fails to heal or that bleeds easily, or a persistent white or red (or mixed) patch. The patient may note a lump, thickening, or soreness in the mouth, throat, or tongue; difficulty chewing or swallowing food; difficulty moving the jaw or tongue; chronic hoarseness; numbness of the tongue or other areas of the mouth; or a swelling of the jaw, causing dentures to fit poorly or become uncomfortable.

O: Objective

Perform a thorough evaluation of the oropharynx, as well as lymph nodes in the head and neck. Suspicious lesions may occur on the lips, tongue, floor of the mouth, palate, gingiva, or oral mucosa, and may appear as an ulcer or a soft-tissue mass or masses that can be pink, reddish, purple, white, or mixed red and white. The lesion typically is indurated and may be painful. It may enlarge rapidly between examinations.

A: Assessment

The differential diagnosis includes oral squamous cell carcinoma, lymphoma, Kaposi sarcoma, traumatic ulcer, hyperplasia, and hyperkeratosis.

P: Plan

An ulcerated lesion or symptom described above that is present for 2 weeks or longer should be evaluated promptly by a dentist or physician. If cancer is suspected, a biopsy should be obtained to make a definitive diagnosis. Treatment will be based on the specific diagnosis.

Bruxism**S: Subjective**

The patient may complain of chronic facial or jaw pain, sensitive teeth, earache, or waking up with a headache or facial pain. Often, the patient is not aware that he or she is clenching or grinding the teeth. Bruxism very often is a result of increased stress or anxiety, causing the patient consciously or unconsciously to clench or grind the teeth. However, some people may be “nighttime bruxers” and grind their teeth while sleeping, often loudly enough to wake others sleeping in the same room.

O: Objective

Perform a focused evaluation of the oropharynx, jaw, and facial muscles. The teeth may appear shortened, flattened, or worn down as a result of chronic grinding or clenching of the teeth. There may be hyperkeratotic lesions on the inside of cheeks as a result of chronic grinding or biting. There may be tenderness with palpation of facial muscles.

A: Assessment

The differential diagnosis includes other causes of facial or jaw pain, such as caries, dental abscesses, and trauma.

P: Plan

Refer the patient to a dentist for treatment. Treatment may include wearing a bite guard or psychological or behavioral management therapy.

Oral Piercing**S/O/A: Subjective/Objective/
Assessment**

Jewelry worn in piercings in the tongue, lips, or cheeks can chip or fracture the teeth. Chronic rubbing of jewelry against the gingiva can cause the gingiva to recede, leading to periodontal problems. (These complications occur apart from procedure- or technique-associated complications associated with body piercing, such as inflammation and infection, bleeding, and transmission of bloodborne pathogens.)

P: Plan

Refer the patient to a dentist for treatment. Recommend plastic tongue jewelry as opposed to metal to prevent fracture of teeth. Removal of the jewelry may be warranted.

Maxillary Tori; Mandibular Tori

S: Subjective

The patient may complain of a “lump” in the roof or floor of the mouth, or behind the lower front teeth.

O: Objective

Exostosis of normal bone (covered by oral mucosal tissue) can appear as a nodular or lobulated protuberance centrally located on the hard palate (maxillary tori) or unilaterally or bilaterally located behind the mandibular incisors (mandibular tori). This develops slowly and the patient may become aware of exophytic growth only if the area is inadvertently traumatized.

A: Assessment

Differential diagnosis includes other benign or malignant lesions, including oral cancer.

P: Plan

No treatment is indicated unless the exostosis interferes with speech or swallowing, or removal is needed for fabrication of dentures or a partial denture. Tori are a variation of normal anatomy.

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Oral Ulceration

Background

Oral ulcerations appear as necrotic or eroded areas on the oral mucosa, including the tongue. Most such lesions are idiopathic (aphthous) or of viral etiology (e.g., herpes simplex virus [HSV]; rarely herpes zoster [VZV]). Oral ulcerations may be caused by fungal, parasitic, or bacteriologic pathogens; malignancy; or other systemic processes. This chapter will focus on herpetic and aphthous ulcers.

Herpetic ulcerations tend to appear on keratinized tissues such as the hard palate or gingiva. Recurrent aphthous ulcers tend to manifest on nonkeratinized tissues such as buccal mucosa, soft palate, and lingual (bottom) surface of the tongue, and, by definition, recur.

S: Subjective

The patient complains of painful ulcerated areas in mouth. He or she may have difficulty eating, drinking, swallowing, or opening the mouth, and may complain of sore throat.

Inquire about previous occurrences of oral ulcerative disease as well as ulcerative gastrointestinal diseases, including HSV, cytomegalovirus (CMV), or histoplasmosis. Ask about recent sexual exposures. Inquire about recent trauma or burns. Note current medications and any recent changes in medications; obtain history of tobacco (smoked and chewed) and alcohol use.

O: Objective

Look for red or white-bordered erosions or ulcerations varying in size from 1 mm to 2 cm on the buccal mucosa, oropharynx, tongue, lips, gingiva, and hard or soft palate. Lesions caused by HSV tend to be shallow and occur on keratinized tissues. HSV lesions may appear as clusters of vesicles that may coalesce into ulcerations with scalloped borders. Aphthous ulcers present with a white or gray pseudomembrane surrounded by a halo of inflammation.

A: Assessment

Rule out syphilis and other suspected pathogens as well as trauma, seizure, and other physical injury.

P: Plan

Diagnostic Evaluation

The diagnosis of HSV and aphthous ulcers usually is made on the basis of characteristic lesions. Location, duration, and recurrence are key elements in determining the nature of the oral ulcer. As mentioned previously, HSV-related ulcers most often present on keratinized fixed tissues; aphthous ulcers appear on nonfixed tissues such as buccal mucosa, and have a tendency to recur. Check the absolute neutrophil count (ANC), as a low count (<500 cells/ μ L) may be associated with nonresponsive ulcerative disease. If diagnosis is uncertain, it is possible to perform HSV culture or polymerase chain reaction (PCR) testing on oral ulcerations that appear on keratinized tissues or the dorsal and lateral surfaces of the tongue, scraping near the margin of the lesion or unroofing a fresh vesicle, if available, and scraping the base. The sensitivity of HSV testing decreases when collections are taken from older, resolving herpetic areas; herpetic lesions >72 hours old usually will not yield a positive culture.

If other diagnoses are suspected, perform culture or biopsy as indicated. Also perform biopsy for ulcers that do not respond to therapy (in nonneutropenic patients).

Note that syphilis is very common among some HIV-infected populations. For patients in whom primary syphilis (manifested by an oral chancre) is suspected, perform (or refer for) darkfield examination; check Venereal Disease Research Laboratory (VDRL) or rapid plasma reagin (RPR) results (note that VDRL or RPR results may be negative in primary syphilis); see chapter *Syphilis* for further information. It is worth noting that, whereas chancres are described as painless, open sores in the mouth usually are associated with some degree of pain.

Treatment

If HSV culture is positive, or if HSV is strongly suspected owing to the appearance of the lesions or the patient's history, treat with HSV antiviral medication (e.g., valacyclovir, famciclovir, or acyclovir) while waiting for results of culture. Do not use topical steroids without a concomitant oral HSV antiviral if the lesion is of possible herpetic etiology. Refer to chapter *Herpes Simplex, Mucocutaneous* for more information regarding management and treatment of HSV lesions.

Recalcitrant minor aphthous ulcerations should be treated with topical corticosteroids (e.g., fluocinonide 0.05% or clobetasol 0.05% ointments mixed 1:1 with Orabase). For multiple small lesions or lesions in areas where topical ointments are difficult to apply, consider dexamethasone elixir (0.5 mg/5 mL); the patient is to rinse TID with 5 mL for 1 minute, then expectorate. As with all oral topical steroids, patients should not drink or eat for 30 minutes after rinsing. Continue treatment for 1 week or until lesions resolve.

In some cases, recurrent aphthous ulcers may respond to one of the various “magic mouthwashes” that contain combinations of antibiotic, antifungal, corticosteroid, antihistamine, and anesthetic medication. The inclusion of an antihistamine (e.g., diphenhydramine) or an anesthetic (e.g., lidocaine) may be helpful in treating pain associated with these ulcers.

For large or extensive aphthous ulcers, systemic corticosteroids may be needed: prednisone 40–60 mg PO daily for 1 week followed by a taper should prove beneficial. If this is ineffective, refer for biopsy to rule out CMV, other infection, or neoplastic disease.

For patients with major oral aphthous ulcers that are recalcitrant to other therapies, thalidomide 200 mg daily for 2 weeks may be considered. Thalidomide is teratogenic and should not be used for women of childbearing potential without thorough patient education and two concomitant methods of birth control. Consult with an expert.

Pain control may be needed in order for the patient to maintain food intake and prevent weight loss. Most of the topical treatments noted above will ease pain as well as treat the ulcer. Additional considerations for pain control include the following:

- **Oral anesthetics:** Various products are available, including gels (e.g., Gelclair, an adherent oral rinse that acts as an oral bandage), viscous liquids, and sprays (e.g., benzocaine, lidocaine). These may be applied topically or swished and expectorated. They will provide temporary relief, but may lead to a temporary loss of taste sensation.
- **Systemic:** If topical treatments are inadequate, consider systemic analgesics (e.g., nonsteroidal antiinflammatory drugs or opiates). Refer to chapter *Pain Syndrome and Peripheral Neuropathy*.

Assess nutritional status and consider adding liquid food supplements, if indicated. Suggest soft, nonspicy, or salty foods if the ulcer is interfering with food intake. Refer to a registered dietitian if client is experiencing pain, problems eating, or weight loss.

Refer to an oral health specialist or an HIV-experienced dentist as needed.

Patient Education

- Advise patients to report any oral pain or difficulty swallowing to their health care provider.
- Instruct patients in the application of topical ointments, and indicate that they may require assistance if the lesion is difficult for them to see on their own.
- It is important for patients to maintain good nutrition and food intake while their oral ulcers heal. Advise them to eat soft, bland foods, and refer to a nutritionist if they have difficulty.
- Antiretroviral therapy should be initiated or optimized to improve immune function in patients with recurrent aphthous ulcers.

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Oral Warts

Background

Oral warts are caused by human papillomavirus (HPV) and may appear anywhere within the oral cavity or on the lips. They occur more frequently and more extensively in people with HIV infection than in those with normal immune function, especially in patients with advancing immune suppression (CD4 counts of <200 - 300 cells/ μ L). Oral warts may be refractory to therapy. The frequency of oral warts may increase, at least temporarily, in patients treated with antiretroviral therapy.

It should be noted that HPV infection is strongly associated with oropharyngeal cancer among subjects with or without the established risk factors of tobacco and alcohol use, although oral warts normally are not caused by the HPV types that are associated with oncogenic changes. One analysis of stored samples suggests that the percentage of all oropharyngeal cancers that are HPV-positive has increased from about 20% to 60% since about 1980. Researchers also have reported that HPV-related oral cancers were among the most responsive to chemotherapy and radiation.

S: Subjective

The patient notices raised lesions in the mouth or on the lips. Warts are not painful unless they have been traumatized.

O: Objective

Examine the oral cavity carefully for abnormalities. Wart lesions may vary in appearance from smooth, small, and slightly raised lesions to cauliflower-like or spiked masses with prominent folds or projections. They may be single or multiple.

Review recent CD4 counts. In patients with oral warts, the CD4 count usually is <300 cells/ μ L.

A: Assessment

A partial differential diagnosis includes: squamous cell carcinoma, lichen planus, and traumatic hyperkeratinized areas resulting from cheek biting or tongue thrusting.

P: Plan

Diagnostic Evaluation

- The diagnosis of oral warts usually is based on the appearance of the lesions. If lesions are unusual in appearance, are ulcerated, or have grown rapidly, perform biopsy to rule out cancer. If there is suspicion of other causes, perform other diagnostic evaluations as indicated.
- HPV may be demonstrated with electron microscopy or in situ hybridization; this testing is not routinely required.
- Observation of these lesions is important because of the potential, however minimal, for development of squamous cell carcinoma.

Treatment

- Treatment is difficult, as these lesions tend to recur. Treatment options include cryosurgery and surgical or laser excision. Care must be taken when using laser excision, as HPV can survive in an aerosol. Extraoral lesions (lip or corner of mouth) may be treated with topical agents such as podofilox topical solution (Condylox) or fluorouracil 5% topical (Efudex). Imiquimod 5% cream (Aldara) may help to prevent recurrence once the lesions have resolved.
- Refer to an oral health specialist or dentist for treatment.

Patient Education

- Instruct patients to comply with regular dental and medical care regimens.
- Instruct patients to use medications exactly as prescribed.

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Oral Hairy Leukoplakia

Background

Oral hairy leukoplakia (OHL) is an oral infection caused by Epstein-Barr virus (EBV). It appears as white corrugated lesions (sometimes “hairy” in appearance) primarily on the lateral aspects of the tongue. The infection may spread across the entire dorsal surface onto the ventral surface of the tongue, and occasionally may be found on buccal mucosa. It is common in people with HIV infection, particularly in those with advanced immunosuppression (CD4 count <200 cells/ μ L), and may serve as a marker of HIV.

S: Subjective

The patient notices new, white lesions on the tongue that cannot be wiped off or removed by scraping or brushing. The OHL lesions usually are asymptomatic, but occasionally may cause alteration in taste, discomfort, or other symptoms.

O: Objective

Perform a focused examination of the oropharynx. OHL appears as unilateral or bilateral white plaques or papillary lesions on the lateral, dorsal, or ventral surfaces of the tongue or on buccal mucosa. The lesions may vary in appearance from smooth, flat, small lesions to irregular, “hairy” or “verrucous” lesions with prominent vertical folds or projections.

A: Assessment

A partial differential diagnosis for OHL includes:

- Oral candidiasis
- Squamous cell carcinoma
- Geographic tongue
- Lichen planus
- Smoker’s leukoplakia
- Epithelial dysplasia
- White sponge nevus
- Irritation leukoplakia

P: Plan

Diagnostic Evaluation

A presumptive diagnosis of OHL usually is made on the basis of the clinical appearance of the lesions. OHL often is confused with candidiasis; the diagnosis of OHL should be considered for lesions that do not wipe away, as would be the case for pseudomembranous candidiasis. Definitive diagnosis of OHL requires biopsy and demonstration of EBV.

- Perform biopsy of lesions only if they are ulcerated or unusual in appearance, to distinguish OHL from cancer or other causes.

Treatment

- Because OHL usually is asymptomatic, specific treatment generally is not necessary.
- Immune system reconstitution through antiretroviral therapy will resolve OHL; encourage initiation of HIV treatment if the patient is not yet on antiretroviral therapy.
- If specific treatment is required, the following options may be considered. Relapse is common after discontinuation of treatment.
 - Acyclovir 800 mg PO 5 times per day for 2 weeks; famciclovir and valacyclovir may be considered.
 - Topical tretinoin (Retin-A) 0.025-0.05% solution, podophyllin 25% in tincture of benzoin, and other treatments also have been used.

- For relapse of severe OHL, consider maintenance therapy with high-dose acyclovir, famciclovir, or valacyclovir.
- For severe symptomatic cases, surgical treatment (e.g., cryosurgery, excision) may provide temporary resolution.
- Candidiasis may be present concurrently; treat candidiasis if it is present (see chapter *Candidiasis, Oral and Esophageal*).

Patient Education

- Advise patients that OHL rarely is a problem in itself, but may be a marker of HIV progression.
- Encourage patients to start antiretroviral therapy.
- Advise patients to contact their care providers if new symptoms develop.
- Instruct patients to comply with regular dental and medical care regimens.

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Necrotizing Ulcerative Periodontitis and Gingivitis

Background

Necrotizing ulcerating periodontitis (NUP) is a marker of severe immunosuppression that affects gingival tissues (gums) and extends to the underlying bone or periodontium. It may or may not be distinct from necrotizing ulcerative gingivitis (NUG), which is considered to be confined to the gingiva. This discussion will focus primarily on NUP, but the microbial profiles and treatment recommendations for these two periodontal diseases are similar.

NUP in HIV-infected individuals is believed to be an endogenous infection that progresses to necrosis of the gingiva. Pathogens may include anaerobic bacteria and fungi. NUP usually presents as “blunting” or ulceration of the interdental papillae, but rapidly progresses to destruction of underlying alveolar bone. It usually is associated with severe pain and spontaneous bleeding. Several case reports have described extensive destruction leading to exfoliation of teeth within 3-6 months of onset, with sequestration of necrotic alveolar bone and necrotic involvement of the adjacent mandible and maxilla. Patients may present with concomitant malnutrition resulting from inability to take food by mouth. The prevalence of NUP in the HIV-infected population has been reported as 0-5%. NUP is the most serious form of periodontal disease associated with HIV.

S: Subjective

The patient complains of painful, spontaneously bleeding gums, diminished or metallic taste, bad breath, or loose teeth (with a prevalence toward anterior teeth and first molars). “Deep jaw pain” is a common complaint and may reflect extension to adjacent mucosa.

O: Objective

Examine the oral cavity carefully. NUP and NUG present with fiery red, ulcerated gingival tissues, and grayish exudate. Teeth may be very loose or missing and there will be a fetid odor from the mouth. The ulcerated tissues can extend past the attached gingiva to the adjacent mucosa. Necrosis of adjacent bone also is common.

A: Assessment

The differential diagnosis includes other causes of gingival ulceration, such as herpes simplex

virus, herpes zoster, and cytomegalovirus. (See relevant chapters on these conditions.)

P: Plan Treatment

Treatment usually is divided into the acute phase and the maintenance phase. The primary concern in the acute phase is pain control. For the maintenance phase, treatment is directed toward reducing the burden of potential pathogens, preventing further tissue destruction, and promoting healing.

- For uncomplicated NUP or NUG, the primary care provider should prescribe an antimicrobial rinse (see below), antibiotic therapy (see below), medications for pain management, and nutritional supplementation; the patient should be referred to a dental health care professional.
- Chlorhexidine gluconate rinse (0.12%) twice daily after brushing and flossing (an alcohol-free preparation is preferred).

- Antibiotic therapy (preferably narrow spectrum, to leave gram-positive aerobic flora unperturbed).
- Metronidazole is the drug of choice, 500 mg PO BID for 7-10 days.
- If the patient cannot tolerate metronidazole: clindamycin 150 mg QID or amoxicillin-clavulanate (Augmentin) 875 mg PO BID for 7-10 days, if no hypersensitivity or allergy to either drug exists.
- Refer to a dentist for the following:
 - Removal of plaque and debris from the site of infection and inflammation.
 - Debridement of necrotic hard and soft tissues, with a 0.12% chlorhexidine gluconate or povidone-iodine lavage.
 - Regular deep cleaning.

Patient Education

- Advise the patient of the following: Good oral hygiene is critical for arresting gingival infection and tooth loss. Avoid smoking and try to eliminate emotional stress. When primary stabilization is achieved, resume daily brushing and flossing after every meal. This may be difficult during the acute phase, but it is very important to keep the mouth as clean as possible. Nutrition education and supplements (liquid diet, plus vitamins/minerals) are recommended.
- Frequent professional cleaning (every 3 months) may be needed during the maintenance phase.
- Patients taking metronidazole should not drink alcohol for at least 24-48 hours after taking the last dose, in order to avoid severe nausea and vomiting from a disulfiram-like reaction.
- Instruct patients not to drink or eat for 30 minutes after rinsing with chlorhexidine.

- HIV (and hepatitis C) may (rarely) be transmitted from bleeding gums during “deep kissing” or other activities (oral-genital contact). Advise patients/clients to avoid exposing partners to HIV by taking all necessary precautions, including abstinence from risky activities until this condition is healed and stable (no oozing of oral fluids).

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Web-Based Resources

Background

The care and management of HIV-infected patients is a rapidly evolving field. Keeping up to date with clinical information about HIV care has in the past required attendance at national and international conferences. With the increasing availability of the Internet, clinicians and patients are able to access the most current advances through Web coverage, without requiring travel or time away from work.

The challenge of using Internet resources is in determining which websites are accurate and current. Check for dates of authorship, the credentials of the site sponsors and authors, and how well supported any recommendations or analysis may be. Be aware of any possible commercial bias. Finally, it is important to remember that information on these sites does not replace clinical judgment or consultation with HIV experts.

Listed below is a selection of useful and accurate Internet sites. Many of these websites also link out to additional information resources, and many allow users to subscribe to receive updates via email. Many providers find it helpful to review sites geared toward patients, in order to maintain familiarity with patients' concerns and patient-based information resources.

Resources for Clinicians

- **AIDSInfo** (aidsinfo.nih.gov)
Official repository for HIV/AIDS information from the U.S. Public Health Service. Content includes national clinical trial information, drug and vaccine overviews, fact sheets for patients, and a clinical guidelines portal that includes the following:
 - Adult and Adolescent ARV Guidelines
 - Adult and Adolescent OI Prevention and Treatment Guidelines
 - Perinatal Guidelines
 - Pediatric ARV Guidelines
 - Pediatric OI Prevention and Treatment Guidelines
 - Guidelines on Care for HIV-Infected Residents Displaced from Disaster Areas
 - Preexposure Prophylaxis (PrEP) Guidelines
 - Occupational Postexposure Prophylaxis (PEP) Guidelines
 - Nonoccupational Postexposure Prophylaxis (nPEP) Guidelines
 - Recommendations for Hormonal Contraception
 - HIV Counseling, Testing, and Referral Guidelines
 - Guidelines on Incorporating HIV Prevention into Medical Care
- **TARGET Center** (careacttarget.org)
The central source of Ryan White training and technical assistance, including clinical care resources funded by HRSA's HIV/AIDS Bureau.
- **AIDS Education and Training Centers National Resource Center** (www.aidsetc.org)
Clinical training resources, including curricula, self-study, and slide sets, including slides for all national guidelines.

- **National HIV/AIDS Clinicians' Consultation Center** (www.nccc.ucsf.edu)
An AIDS Education and Training Centers clinical resource for health care professionals, with contact information for the Warmline, PEpline, and Perinatal HIV Hotline.
- **Aidsmap** (www.aidsmap.com)
London-based HIV/AIDS news and treatment information site. Patient information is written at both lower and higher literacy levels. International focus.
- **Clinical Care Options for HIV** (clinicaloptions.com)
Continuing Medical Education (CME) materials related to HIV/AIDS, including conference reviews.
- **HIV InSite** (hivinsite.ucsf.edu)
Major HIV/AIDS portal from the University of California San Francisco. Includes *HIV InSite Knowledge Base*, updated ARV information, including an ARV interactions database, global country profiles, and links out to other useful sites.
- **HIV Drug Resistance Database** (hivdb.stanford.edu)
Information on resistance mutations to antiretroviral medications from Stanford University.
- **HIV Web Study** (depts.washington.edu/hiv aids)
Northwest AETC, University of Washington. Dozens of online clinical cases featuring downloadable tables, charts, and images.
- **International Training and Education Center on HIV** (www.go2itech.org)
The international AETC. Website features extensive database of international HIV/AIDS training materials.
- **International Antiviral Society-USA** (www.iasusa.org)
ARV resistance mutations charts and "Cases on the Web" online CME courses.
- **Journal Watch: HIV/AIDS Clinical Care** (www.jwatch.org/hiv-aids-clinical-care)
From the publishers of the New England Journal of Medicine, Journal Watch features updates and analysis online or via a weekly email newsletter.
- **Medscape HIV/AIDS Topic Area** (www.medscape.com/hiv?src=pdown)
CME materials related to HIV/AIDS, including conference coverage, news, and special features.
- **VA National HIV/AIDS Program** (www.hiv.va.gov)
Comprehensive information portal for providers. Also has a section for veterans and patients.
- **Women, Children, and HIV** (www.womenchildrenhiv.org)
Expert-selected, evidence-based information on prevention of mother-to-child transmission of HIV, care of women and children with HIV, and related topics.

Resources for Patients and the Community

- **AIDS.gov** (aids.gov)
AIDS.gov provides access to Federal HIV/AIDS information through a variety of new media channels, and supports the use of new media tools by Federal and community partners to improve domestic HIV programs serving minority and other communities most at-risk of, or living with, HIV.
- **AIDS.org** (www.aids.org)
Online home of AIDS Treatment News.
- **AIDS InfoNet** (www.aidsinfonet.org)
Comprehensive collection of fact sheets on clinical topics, available in English and Spanish, in print-friendly and downloadable formats. Regularly updated.
- **AIDSmeds** (aidsmeds.com)
Information regarding HIV-related medications for patients, including drug interactions calculator.
- **AIDS Project Los Angeles** (www.apla.org)
Fact sheets, newsletters, and program information. Some information in Spanish.
- **The Body** (www.thebody.com)
Major HIV information resource geared toward patients and the community.
- **Gay Men's Health Crisis** (www.gmhc.org)
Patient and program information from one of the oldest community organizations. Some information in Spanish.
- **Project Inform** (www.projectinform.org)
Comprehensive information and advocacy information geared toward individuals infected and affected by HIV.
- **San Francisco AIDS Foundation** (www.sfaf.org)
AIDS 101, BETA treatment newsletter, and prevention and program information. Some information in Spanish.
- **The Well Project** (www.thewellproject.org/en_US)
Health resources for women diagnosed with HIV and AIDS.

Sulfa Desensitization

Background

Trimethoprim-sulfamethoxazole (TMP-SMX), also known as Septra, Bactrim, and cotrimoxazole, is a key antibiotic for prophylaxis and treatment of several HIV-related illnesses. It is the most effective prophylaxis and the first-line treatment for *Pneumocystis jiroveci* pneumonia (PCP). In addition, it is effective in preventing toxoplasmosis encephalitis in severely immunocompromised patients who have evidence of previous exposure (see chapter *Opportunistic Infection Prophylaxis*), and it is effective against certain bacterial infections. TMP-SMX is quite inexpensive, which is a rarity in the field of HIV treatment. Because of its effectiveness and availability, it is used widely throughout the world. However, adverse reactions to TMP-SMX and other sulfa drugs occur in a high proportion of HIV-infected patients (roughly 25%), and such reactions may limit treatment options.

Desensitization to TMP-SMX should be considered when there are no reasonable or available alternatives and the patient has not experienced severe reactions (e.g., Stevens-Johnson syndrome or toxic epidermal necrolysis) to sulfa drugs. Several methods of desensitizing patients with previous reactions to TMP-SMX have been tried. These methods vary in starting dosage and length of dosage escalation, but success rates are around 80% in most cases and may be higher in patients with CD4 counts of <200 cells/ μ L.

S: Subjective

The patient reports a previous adverse reaction to sulfa drugs, such as erythema, pruritus, or rash. The patient has no history of anaphylaxis, Stevens-Johnson syndrome, or toxic epidermal necrolysis, and no reaction involving vesiculation, desquamation, ulceration, exfoliative dermatitis, etc.

O: Objective

CD4 count <200 cells/ μ L, or other important indication for TMP-SMX.

A: Assessment

Reaction to sulfa, possibly reversible with desensitization protocol.

P: Plan

Begin 9- to 13-day desensitization protocol, starting with pediatric oral suspension, which contains 40 mg of TMP and 200 mg of SMX per 5 mL (1 teaspoon). Gradually increase the dosage according to the protocol.

If there is any concern about the severity of a previous reaction, have the patient take the initial morning dose in the clinic so that the patient may be monitored for 3-4 hours before going home. (This assumes that emergency treatment, including IV access materials, IV fluids, epinephrine, antihistamines, and steroids, are readily available.)

Many experts recommend treatment with an antihistamine medication starting 1 day before initiation of the desensitization regimen and continuing daily until the dosage escalation is completed.

More rapid desensitization protocols are available (see “References,” below) for patients urgently needing treatment with TMP-SMX.

Desensitization Regimen

Use commercially available pediatric suspension (containing TMP 8 mg and SMX 40 mg per mL [40 mg/200 mg per 5 mL]), followed by double-strength tablets, as follows:

Table 1. Sulfa Desensitization Regimen

Days	Dosage (TMP/SMX)	Volume or Tablet
1-3	8 mg/40 mg	1 mL
4-6	16 mg/80 mg	2 mL
7-9	40 mg/200 mg	5 mL (or 1/2 single-strength tablet)
9-12	80 mg/400 mg	1/2 double-strength tablet (or 1 single-strength tablet)
13 and thereafter	160 mg/800 mg	1 double-strength tablet
Note: These day ranges are approximate; patients can be advanced more quickly or more slowly, depending on their reactions to the dosages. In the event of mild reaction: If the patient experiences a mild reaction or itching (i.e., mild morbilliform rash without fever, systemic symptoms, or mucosal involvement), the dosage can be reduced to the last tolerated step or continued at the same dosage for an additional day, while simultaneously treating the rash or reaction. Antihistamines or antipyretics may be used to treat symptoms of mild reactions. If the reaction diminishes, the patient may advance to the next dosage (consider more gradual increase of dosages); if the reaction worsens or if systemic symptoms develop, TMP-SMX should be discontinued. In the event of severe reaction: The desensitization regimen should be discontinued and the patient should be treated appropriately for the reaction.		

Patient Education

For home desensitization regimen

- Explain the benefits of using TMP-SMX. Be sure the patient understands and is able to follow these instructions:
 - The patient should measure the dose carefully and take it each morning, followed by a glass (6-8 oz) of water. (The patient should do a demonstration, if possible, using an oral syringe that will be used for the actual measuring at home.)
- TMP-SMX can cause severe illness unless close attention is paid to any problems that may occur. It is extremely important for the patient to check his/her body temperature each afternoon. If the temperature is more than 100.5°F by mouth, the patient should stop taking the drug and contact the clinic. Note: If shaking chills occur, the body temperature should be checked as soon as the shaking stops, and the patient should contact the clinic.
- If the patient develops a rash, blisters on the skin or in the mouth, or vomiting, he or she should stop taking TMP-SMX and go the clinic or emergency room immediately. The skin should be checked each evening, and any time itching occurs.
- If mild itching or a faint rash occurs, diphenhydramine (Benadryl) 25-50 mg PO can be taken Q4H as needed. If itching or rash persists, continue with the same dosage for an additional day; the patient should contact the clinic if there are questions or concerns.
- The patient should contact the clinic for alternative dosage instructions in the event of persistent itching without rash.
- Other adverse events should be reported immediately.

For all desensitized patients

- Desensitization may be effective only as long as the allergic individual is continuously exposed to the drug. After desensitization is complete, continue with the daily dosage. If the drug is stopped (even for a few days), the entire regimen may have to be repeated, as patients may have a recurrence of the adverse reaction.

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Antiretrovirals Available in the United States and Mexico

Brand and Generic Names of ARVs in the United States and Mexico

This chart was developed to facilitate continuity of care for people living with HIV who may receive care in both the United States and Mexico. Although most HIV medications are available in both countries, some are sold under different brand names.

Antirretrovirales Disponibles en los Estados Unidos		Antiretrovirals Available in Mexico	
Generic	Brand Name	Genérico	Nombre Comercial
Nucleoside/Nucleotide Analogues (NRTIs)		Inhibidores de la Transcriptasa Reversa Análogos a Nucleósidos (ITRAN)	
Abacavir*	Ziagen	Abacavir*	Ziagenavir
Didanosine*	Videx	Didanosina*	Videx
Emtricitabine	Emtriva	Emtricitabina*	Emtriva
Lamivudine*	Epivir	Lamivudina*	Epivir/3TC
Stavudine*	Zerit	Estavudina*	Zerit
Tenofovir	Viread	Tenofovir	Viread
Zidovudine*	Retrovir	Zidovudina*	Retrovir
Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs)		Inhibidores de la Transcriptasa Reversa No Nucleósidos (ITRNN)	
Delavirdine	Rescriptor	No disponible/not available	
Efavirenz	Sustiva	Efavirenz	Stocrin
Etravirine	Intelence	Etravirina	Etravirina
Nevirapine*	Viramune	Nevirapina*	Viramune
Rilpivirine	Edurant	No disponible/not available	
Protease Inhibitors (PIs)		Inhibidores de Proteasa (IP)	
Atazanavir	Reyataz	Atazanavir	Reyataz
Darunavir	Prezista	Darunavir*	Prezista
Fosamprenavir	Lexiva	Fosamprenavir	Telzir
Indinavir	Crixivan	Indinavir	Crixivan
Lopinavir/Ritonavir	Kaletra	Lopinavir/Ritonavir	Kaletra
Nelfinavir	Viracept	Fuera de mercado/off market	
Ritonavir	Norvir	Ritonavir	Norvir
Saquinavir (hard-gel caps)	Invirase	Saquinavir (cápsula de gel duro)	Invirase
Tipranavir	Aptivus	Tipranavir	Aptivus

Antirretrovirales Disponibles en los Estados Unidos		Antiretrovirals Available in Mexico	
Generic	Brand Name	Genérico	Nombre Comercial
Chemokine Coreceptor Antagonists		Inhibidores de Acoplamiento	
Maraviroc	Selzentry	Maraviroc	Celsentri
Fusion Inhibitors		Inhibidores de Fusion	
Enfuvirtide (T20)	Fuzeon	Enfuvirtida*	Fuzeon
Integrase Inhibitors		Inhibidores de Integrasa	
Dolutegravir	Tivicay	No disponible/not available	
Elvitegravir	**	No disponible/not available	
Raltegravir	Isentress	Raltegravir	Isentress
Fixed-Dose Combinations		Combinaciones en Tableta Única	
Efavirenz + tenofovir + emtricitabine	Atripla	Efavirenz + tenofovir + emtricitabina	Atripla
Lamivudine + zidovudine*	Combivir	Lamivudina + zidovudina	Combivir
Rilpivirine + tenofovir + emtricitabine	Complera	No disponible/not available	
Abacavir + lamivudine	Epzicom	Abacavir + lamivudina	Kivexa
Elvitegravir + cobicistat + tenofovir + emtricitabine	Stribild	No disponible/not available	
Zidovudine + lamivudine + abacavir	Trizivir	Zidovudina + lamivudina + abacavir	Trizivir
Tenofovir + emtricitabine	Truvada	Tenofovir + emtricitabina	Truvada

* Available as generic/Disponible en forma genérica

** Available only in fixed-dose combination (Stribild)

Sources / Fuentes:

- *Guía de Manejo Antirretroviral de las Personas que Viven con el VIH/SIDA, Quinta Edición.* Secretaría de Salud, Consejo Nacional para la Prevención y Control del SIDA (CONASIDA); Subsecretaría de Prevención y Promoción de la Salud, Centro Nacional para la Prevención y el Control del VIH/SIDA (CENSIDA). México 2012. Available at www.censida.salud.gob.mx/. Accessed December 1, 2013.
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Antiretroviral Reference Tables

Adapted from Panel on Antiretroviral Guidelines for Adults and Adolescents. *Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents*. Department of Health and Human Services. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Table 5a. Antiretroviral Regimens Recommended for Treatment-Naïve Patients

Preferred Regimens (Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use) The preferred regimens for non-pregnant patients are arranged by chronological order of FDA approval of components other than nucleosides and, thus, by duration of clinical experience.		
NNRTI-based Regimens - EFV/TDF/FTC (AI) PI-based Regimens (in alphabetical order) - ATV/r + TDF/FTC (AI) - DRV/r (once daily) + TDF/FTC (AI) INSTI-based Regimen (in order of drug approval) - RAL + TDF/FTC (AI) - EVG/COBI/TDF/FTC (AI) - DTG + ABC/3TC (AI) - DTG + TDF/FTC (AI) Preferred Regimen¹ for Pregnant Women - LPV/r (twice daily) + ZDV/3TC¹ (AI)	Comments EFV: - Teratogenic in nonhuman primates. A regimen that does not include EFV should be strongly considered in women who are planning to become pregnant or who are sexually active and not using effective contraception. TDF: - Should be used with caution in patients with renal insufficiency. ATV/r: - Should not be used in patients who require >20 mg omeprazole equivalent per day. Refer to Table 15a for dosing recommendations regarding interactions between ATV/r and acid-lowering agents.	EVG/COBI/TDF/FTC: - Should not be started in patients with an estimated CrCl <70 mL/min, and should be changed to an alternative regimen if the CrCl falls below 50 mL/min - Should not be used with other ARV drugs or with nephrotoxic drugs - COBI is a potent CYP 3A inhibitor. It can increase the concentration of other drugs metabolized by this pathway. Refer to Tables 15d and 16c for drug interaction information on concomitantly administered drugs. Once-daily LPV/r is not recommended in pregnant women.
Alternative Regimens (Regimens that are effective and tolerable but have potential disadvantages compared with preferred regimens. An alternative regimen may be the preferred regimen for some patients.)		
NNRTI-based Regimens (in alphabetical order) - EFV + ABC/3TC (BI) - RPV/TDF/FTC (BI) - RPV + ABC/3TC (BIII) PI-based Regimens (in alphabetical order) - ATV/r + ABC/3TC (BI) - DRV/r + ABC/3TC (BIII) - FPV/r (once or twice daily) + ABC/3TC or TDF/FTC (BI) - LPV/r (once or twice daily) + ABC/3TC or TDF/FTC (BI) INSTI-based Regimen - RAL + ABC/3TC (BIII)	Comments RPV: - Not recommended in patients with pretreatment HIV RNA >100,000 copies/mL - Higher rate of virologic failures reported in patients with pre-ART CD4 count of <200 cells/μL who are treated with RPV + 2 NRTIs - Contraindicated for use with protein pump inhibitors (PPIs)	ABC: - Should not be used in patients who test positive for HLA-B*5701 - Use with caution in patients with high risk of cardiovascular disease or with pretreatment HIV-RNA >100,000 copies/mL (see text)

Note: 3TC may substitute for FTC or vice versa.

¹ For more detailed recommendations on antiretroviral use in an HIV-infected pregnant woman, refer to *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States*. Available at aidsinfo.nih.gov/guidelines. Accessed December 1, 2013.

Abbreviations:

INSTI = integrase strand transfer inhibitor
 NNRTI = non-nucleoside reverse transcriptase inhibitor
 NRTI = nucleos(t)ide reverse transcriptase inhibitor
 PI = protease inhibitor

ABC = abacavir
 ATV = atazanavir
 3TC = lamivudine
 COBI = cobicistat
 ddI = didanosine
 DRV = darunavir

DTG = dolutegravir
 EFV = efavirenz
 EVG = elvitegravir
 FPV = fosamprenavir
 FTC = emtricitabine
 LPV = lopinavir

NVP = nevirapine
 r = low dose ritonavir
 RAL = raltegravir
 SQV = saquinavir
 TDF = tenofovir
 ZDV = zidovudine

Table 5b. Other Antiretroviral Regimens for Treatment-Naive Patients

Regimens that may be selected for some patients but are less satisfactory than preferred or alternative regimens listed in Table 5a.	
NNRTI-based Regimens • EFV + ZDV/3TC • NVP + (ABC/3TC or TDF/FTC or ZDV/3TC) • RPV + ZDV/3TC PI-based Regimens • (ATV or ATV/r or DRV/r or FPV/r or LPV/r or SQV/r) + ADV/3TC • ATV + ABC/3TC • SQV/r + (ABC/3TC or TDF/FTC) INSTI-based Regimen • RAL + ZDV/3TC CCR5 Antagonist-Based Regimens • MVC + (ABC/3TC or TDF/FTC or ZDV/3TC)	Comments NVP: • Should not be used in patients with moderate to severe hepatic impairment (Child-Pugh B or C).¹ • Should not be used in women with pre-ART CD4 counts of >250 cells/μL or in men with pre-ART CD4 counts of >400 cells/μL. • Use with caution when coadministered with ABC; both NVP and ABC can cause HSR within the first few weeks after initiation of therapy. ZDV: • Can cause bone marrow suppression, myopathy, lipoatrophy, and rarely, lactic acidosis with hepatic steatosis. ATV/r: • Generally preferred over unboosted ATV. MVC • Perform tropism testing before initiation of therapy; may be considered for patients who have only CCR5-tropic virus. SQV/r: • Not recommended for patients with: • Pretreatment QT interval >450 msec • Refractory hypokalemia or hypomagnesemia • Concomitant therapy with other drugs that prolong QT interval • Complete AV block

Note: 3TC may substitute for FTC or vice versa.

¹ Refer to Appendix B, Table 7 for the criteria for Child-Pugh classification.

Abbreviations: 3TC = lamivudine; ABC = abacavir; ATV = atazanavir; ATV/r = atazanavir/ritonavir; AV = atrioventricular; COBI = cobicistat; ddl = didanosine; DRV = darunavir; DRV/r = darunavir/ritonavir; DTG = dolutegravir; ECG = electrocardiogram; EFV = efavirenz; EVG = elvitegravir; FPV = fosamprenavir; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; INSTI = integrase strand transfer inhibitor; msec = millisecond; MVC = maraviroc; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; RAL = raltegravir; RTV = ritonavir; SQV = saquinavir; SQV/r = saquinavir/ritonavir; TDF = tenofovir; ZDV = zidovudine

Table 6. Advantages and Disadvantages of Antiretroviral Components Recommended as Initial Antiretroviral Therapy

ARV Agent(s)	Advantages	Disadvantages
Nonnucleoside Reverse Transcriptase Inhibitors (in alphabetical order)		
	NNRTI Class Advantages: Long half-lives	NNRTI Class Disadvantages: - Greater risk of resistance at the time of treatment failure than with PIs - Potential for cross-resistance - Skin rash - Potential for CYP450 drug interactions (see Tables 14, 15b, and 16b) - Transmitted resistance more common than with PIs
EFV	- Virologic responses noninferior or superior to most comparators to date - Once-daily dosing - Coformulated with TDF/FTC	- Neuropsychiatric side effects - Teratogenic in nonhuman primates. Several cases of neural tube defect in infants born to women who were exposed to EFV in the first trimester of pregnancy reported. EFV use should be avoided in women with potential for pregnancy and is contraindicated in the first trimester. - Dyslipidemia
NVP	- No food requirement - Fewer lipid effects than EFV - Once-daily dosing with extended-release tablet formulation	- Higher incidence of rash, including rare but serious hypersensitivity reactions (Stevens-Johnson syndrome or toxic epidermal necrolysis), than with other NNRTIs - Higher incidence of hepatotoxicity, including serious and even fatal cases of hepatic necrosis, than with other NNRTIs - Contraindicated in patients with moderate or severe (Child-Pugh B or C) hepatic impairment - Some data suggest that ARV-naïve patients with high pre-NVP CD4 counts (>250 cells/μL for females, >400 cells/μL for males) are at higher risk of symptomatic hepatic events. NVP is not recommended in these patients unless benefit clearly outweighs risk. - Early virologic failure of NVP + TDF (FTC or 3TC) in small clinical trials
RVP	- Once-daily dosing - Coformulated with TDF/FTC - Smaller pill size than coformulated TDF/FTC/EFV or TDF/FTC/EVG/COBI - Compared with EFV: - Fewer discontinuations for central nervous system adverse effects - Fewer lipid effects - Fewer rashes - Smaller pill size	- Not recommended for use in patients with pre-ART HIV RNA >100,000 copies/mL because the rate of virologic failures is higher in these patients - Higher rate of virologic failures observed in patients with pre-ART CD4 count of <200 cells/μL - More NNRTI-, TDF-, and 3TC-associated mutations at virological failure than with regimen containing EFV + two NRTIs - Meal requirement - Absorption depends on lower gastric pH. (See Table 15a for detailed information regarding interactions with H2 antagonists and antacids.) - Contraindicated with PPIs - RPV-associated depression reported - Use RPV with caution when coadministered with a drug having known risk of torsades de pointes.

ARV Agent(s)	Advantages	Disadvantages
Protease Inhibitors (in alphabetical order)		
	PI Class Advantages: - Higher genetic barrier to resistance than NNRTIs and RAL - PI resistance at the time of treatment failure uncommon with RTV-boosted PIs	PI Class Disadvantages: - Metabolic complications such as dyslipidemia, insulin resistance, and hepatotoxicity - Gastrointestinal adverse effects - CYP3A4 inhibitors and substrates: potential for drug interactions (more pronounced with RTV-based regimens) (See Tables 14 and 15a.)
ATV (un-boosted)	- Fewer adverse effects on lipids than other PIs - Once-daily dosing - Low pill burden - Good gastrointestinal tolerability - Signature mutation (I50L) not associated with broad PI cross-resistance	- Indirect hyperbilirubinemia sometimes leading to jaundice or scleral icterus - PR interval prolongation: generally inconsequential unless ATV combined with another drug with similar effect - Unboosted ATV should not be coadministered with TDF, EFV, or NVP (see ATV/r). - Nephrolithiasis, cholelithiasis - Skin rash - Food requirement - Absorption depends on food and low gastric pH (See Table 15a for detailed information regarding interactions with H2 antagonists, antacids, and PPIs.)
ATV/r	- RTV boosting: higher trough ATV concentration and greater antiviral effect - Once-daily dosing - Low pill burden	- More adverse effects on lipids than unboosted ATV - More hyperbilirubinemia and jaundice than unboosted ATV - Food requirement - Absorption depends on food and low gastric pH (See Table 15a for interactions with H2 antagonists, antacids, and PPIs) - RTV boosting is required with TDF and EFV. With EFV, use ATV 400 mg and RTV 100 mg, once daily (PI-naïve patients only). - Should not be coadministered with NVP. - Nephrolithiasis, cholelithiasis
DRV/r	- Once-daily dosing - Potent virologic efficacy	- Skin rash - Food requirement
FPV/r	- Twice-daily dosing resulted in efficacy comparable to LPV/r - Once-daily dosing possible with RTV 100 mg or 200 mg daily - No food effect	- Skin rash - Hyperlipidemia - Once-daily dosing results in lower amprenavir concentrations than twice-daily dosing - For FPV 1,400 mg + RTV 200 mg: requires 200 mg of ritonavir and no coformulation - Fewer data on FPV 1,400 mg + RTV 100 mg dose than on DRV/r and ATV/r

ARV Agent(s)	Advantages	Disadvantages
Protease Inhibitors (in alphabetical order) <i>continued</i>		
LPV/r	• Coformulated • No food requirement • Greater CD4 T-cell count increase than with EFV-based regimens	• Requires 200 mg per day of RTV • Lower drug exposure in pregnant women – may need dosage increase in third trimester • Once-daily dosing not recommended in pregnant women • Once-daily dosing results in lower trough concentration than twice-daily dosing • Possible higher risk of myocardial infarction associated with cumulative use of LPV/r • PR and QT interval prolongation have been reported. Use with caution in patients at risk of cardiac conduction abnormalities or receiving other drugs with similar effect.
SQV/r	• Similar efficacy but less hyperlipidemia than with LPV/r	• Highest pill burden among available PI regimens (6 pills per day) • Requires 200 mg of RTV • Food requirement • PR and/or QT interval prolongations in a healthy volunteer study • Pretreatment ECG recommended • SQV/r is not recommended for patients with any of the following conditions: • Congenital or acquired QT prolongation • Pretreatment ECG >450 msec • On concomitant therapy with other drugs that prolong QT interval • Complete atrioventricular block without implanted pacemakers • Risk of complete atrioventricular block

ARV Agent(s)	Advantages	Disadvantages
Integrase Strand Transfer Inhibitors (in alphabetical order)		
DTG	- Once daily dosing if no resistance to integrase inhibitors - Virologic response noninferior to RAL, superior to DTV/r and EFV	- Inhibits tubular secretion of creatinine and can decrease CrCL without affecting renal glomerular function - May cause headache or sleep disturbance
EVG	- Coformulation with COBI/TDF/FTC - Once-daily dosing - Noninferior to EFV/TDF/FTC and ATV/r + TDF/FTC	- COBI is a potent CYP3A4 inhibitor, which can result in significant interactions with CYP3A substrates. - COBI inhibits active tubular secretion of creatinine and can decrease CrCl without affecting renal glomerular function. - Has potential for new onset or worsening off renal impairment - Only recommended for patients with baseline CrCl >70 mL/min; therapy should be discontinued if CrCl decreased to <50 mL/min - Lower genetic barrier to resistance than with boosted PI-based regimens - Food requirement
RAL	- Virologic response noninferior to EFV - Fewer drug-related adverse events and lipid changes than with EFV - No food effect - Fewer drug-drug interactions than with EVG/COBI/TDF/FTC-, PI-, NNRTI- MVC-based regimens	- Twice-daily dosing - Lower genetic barrier to resistance than with boosted PI-based regimens - Increase in creatine kinase, myopathy, and rhabdomyolysis have been reported - Rare cases of severe hypersensitivity reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis) have been reported
CCR5 Antagonist		
MVC	- Virologic response noninferior to EFV in post-hoc analysis of MERIT study (See text.) - Fewer adverse effects than EFV	- Requires viral tropism testing before initiation of therapy, which results in additional cost and possible delay in initiation of therapy - In the MERIT study, more MVC-treated than EFV-treated patients discontinued therapy owing to lack of efficacy - Less long-term experience in ART-naïve patients than with boosted PI- or NNRTI-based regimens - Limited experience with dual NRTIs other than ZDV/3TC - Twice-daily dosing - CYP 3A4 substrate: dosing depends on presence or absence of concomitant CYP3A4 inducer(s) or inhibitor(s)

ARV Agent(s)	Advantages	Disadvantages
Dual-Nucleoside Reverse Transcriptase Inhibitor Pairs (in alphabetical order)		
ABC/3TC	• Virologic response noninferior to ZDV/3TC • Better CD4 T-cell count responses than with ZDV/3TC • Once-daily dosing • Coformulation • No food effect • No cumulative TAM-mediated resistance	• Potential for abacavir hypersensitivity reaction in patients with HLA-B*5701 • Inferior virologic responses when compared with TDF/FTC in patients with baseline HIV RNA >100,000 copies/mL in ACTG 5202 study; however, this was not seen in the HEAT study • Some observational cohort studies show increased potential for cardiovascular events, especially in patients with cardiovascular risk factors
TDF/FTC	• Better virologic responses than with ABC/3TC in patients with baseline HIV RNA >100,000 copies/mL in ACTG 5202 study; however, this was not seen in the HEAT study • Active against HBV; recommended dual-NRTI for HBV/HIV coinfection • Once-daily dosing • No food effect • Coformulated (TDF/FTC, EFV/TDF/FTC, EVG/COBI/TDF/FTC, and RPV/TDF/FTC) • No cumulative TAM-mediated resistance	• Potential for renal impairment, including proximal tubulopathy and chronic renal insufficiency • Early virologic failure of NVP + TDF + (FTC or 3TC) in small clinical trials • Potential for decrease in bone mineral density
ZDV/3TC	• Coformulated (ZDV/3TC and ZDV/3TC/ABC) • No food effect (although better tolerated with food) • Preferred dual NRTI in pregnant women	• Bone marrow suppression, especially anemia and neutropenia • Gastrointestinal intolerance, headache • Mitochondrial toxicity, including lipoatrophy, lactic acidosis, hepatic steatosis • Compared with TDF/FTC, inferior in combination with EFV • Less CD4 increase compared with ABC/3TC • Twice-daily dosing

Abbreviations: /r = ritonavir boosted; 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV = atazanavir; COBI = cobicistat; CrCl = creatinine clearance; CYP = cytochrome P; d4T = stavudine; ddI = didanosine; DRV = darunavir; DTG = dolutegravir; ECG = electrocardiogram; EFV = efavirenz; EVG = elvitegravir; FPV = fosamprenavir; FTC = emtricitabine; HPV = hepatitis B virus; LPV = lopinavir; MVC = maraviroc; NNRTI = nonnucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PPI = proton pump inhibitor; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQV = saquinavir; TAM = thymidine analogue mutation; TDF = tenofovir; ZDV = zidovudine

EXHIBIT K



Providing Gender-Affirming Care to People with HIV

2022 National Ryan White Conference on HIV Care and Treatment

August 25, 2022

Dana Hines, PhD, RN

Nurse Consultant, Division of Community HIV/AIDS Programs (DCHAP)

HIV/AIDS Bureau (HAB)

Vision: Healthy Communities, Healthy People



Health Resources and Services Administration (HRSA)

Overview



Supports more than 90 programs that provide health care to people who are geographically isolated, economically or medically challenged



HRSA does this through grants and cooperative agreements to more than 3,000 awardees, including community and faith-based organizations, colleges and universities, hospitals, state, local, and tribal governments, and private entities



Every year, HRSA programs serve tens of millions of people, including people with HIV/AIDS, pregnant women, mothers and their families, and those otherwise unable to access quality health care



HRSA's HIV/AIDS Bureau Vision and Mission

Vision

Optimal HIV care and treatment for all to end the HIV epidemic in the U.S.

Mission

Provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities.



HRSA's Ryan White HIV/AIDS Program (RWHAP) Overview

- Provides a comprehensive system of HIV primary medical care, medications, and essential support services for low-income people with HIV.
- Funds grants to states, cities, counties, and local community-based organizations to improve health outcome and reduce HIV transmission.
 - Recipients determine service delivery and funding priorities based on local needs and planning process.
- Provided services to nearly 562,000 people in 2020—more than half of all people with diagnosed HIV in the United States.
- 89.4% of RWHAP clients receiving HIV medical care were virally suppressed in 2020, exceeding national average of 65.5%ⁱ.



i. Centers for Disease Control and Prevention. Core indicators for monitoring the Ending the HIV Epidemic initiative (early release): National HIV Surveillance System data reported through December 2020; and pre-exposure prophylaxis (PrEP) data reported through September 2020. HIV Surveillance Data Tables [Table 5a] 2021;2(No. 2). <http://www.cdc.gov/hiv/library/reports/surveillance-data-tables/vol-2-no-2/index.html>. Published March 2021.

Objectives

- Understand and define the unique gender affirming care and treatment needs of transgender people with HIV
- Help better articulate the principles of gender affirming care
- Identify Ryan White HIV/AIDS Program and other services that can be used to provide gender affirming care to transgender people with HIV



Gender Affirming Care in the RWHAP Program Letter

- Reaffirms the importance of providing culturally-affirming health care and social services to the transgender community
- Letter is *not* new policy or approach to the services delivered by the RWHAP
- Accessible via:
<https://hab.hrsa.gov/sites/default/files/hab/About/RyanWhite/gender-affirming-care-in-the-rwhap.pdf>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville, MD 20857
HIV/AIDS Bureau

December 16, 2021

Dear Ryan White HIV/AIDS Program Colleagues,

Ensuring that transgender people with HIV have access to care, treatment and support services that improve their health and decrease risk of morbidity and mortality related to HIV is a priority for the Health Resources Services Administration's (HRSA) HIV/AIDS Bureau (HAB). Of the more than half a million people served by the Ryan White HIV/AIDS Program (RWHAP) 2.1 percent, approximately 11,600, are transgender.¹ Providing gender-affirming care is an important strategy to effectively address the health and medical needs of transgender people with HIV. HRSA HAB strongly encourages RWHAP service providers to harness and mobilize the existing RWHAP infrastructure and services to support gender-affirming services within allowable RWHAP parameters.

Gender-affirming care and treatment services are described in the *HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (Guidelines).² According to the Guidelines, gender affirmation describes processes whereby a person receives social recognition, value, and support for their gender identity and expression. Gender affirmation is often described across several dimensions, including: social (e.g., social support and acceptance, use of pronouns, names, or clothing that align with their gender identity); medical (e.g., use of hormones or surgery); legal (e.g., legal name change or changing gender markers on identity documents); and psychological (e.g., the degree of self-acceptance and comfort with their gender identity).

RWHAP funds may be used to support gender affirming care across various HRSA RWHAP core medical and support service categories as outlined in *Policy Clarification Notice #16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*.³ Many RWHAP AIDS Drug Assistance Programs (ADAPs) provide access to gender-affirming




Ryan White HIV/AIDS Program

Gender Diverse People with HIV

- Transgender and non-binary people bear a **disproportionate burden of HIV**.
- Encounter a number of social and structural barriers to HIV care.
- Gender affirming care and inclusive environments of care play a key role in entry and engagement in HIV care.

Gender affirmation:

- ✓ Improves engagement in care
- ✓ Improves viral suppression
- ✓ Improves adherence to ART
- ✓ Improves mental health outcomes and well being

Examples of Gender-Affirming Care in the RWHAP

Training on cultural humility, cultural sensitivity, and inclusive environments of care

Behavioral & Mental Health Services

Housing & Case Management

Access to gender affirming hormone therapy

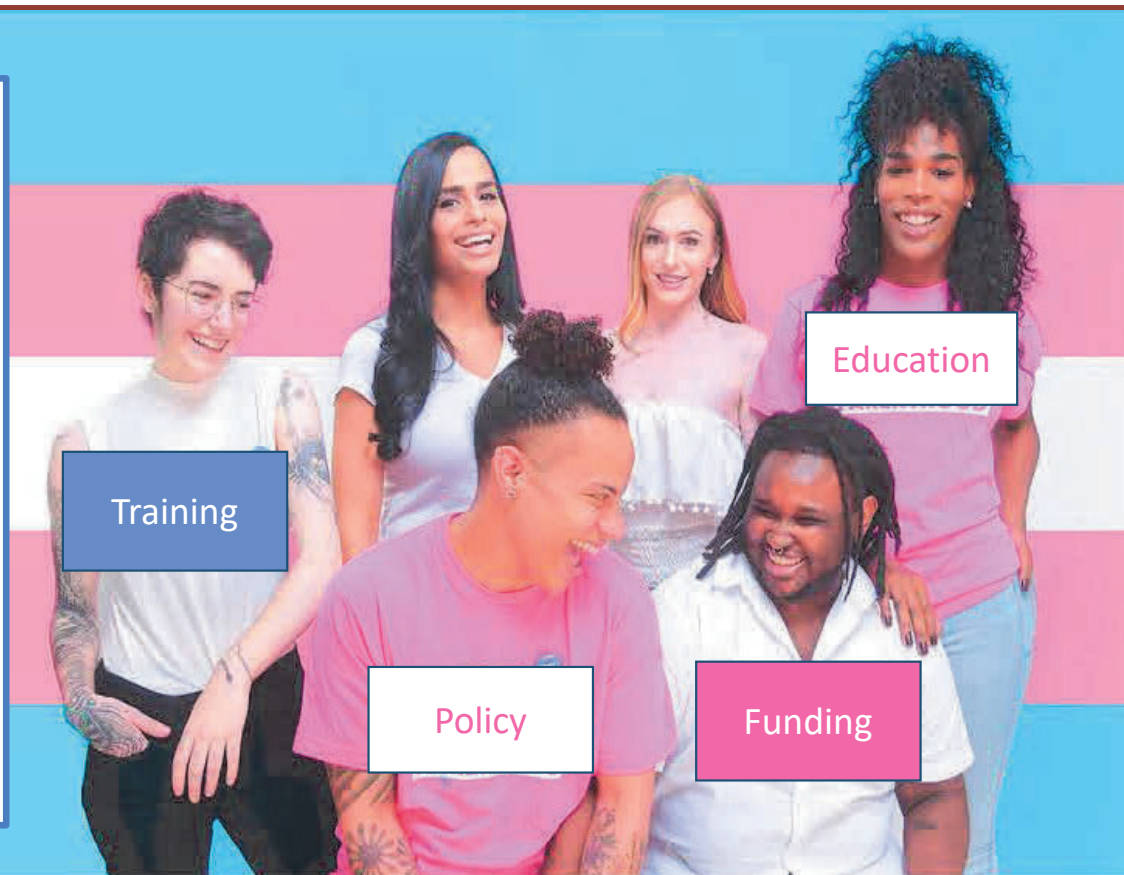
Purchase and maintenance of private health insurance, Medicaid and Medicare coverage

Activities that support patient centered, trauma informed, and inclusive environments of care



Gender Affirming Care Activities in the RWHAP

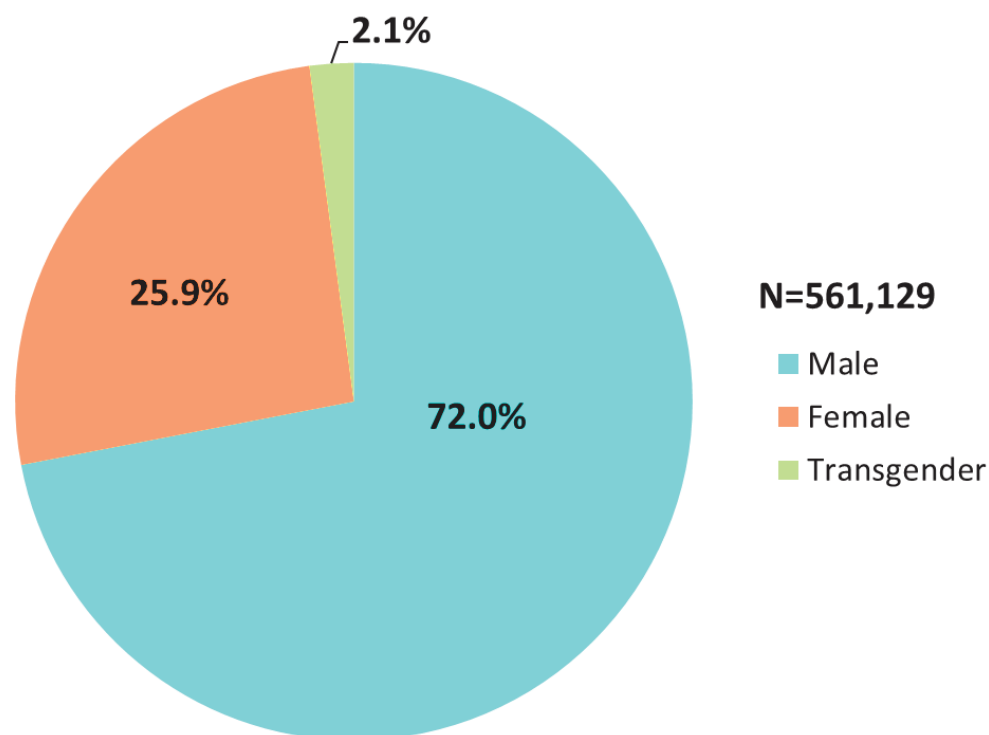
- Updated language in the RWHAP Part D NOFO FY22
- Considering supplemental RWHAP Part D FY23 funding for gender affirming care innovation.
- Gender affirming care presentations at the 2022 NRWC.
- Collaborating with other federal partners to integrate and consolidate gender-affirming care resources and leverage expertise across various agencies.



Transgender Clients served by the RWHAP



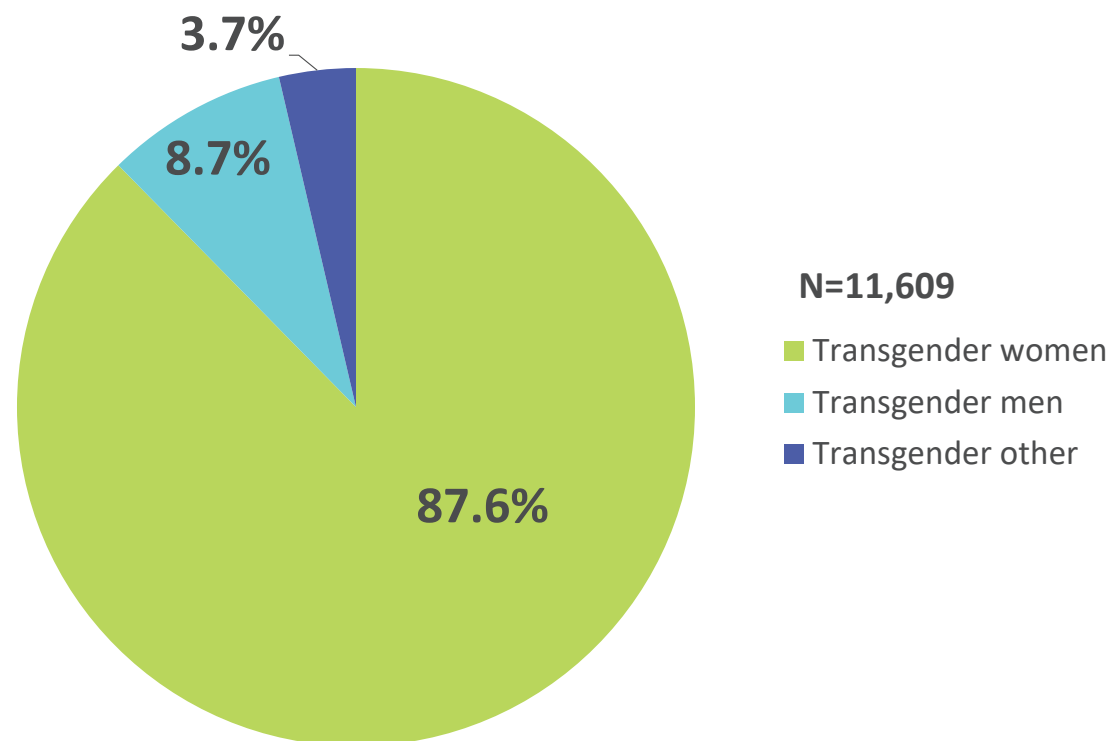
Clients Served by the Ryan White HIV/AIDS Program, by Gender, 2020—United States and 3 Territories^a



^a Guam, Puerto Rico, and the U.S. Virgin Islands.



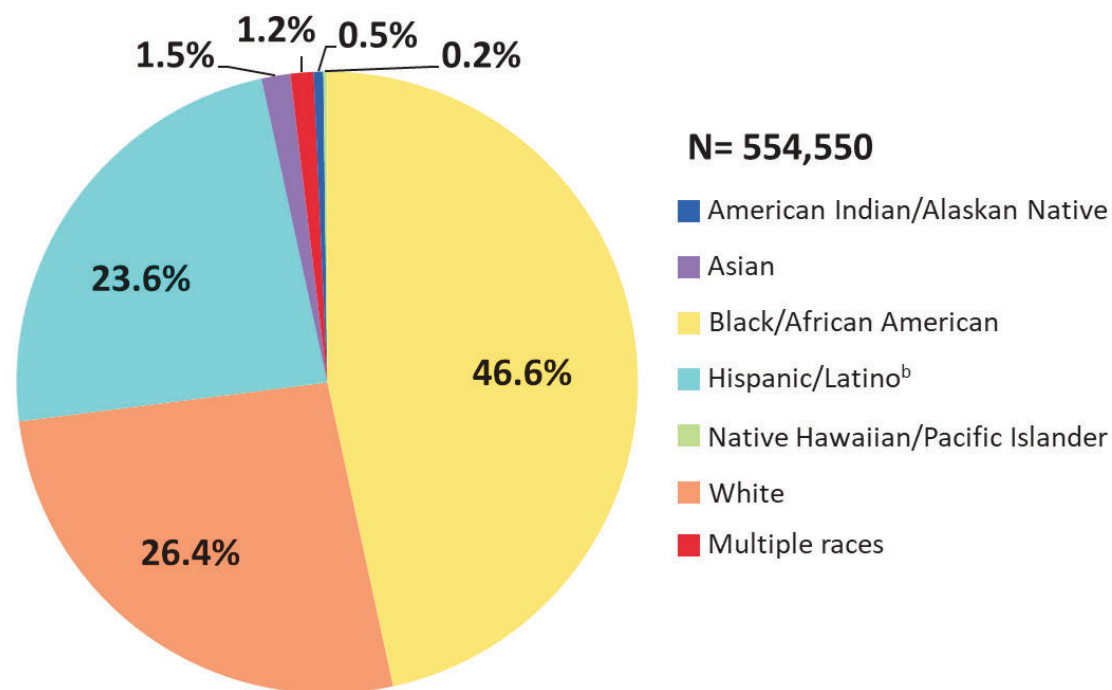
Transgender Clients Served by the Ryan White HIV/AIDS Program, by Gender Identity, 2020—United States and 3 Territories^a



^a Guam, Puerto Rico, and the U.S. Virgin Islands.



Clients Served by the Ryan White HIV/AIDS Program, by Race/Ethnicity, 2020—United States and 3 Territories^a

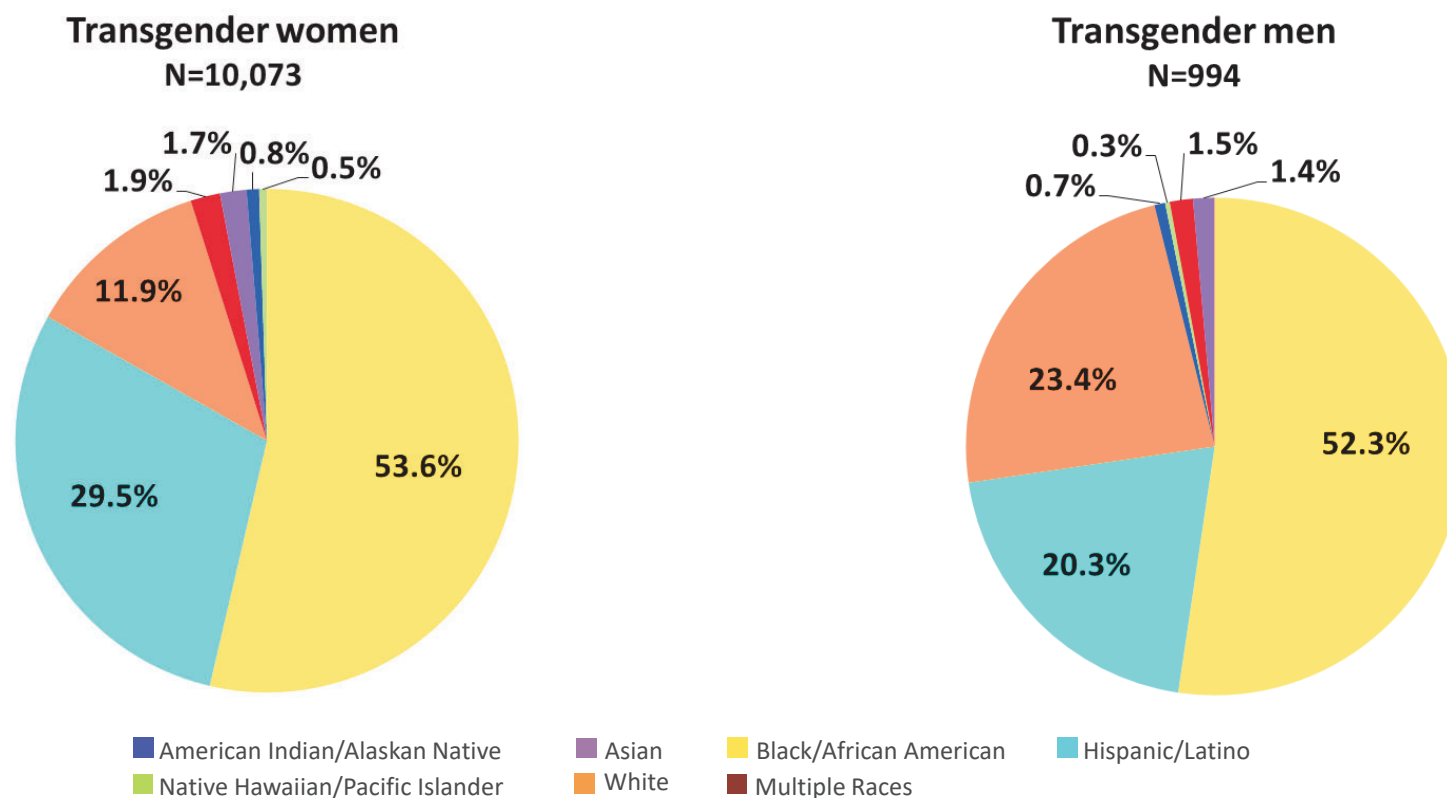


^a Guam, Puerto Rico, and the U.S. Virgin Islands.

^b Hispanics/Latinos can be of any race.



Transgender Clients Served by the Ryan White HIV/AIDS Program, by Gender Identity and Race/Ethnicity, 2020—United States and 3 Territories^a

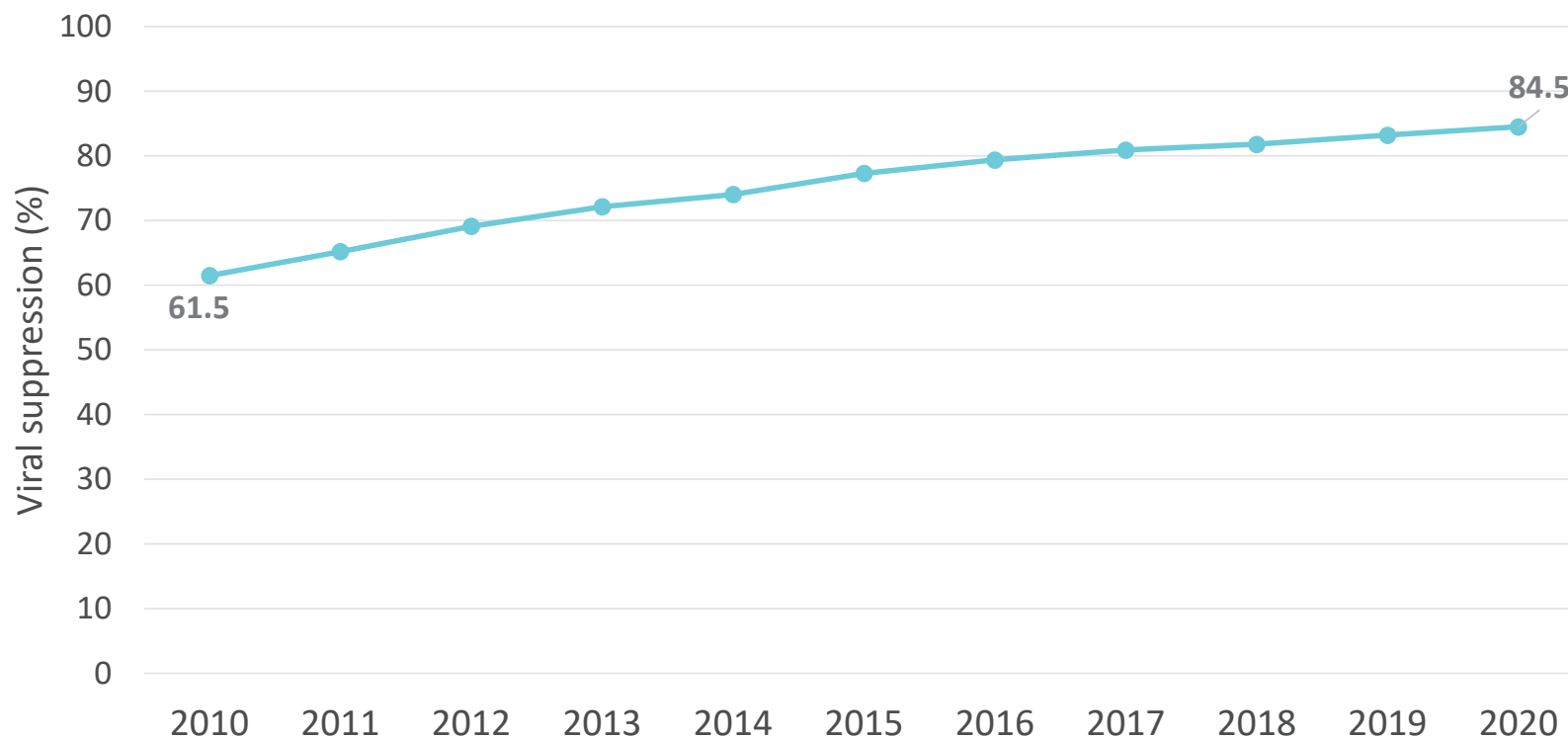


Hispanics/Latinos can be of any race.

^a Guam, Puerto Rico, and the U.S. Virgin Islands.



Viral Suppression among Transgender Clients Served by the Ryan White HIV/AIDS Program, 2010–2020—United States and 3 Territories^a

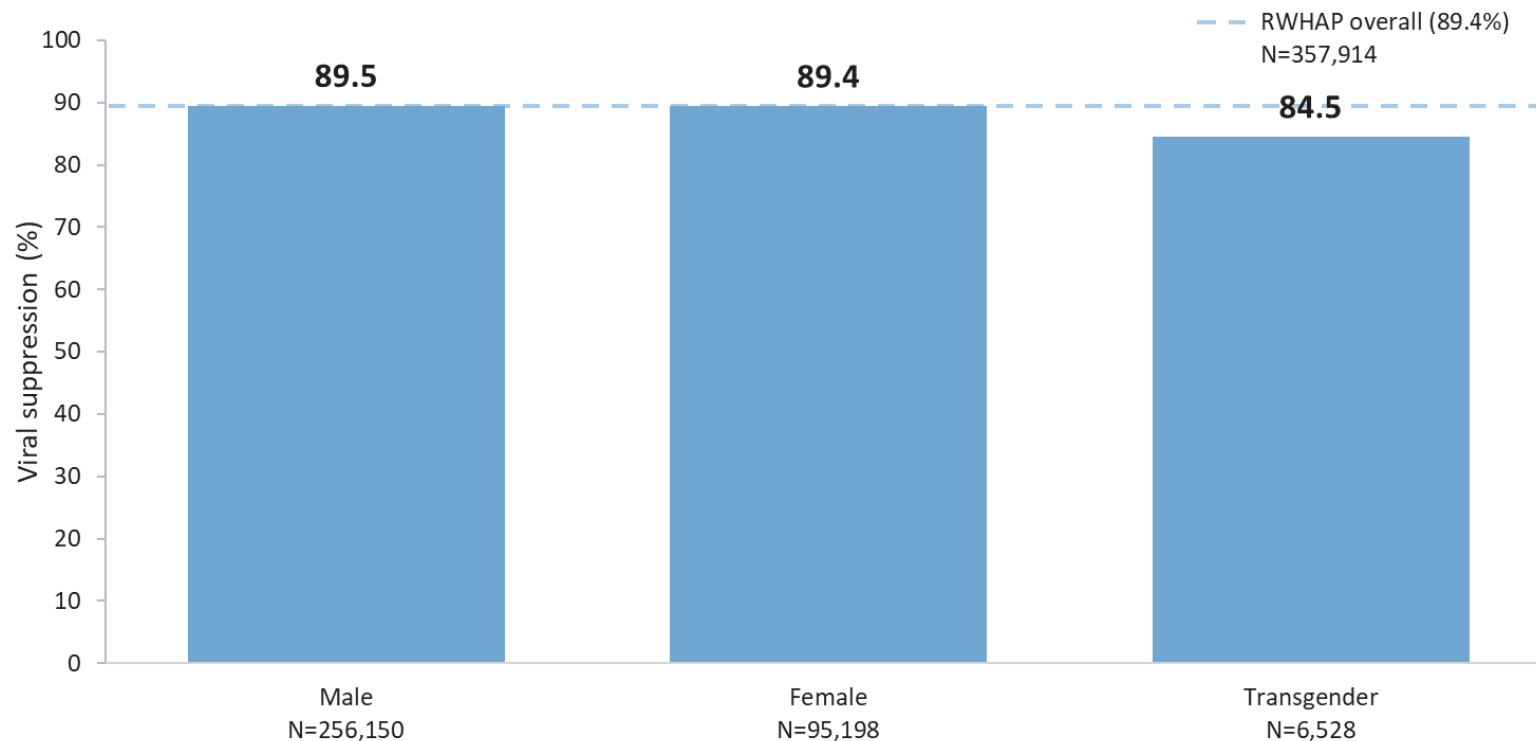


Viral suppression: ≥ 1 OAHS visit during the calendar year and ≥ 1 viral load reported, with the last viral load result < 200 copies/mL.

^a Guam, Puerto Rico, and the U.S. Virgin Islands.



Viral Suppression among Clients Served by the Ryan White HIV/AIDS Program, by Gender, 2020—United States and 3 Territories^a



N represents the total number of clients in the specific population.

Viral suppression: ≥ 1 OAHS visit during the calendar year and ≥ 1 viral load reported, with the last viral load result < 200 copies/mL.

^a Guam, Puerto Rico, and the U.S. Virgin Islands.

Contact Information

Dana Hines, PhD, RN

**Nurse Consultant, Division of Community HIV/AIDS Programs
(DCHAP)**

HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)

Email: dhines@hrsa.gov

Phone: (240) 47-3088

Web: hab.hrsa.gov



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www.ryanwhite.hrsa.gov



Sign up for the Ryan White HIV/AIDS Program Listserv:

<https://public.govdelivery.com/accounts/USHHSRSA/signup/29907>



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Care for Transgender and Gender Diverse Communities

- Alex Keuroghlian, MD, MPH
 - Director, Division of Education and Training, The Fenway Institute
 - Director, Division of Public and Community Psychiatry, Massachusetts General Hospital
 - Associate Professor of Psychiatry, Harvard Medical School

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22

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Disclosures

Alex Keuroghlian received royalties as editor of a McGraw Hill textbook on transgender and gender diverse health care.

Disclosure will be made when a product is discussed for an unapproved use.

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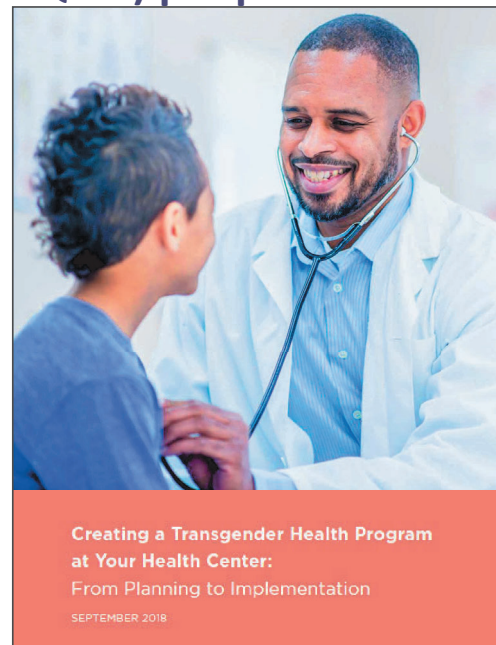
There was no commercial support for this activity.

Education and Training in Gender-affirming Care

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The National LGBTQIA+ Health Education Center offers educational programs, resources, and consultation to health care organizations with the goal of providing affirmative, high quality, cost-effective health care for lesbian, gay, bisexual, transgender, queer, intersex and asexual, and all sexual and gender minority (LGBTQIA+) people.

- Training and Technical Assistance
- Grand Rounds
- ECHO Programs
- Online Learning
 - Webinars and Learning Modules
 - CE, and HEI Credit
- Resources and Publications
- www.lgbtqiahealtheducation.org



Sexual Orientation and Gender Identity are Not the Same



- All people have a sexual orientation and gender identity
 - How people identify can change
 - Terminology varies
- Gender Identity $\neq$ Sexual Orientation



Sex Assigned at Birth



- Female
- Male
- Intersex

Gender Identity and Gender Expression



- Gender identity
 - A person's inner sense of being a girl/woman, boy/man, both, beyond, or having no gender
 - All people have a gender identity
- Gender expression
 - How one presents themselves through their behavior, mannerisms, speech patterns, dress, and hairstyles
 - May be on a continuum

A complete glossary of terms is available at <https://www.lgbtqiahealtheducation.org/publication/lgbtqia-glossary-of-terms-for-health-care-teams/>

Gender Identity Terminology

- Transgender: gender identity beyond societal expectations related to sex assigned at birth
- Binary terminology
 - Transgender woman, trans woman
 - Transgender man, trans man
- Non-binary
 - Genderqueer person, gender fluid person
- Trans masculine, Trans feminine
- Gender identity is increasingly described as being on a continuum



Understanding Gender Transition/Affirmation



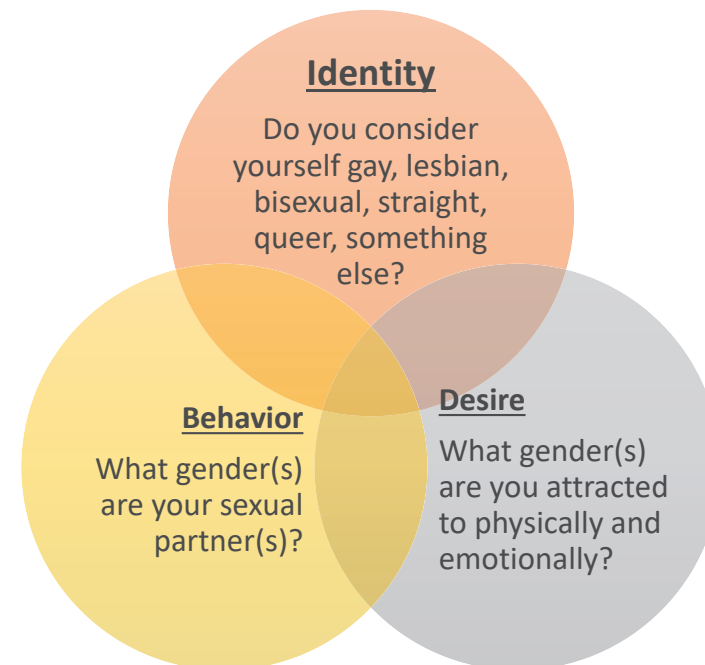
- The process of changing from living and being perceived as the gender traditionally associated with the sex assigned at birth (e.g., F or M) to living and being perceived as the individual sees and understands themselves.
 - Social affirmation
 - Legal/document changes
 - Hormone therapy
 - Surgical affirmation

Sexual Orientation



- Sexual orientation: how a person experiences their physical, emotional and romantic attachments to others
- Desire
- Behavior
 - Risk of sexually transmitted infections is related to behavior, not identity
- Identity
 - e.g., gay, straight, lesbian, bisexual, queer, asexual, pansexual

Dimensions of Sexual Orientation:

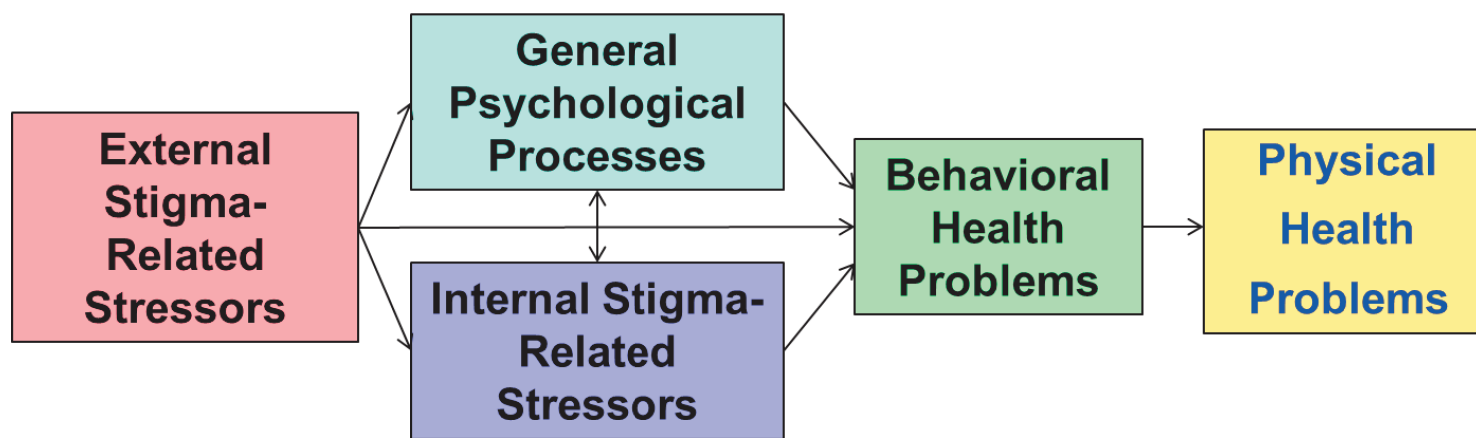


What Does 'Q' Stand For?

- 'Q' may reflect someone who is 'questioning' their gender identity or sexual orientation.
- 'Q' may stand for 'queer,' a way some people identify to state they are not straight or cisgender. It is now also a term of self-identification for many transgender and gender diverse people. The term queer is particularly commonly used by younger people, and also by people of all ages.

Gender Minority Stress Framework

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Adapted from Hatzenbuehler (2009)

Gender Minority Stress Care Principles

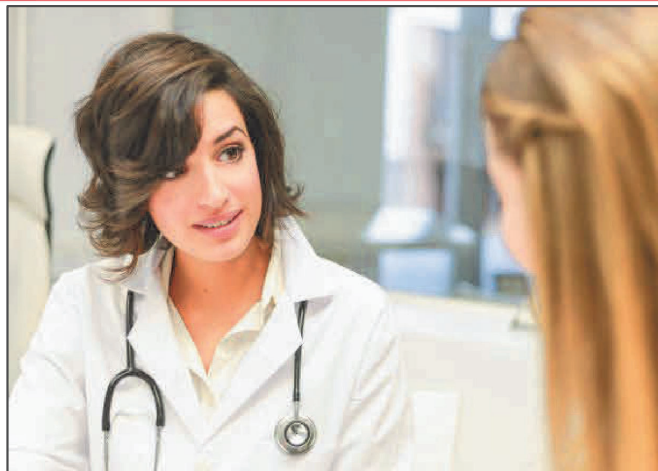


- Normalize adverse impact of gender minority stress
- Facilitate emotional awareness, regulation, and acceptance
- Empower assertive communication
- Restructure minority stress cognitions
- Validate unique strengths of transgender and gender diverse people
- Foster supportive relationships and community
- Affirm healthy, rewarding expressions of gender

Adapted from Pachankis (2015)

Gender Minority Stress Care Principles

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Learning to Address Implicit Bias Towards LGBTQ Patients: Case Scenarios

September 2018

 NATIONAL LGBT HEALTH
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Psychosomatics 2020; ■■■ ■ © 2020 Academy of Consultation-Liaison Psychiatry. Published by Elsevier Inc. All rights reserved.

Perspective

Strategies to Mitigate Clinician Implicit Bias Against Sexual and Gender Minority Patients

Michal J. McDowell, M.D., M.P.H., Hilary Goldhammer, S.M., Jennifer E. Potter, M.D.,
Alex S. Keuroghlian, M.D., M.P.H.

Background: *Implicit bias is an ingrained, unconscious cultural stereotype that can negatively affect a person's interactions with members of stigmatized groups, including sexual and gender minorities. Clinician implicit biases may negatively impact the quality of patient care.*
Methods: *This article uses 4 case scenarios to illustrate how implicit bias among psychiatrists and other clinicians can affect patient-clinician communication and diminish the quality of health care provided to sexual and*

gender minority people. We offer strategies for clinicians to recognize, challenge, and address implicit bias.
Discussion: *Through continuing education, self-reflection, and practice, psychiatrists and other clinicians can improve communication and foster more affirming care experiences for their sexual and gender minority patients, with the goal of addressing and ultimately eliminating sexual and gender minority health disparities.*

(*Psychosomatics* 2020; ■■■ ■)

Key words: sexual minority, gender minority, implicit bias, unconscious bias, LGBT, communication.

Health Disparities: U.S. Transgender Survey



- 39% of respondents experienced **serious psychological distress** in the month prior (compared to 5% of the U.S. population)
- 40% had **lifetime suicide attempt** (compared to 4.6% of US population)
- In the preceding 12 months:
 - 48% had seriously thought about suicide
 - 24% made a plan to kill themselves
 - 7% had attempted suicide
- Of the 40% who attempted suicide at one point in their lives:
 - 34% had first attempt by age 13
 - 92% had first attempt by age 25

James *et al.* (2016)

Prevalence of Status Quo Interventions

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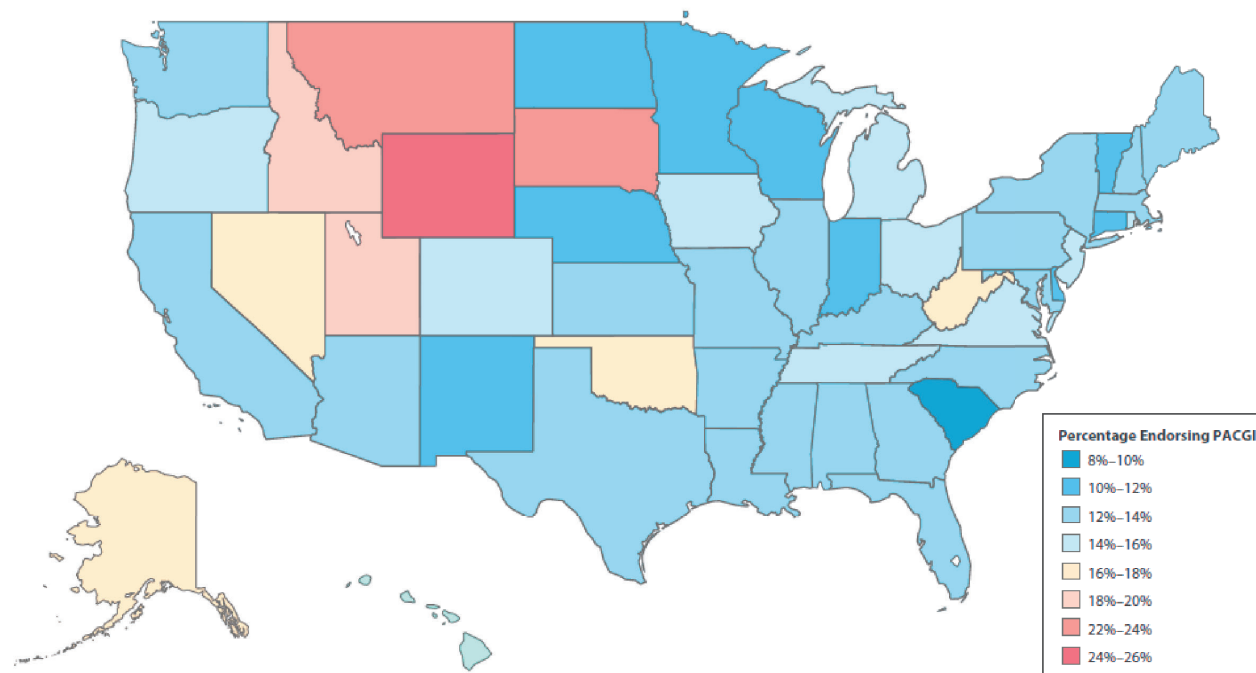
AJPH OPEN-THEMED RESEARCH

Psychological Attempts to Change a Person's Gender Identity From Transgender to Cisgender: Estimated Prevalence Across US States, 2015

Jack L. Turban, MD, MHS, Dana King, ALM, Sari L. Reisner, ScD, and Alex S. Keuroghlian, MD, MPH

Gender Identity Conversion Efforts Across the United States

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Note. Heat map depicts the percentage of respondents from the 2015 US Transgender Survey reporting lifetime exposure to PACGI.

FIGURE 1—Estimated Proportion of Transgender People Exposed to Psychological Attempts to Change a Person's Gender Identity From Transgender to Cisgender (PACGI): United States, 2015

Mental Health Effects of Gender Identity Conversion Efforts

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Research

JAMA Psychiatry | [Original Investigation](#)

Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults

Jack L. Turban, MD, MHS; Noor Beckwith, MD; Sari L. Reisner, ScD, MA; Alex S. Keuroghlian, MD, MPH

Conversion Efforts Associated with Increased Odds of Suicide Attempts



- Lifetime exposure associated with:
 - lifetime suicidal attempt (aOR 2.27; 95% CI 1.09 to 2.24; $P<.001$)
- Exposure before age 10 associated with:
 - lifetime suicide attempt (aOR 4.15; 95% CI, 2.44-7.69; $P<0.001$)
- No difference in outcomes between conversion efforts by religious advisors versus secular-type professionals

Take Two: Asking Communities What Health Care They Want

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PLOS ONE

RESEARCH ARTICLE

Understanding community member and health care professional perspectives on gender-affirming care—A qualitative study

Stephanie Loo^{1,2}, Anthony N. Almazan³, Virginia Vedilago¹, Brooke Stott¹, Sari
L. Reisner^{1,3,4,5}, Alex S. Keuroghlian^{1,3,6*}

PATH

Plan and Act for Transgender Health

Community-led Gender-affirming Priorities



- Psychosocial affirmation for children and adolescents
- Pubertal suppression
- Gender-affirming hormone therapy for adolescents and adults
- Gender-affirming surgery and hair removal
- Debunking 'detransition' and regret narratives
- Moving beyond psychiatric diagnosis requirements
- Guidelines for gender-affirming mental health care
- Harnessing gender identity data in electronic health records
- Blueprint for building a transgender health program

Social Gender Affirmation for Youth Associated with Good Adult Mental Health

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ELSEVIER

JOURNAL OF
ADOLESCENT
HEALTH

www.jahonline.org

Original article

Timing of Social Transition for Transgender and Gender Diverse Youth, K-12 Harassment, and Adult Mental Health Outcomes

Jack L. Turban, M.D., M.H.S.^{a,*}, Dana King, A.L.M.^b, Jason J. Li, B.A.^c, and Alex S. Keuroghlian, M.D., M.P.H.^{b,d}

^a Division of Child & Adolescent Psychiatry, Stanford University School of Medicine, Palo Alto, California

^b The Fenway Institute, Boston, Massachusetts

^c Department of Psychiatry, Harvard Medical School, Boston, Massachusetts

^d Department of Psychiatry, Massachusetts General Hospital, Boston, Massachusetts

Article history: Received February 11, 2021; Accepted June 1, 2021

Pubertal Suppression Associated with Decreased Lifetime Suicidal Ideation

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PEDIATRICS[®]

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation

Jack L. Turban, MD, MHS,^a Dana King, ALM,^b Jeremi M. Carswell, MD,^c Alex S. Keuroghlian, MD, MPH^{ab}



REUTERS JANUARY 23, 2020 / 4:12 PM / UPDATED 2 YEARS AGO

For some trans youth, suicide risk lowers with puberty suppression



health Life, But Better Fitness Food Sleep Mindfulness Relationships

LIVE TV Edition ▾

Puberty blockers can be 'life-saving' drugs for trans teens, study shows

Gender-affirming Hormones Associated with Better Adult Mental Health

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PLOS ONE

RESEARCH ARTICLE

Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults

Jack L. Turban^{1*}, Dana King², Julia Kobe², Sari L. Reisner^{2,3,4,5}, Alex S. Keuroghlian^{2,6,7}

NEWS

Early access to gender-affirming hormones linked to better mental health, study finds

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OUT HEALTH AND WELLNESS

Early access to gender-affirming hormones linked to better mental health, study finds

Trans people who had access to hormones during their early teens had less than half the odds of past-year suicidal thoughts than those who could not access them.

Gender-affirming Surgeries Associated with Decreased Odds of Suicide Attempts

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Research

JAMA Surgery | **Original Investigation**

Association Between Gender-Affirming Surgeries and Mental Health Outcomes

Anthony N. Almazan, BA; Alex S. Keuroghlian, MD, MPH

 **NEWS**

Gender-affirming surgery linked to better mental health, study finds

SHARE THIS —



OUT HEALTH AND WELLNESS

Gender-affirming surgery linked to better mental health, study finds

"We should be expanding gender-affirming care, not limiting it," the report's lead author said.

Gender-affirming Hair Removal Associated with Decreased Suicidal Ideation

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Healio

Dermatology

Hair removal in gender-affirming care not covered by most Medicaid, ACA policies

Letters

RESEARCH LETTER

Association Between Gender-Affirming Hair Removal and Mental Health Outcomes

Michelle S. Lee, BA
Anthony N. Almazan, BA
Vinod E. Nambudiri, MD, MBA
Alex S. Keuroghlian, MD, MPH

JAMA
Dermatology

Understanding “Detransition” and Dynamic Gender Presentations

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Understanding “Detransition” and Dynamic Gender Presentations

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Factors Leading to “Detransition” Among Transgender and Gender Diverse People in the United States:
A Mixed-Methods Analysis

Understanding Pediatric Patients
Who Discontinue Gender-Affirming
Hormonal Interventions
JAMA Pediatrics

**Dynamic Gender Presentations: Understanding
Transition and “De-Transition” Among
Transgender Youth**

Journal of the American Academy of
**CHILD & ADOLESCENT
PSYCHIATRY**

Moving Beyond Psychiatric Diagnosis Requirements

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BJPsych

The British Journal of Psychiatry (2020)
Page 1 of 2. doi: 10.1192/bjp.2020.124

Editorial

Envisioning a future for transgender and gender-diverse people beyond the DSM

Jacob E. Perlson, Oakland C. Walters and Alex S. Keuroghlian

COMMENTARY ►

Why Must We Keep Diagnosing Trans People as Ill?



Thinking of a future where trans identity is not connected to pathology.

BY ALEX KEUROGHLIAN

Developing Guidelines for Gender-affirming Behavioral Health Care

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JAMA Network Insights

Psychopharmacologic Considerations for Transgender and Gender Diverse People

Jack L. Turban, MD, MHS; Marija Kamceva, BS; Alex S. Keuroghlian, MD, MPH

Affirming Gender Identity of Patients With Serious Mental Illness

William B. Smith, M.D., Hilary Goldhammer, S.M., Alex S. Keuroghlian, M.D., M.P.H.

Transgender people who experience serious mental illness represent a uniquely vulnerable population. Because of limited research, however, recommendations for treating this population are scarce. In this article, the authors describe the challenge of recognizing gender dysphoria in people with serious mental illness. They then discuss why existing evidence and clinical experience support provision of gender-affirming

medical and surgical treatments for transgender people who have serious mental illness and also demonstrate capacity to make informed medical decisions. More research is needed to develop evidence-based treatments and programs for transgender people with serious mental illness.

Psychiatric Services 2018; 0:1–3; doi: 10.1176/appi.ps.201802022

PERSPECTIVES

Distinguishing and Addressing Gender Minority Stress and Borderline Personality Symptoms

Hilary Goldhammer, SM, Cary Crall, MD, and Alex S. Keuroghlian, MD, MPH

Abstract: As transgender and gender-diverse people are gaining increased visibility in clinical settings, clinicians are requesting better guidance on providing affirming care to improve the mental health and well-being of these patients. In particular, more direction is needed on whether, when, and how to diagnose and treat borderline personality disorder among gender minorities, partially in response to beliefs among some mental health clinicians that a gender minority identity may be a manifestation of identity diffusion. In this Perspectives article, we argue that gender minority identity, even when fluid, is rarely a sign of identity diffusion. By taking a careful history of a patient's gender identity development, the clinician can clarify and gain more conviction regarding the presence of a patient's gender minority identity. Moreover, multiple stigma-related stressors experienced by gender minorities may produce symptoms and behaviors that can mimic or be consistent with certain diagnostic criteria for borderline personality disorder. We therefore conclude with recommendations for adopting a gender-affirming framework to treat borderline personality symptoms when present among gender minority patients, with implications for future research and practice.

Keywords: borderline personality disorder, gender dysphoria, gender identity, gender minority, transgender

Screening, Counseling, and Shared Decision Making for Alcohol Use with Transgender and Gender-Diverse Populations

Jacob Arellano-Anderson, BS¹ and Alex S. Keuroghlian, MD, MPH¹⁻³

Abstract

At-risk alcohol use occurs among transgender and gender-diverse (TGD) populations, yet current alcohol use screening tools and guidelines do not distinguish between sex- and gender-related characteristics, having been developed without accounting for natal sex-based physiology, effects of gender-affirming medical care, and gendered drinking behavior among TGD people. More research on how sex- and gender-related factors independently influence alcohol use can help validate gender-inclusive screening protocols and develop evidence-based guidelines meaningful for people of all genders. In the interim, clinicians must be mindful of gender diversity and engage in transparent, collaborative discussions when screening for and counseling about alcohol use.

Keywords: alcohol, counseling, gender identity, nonbinary, screening, transgender

Harnessing Patient Gender Identity Data in Electronic Health Records

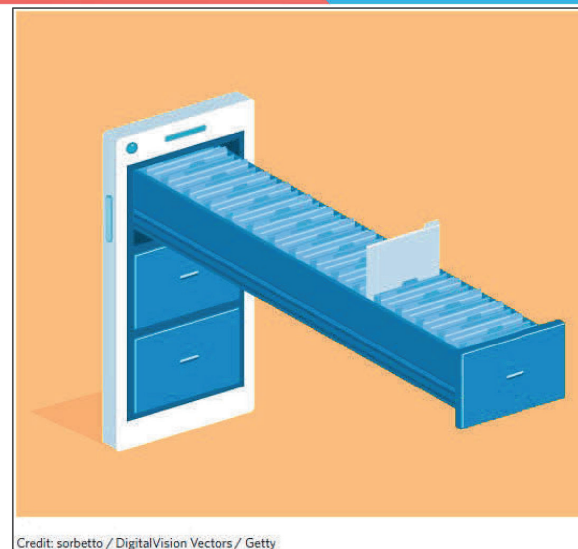
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Planning and implementing sexual orientation and gender identity data collection in electronic health records

Chris Grasso,^{1,*} Michal J McDowell,^{2,4,*} Hilary Goldhammer,³ and Alex S Keuroghlian^{2,3,4}

Optimizing gender-affirming medical care through anatomical inventories, clinical decision support, and population health management in electronic health record systems

Chris Grasso,¹ Hilary Goldhammer,² Julie Thompson,³ and Alex S. Keuroghlian^{4,5}



Credit: sorbetto / DigitalVision Vectors / Getty

Electronic health records as an equity tool for LGBTQIA+ people

Collection of data on sexual orientation, gender identity and intersex status will help to reduce health disparities that affect people from sexual and gender minority communities.

Alex S. Keuroghlian

NATURE MEDICINE | www.nature.com/naturemedicine

A Blueprint for Building a Transgender Health Program

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A Blueprint for Planning and Implementing a Transgender Health Program

Anna M. Morenz, MD¹

Hilary Goldhammer, SM²

Cei A. Lambert, MFA⁴

Ruben Hopwood, MDiv, PhD^{4,5}

Alex S. Keuroghlian, MD, MPH^{2,3,6}

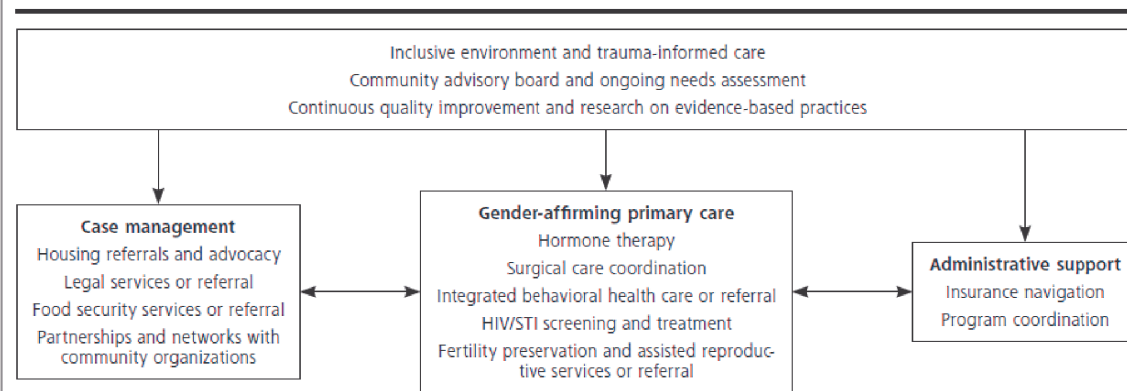
¹Department of Medicine, University of Washington, Seattle, Washington

²Harvard Medical School, Boston, Massachusetts

ABSTRACT

Transgender and gender-diverse people face multiple barriers to accessing appropriate health care, including denial of service, harassment, and lack of clinician knowledge. This article presents a blueprint for planning and implementing a transgender health program within a primary care practice in order to enhance the capacity of the health care system to meet the medical and mental health needs of this underserved population. The steps described, with emphasis on elements specific to transgender care, include conducting a community needs assessment, gaining commitment from leadership and staff, choosing a service model and treatment protocols, defining staff roles, and creating a welcoming environment.

Figure 1. Suggested components of a comprehensive transgender health program.



STI = sexually transmitted infection.

ANNALS OF
FAMILY MEDICINE

Role of Providers in Gender Affirmation Process



- Fostering gender identity exploration, discovery and affirmation
- Presenting appropriate medical and non-medical strategies for gender affirmation
- Assistance in making fully informed decisions regarding personalized gender affirmation process:
 - relevant options
 - risks/benefits
 - evaluate capacity for medical decision making/informed consent
 - arranging suitable referrals to care

Pronouns

People may have a range of pronouns, including she/her/hers and he/him/his, as well as less-common pronouns such as they/them/theirs and ze/hir/hirs (pronounced zee/hear/hears).



Subjective	Objective	Possessive	Examples
He	Him	His	He is in the waiting room. The doctor is ready to see him. That chart is his.
She	Her	Hers	She is in the waiting room. The doctor is ready to see her. That chart is hers.
They	Them	Theirs	They are in the waiting room. The doctor is ready to see them. That chart is theirs.
Ze	Hir	Hirs	Ze is in the waiting room. The doctor is ready to see hir. That chart is hirs.

Collecting Data on Gender Identity

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- What name do you go by?
- What name is on your insurance records?
- What are your pronouns (e.g., she/her, he/him, they/them)?
- What is your current gender identity?
- What sex were you assigned at birth?



Anticipating and Managing Expectations



- Transgender and gender diverse people have a history of experiencing stigma and discrimination in diverse settings
- Don't be surprised if a mistake results in a patient becoming upset
- Don't personalize the reaction
- Apologizing when patients become upset, even if what was said was well-intentioned, can help defuse a difficult situation and re-establish a constructive dialogue

Avoiding Assumptions



- You cannot assume someone's gender identity based on how they look or sound.
- To avoid assuming gender identity:
 - *Instead of:* "How may I help you, Ma'am/Sir?"
 - *Say:* "How may I help you?"
 - *Instead of:* "He/She is here for his/her appointment."
 - *Say:* "The patient is here in the waiting room."

Keeping Up with Terminology

- Obvious “don’ts” include
 - Use of any disrespectful language
 - Gossiping about a person’s appearance or behavior
 - Saying things about someone not necessary for their care:
 - “You look great, you look like a real woman/real man!”

Avoid these Outdated Terms (in English)	Consider these Terms Instead
Homosexual	Gay, lesbian, bisexual, or LGBTQIA+
Transvestite; Transgendered	Transgender
Sexual preference; Lifestyle choice	Sexual orientation
Sex Change	Gender-affirming care

Inclusive Registration and Medical History Forms

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Avoid these terms...	Replace with...
Mother/Father	Parent/Guardian
Husband/Wife	Spouse/Partner(s)
Marital Status	Relationship Status
Family History	Blood Relatives
Nursing Mother	Currently Nursing
Female Only/Male Only	Allow patients to choose <i>not applicable</i>.



Focus on Forms and Policy:

**Creating an Inclusive Environment
for LGBT Patients**

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Gender-inclusive Diagrams

- Images that have a specific gender may limit identification of certain medical issues
- Use gender-inclusive images to document areas of concern

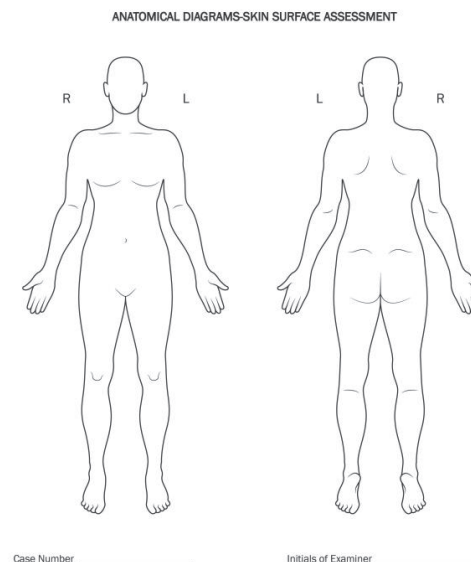
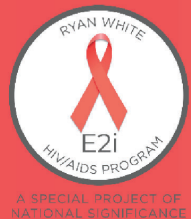


Image by: Katja Tezlaff
(<https://ktetzlaff.com/tag/transgender/#jp-carousel-456>)



Evidence-informed Interventions for transgender women with HIV

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Topical Review

PUBLIC
HEALTH
REPORTS

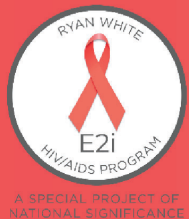
HIV Care Continuum Interventions for Transgender Women: A Topical Review

Hilary Goldhammer, SM¹ ; Linda G. Marc, ScD^{1,2};
Demetrios Psihopaidas, PhD, MA³; Nicole S. Chavis, MPH³ ;
Massah Massaquoi, MPH¹; Sean Cahill, PhD^{1,4,5};
Greg Rebchook, PhD⁶; Sari Reisner, ScD^{1,2,7,8};
Kenneth A. Mayer, MD^{1,2,8,9}; Stacy M. Cohen, MPH³;
and Alex S. Keuroghlian, MD, MPH^{1,8,10}

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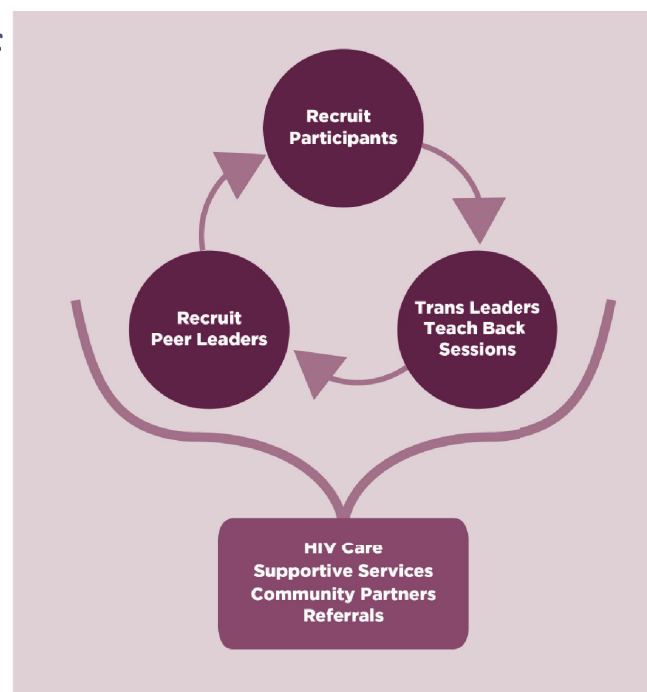
- Culturally affirming programs that serve as gateway to HIV care and combined gender-affirming care and social services with HIV care
- Interventions to improve behavioral health outcomes
- Peer-led counseling, education and navigation
- Technology-based interventions to increase access to care management and online social support

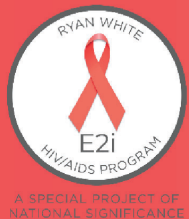


Transgender Women Engagement and Entry to Care Project (T.W.E.E.T.)

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- Link and engage women of transgender experience into HIV care
- Popular Opinion Leaders
- 5 Trans Leaders (TL)-Teach Back Sessions
- Peers engage community partners for supportive services

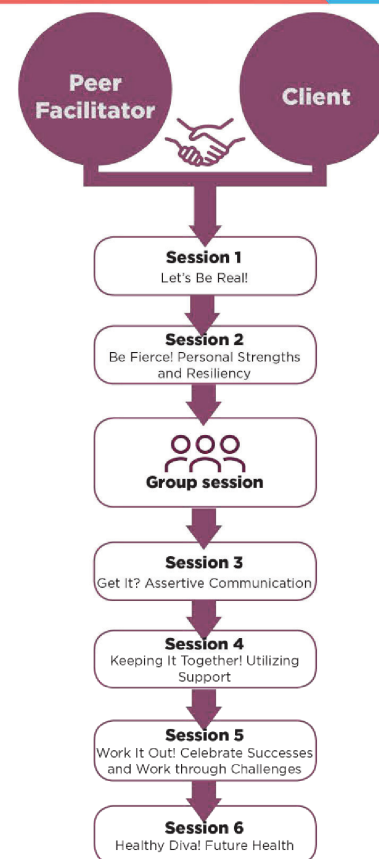


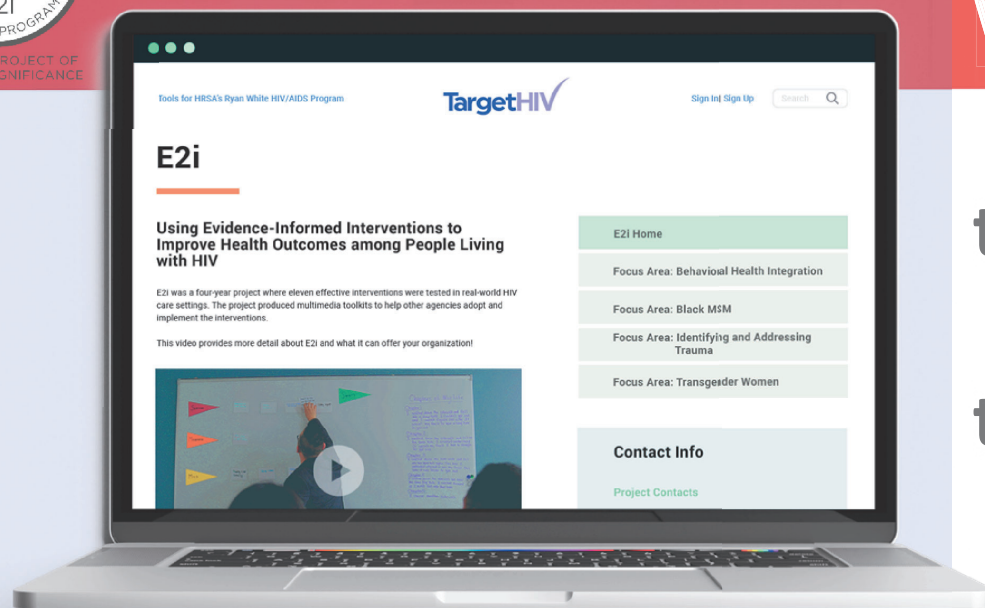
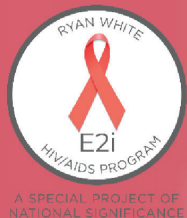


Healthy Divas

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- Gender affirmation framework
- Peer facilitation
- 6 individual sessions
- 1 group workshop
 - Peer facilitators
 - Health care providers
- Supportive services & referrals





E2i's comprehensive and easy-to-use toolkits are designed to support clinical practices, community-based organizations and other direct service providers across the Ryan White HIV/AIDS Program in adapting evidence-informed interventions for their local communities.

E2i's eleven interventions fall into four focus areas:

- Transgender women with HIV
- Black men who have sex with men (BMSM) with HIV
- Integrating behavioral health with primary medical care for people with HIV
- Identifying and addressing trauma for people with HIV

About E2i

- + Overview
- + Funding Source
- + Funded Organizations
- + Intervention Strategy Selection Process

Where?

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targethiv.org/e2i

targethiv.org/bestpractices

- All about the E2i initiative
- Video trailers for focus areas and interventions
- The 11 E2i Toolkits
- Links to peer-reviewed publications

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Providing Gender Affirming Care: El Rio Health – FQHC, Tucson, AZ

Paul Sacamano, PhD, MPH, NP-C, AAHIVS
Jamie Weinand, MD

El Rio Health, Special Immunology Associates

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22

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Disclosures



Drs. Paul Sacamano and Jamie Weinand have no relevant financial interests to disclose.

Disclosure will be made when a product is discussed for an unapproved use.

This continuing education activity is managed and accredited by AffinityCE, in collaboration with the Health Resources and Services Administration (HRSA), LRG, and AffinityCE. AffinityCE, LRG and HRSA staff, as well as planners and reviewers, have no relevant financial interests to disclose. AffinityCE adheres to the ACCME's Standards for Integrity and Independence in Accredited Continuing Education. Any individuals in a position to control the content of a CME activity, including faculty, planners, reviewers, or others, are required to disclose all relevant financial relationships with ineligible entities (commercial interests). All relevant conflicts of interest have been mitigated prior to the commencement of the activity.

There was no commercial support for this activity.

Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Describe potential intersectionality within gender affirming care for diverse communities of people living with HIV
2. Identify the impact of providing gender affirming care on primary care and HIV management.
3. Explain mental health benefits of gender affirming care for transgender individuals.

El Rio Health



- Demographics overview:
 - Total patients within healthcare system: 125,449
 - Total patients within El Rio Ryan White clinic: 1,582
 - Racial and ethnic: White 52%; Hispanic 33%; Black 10%; Native American 3%
 - Note: Data on citizenship status not collected.
 - Gender identity: Male 1,296, Female 205, Transgender 19
 - Substance use disorders: 48%



Intersectionality



Regional considerations with patients living on both sides of the Mexican-American border

- Collaborations: El Rio x Mexican Consulate and El Rio x Mexican Secretariat of Health (CAPASITS)
- Barriers: Immigration status, language, cultural and religious beliefs
- Crossing border to access medications and care, bidirectional
- Opportunities: Navigation to medical home and other services

Intersectionality

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Local indigenous communities

- Native American culture x western culture and religion
- Urban vs tribal residents
- Case 1: Tohono O’Odham Nation: gender non-conforming presentation and roles, “addition” of other
- Case 2: Pascua Yaqui: Tribal nurse navigator, patient rights
- Case 3: Variability of cultural beliefs across tribes



Gender affirming care as primary care



- Gender affirming care:
 - Primary care
 - Case 1: Gender affirming care is part of primary care.^{1,2} Smoking cessation, estradiol, identifying with gender-affirmed body
 - Improves care related to HIV:
 - Case 2: Gender affirming hormone therapy may improve HIV viral suppression.³ Taking antiretrovirals for HIV management and estradiol
 - Life-saving care
 - Case 3: Transgender suicide attempt rate has been cited at 41%, with notable improvements in psychological functioning, depression with gender-affirming hormone therapy.^{4,5} New diagnosis of HIV and restarting of gender affirming hormone therapy.

References: 1. Klein, D., Paradise, S. Goodwin, E. "Caring for Transgender and Gender-Diverse Persons: What Clinicians Should Know", Am Fam Physician 2018;98(11):645-653

2. Safer JD, Tangpricha V. Care of the Transgender Patient. Ann Intern Med. 2019 Jul 2;171(1):ITC1-ITC16. doi: 10.7326/AITC201907020. PMID: 31261405.

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4 Nguyen HB, Chavez AM, Lipner E, et al. Gender-Affirming Hormone Use in Transgender Individuals: Impact on Behavioral Health and Cognition. Curr Psychiatry Rep. 2018;20(12):110. Published 2018 Oct 11. doi:10.1007/s11920-018-0973-0

5. Tanis J. The power of 41%: A glimpse into the life of a statistic. Am J Orthopsychiatry. 2016;86(4):373-7. doi: 10.1037/ort0000200. PMID: 27380151.

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EXHIBIT L

**US Department of Health and Human Services
Centers for Disease Control and Prevention
Health Resources and Services Administration**



**Virtual Meeting of the
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment**

April 26-28, 2022

Record of the Proceedings

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Executive Summary

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

CDC and HRSA Welcome and Updates

The meeting began with detailed updates from CDC and HRSA. The CDC update highlighted a number of important areas of interest from the NCHHSTP HIV, STD, viral hepatitis, and school/adolescent health programs including: a brief update on the continuing impact of COVID-19; NCHHSTP's equity initiative and strategic plan; harm reduction and Syringe Services Programs; discussion of mental health concerns in youth; Ending the HIV Epidemic (EHE) update; discussion on updated hepatitis B vaccination and screening and testing recommendations; and integrating STI and HIV services to address the syndemic. Highlights from the HRSA/HAB presentation included the introduction of a new Administrator, launch of a new Ryan White website, release of the National HIV/AIDS Strategy (2022–2025) in December 2021, and policy and data updates. CHAC members discussed recent policy changes and their potential impacts on LGBTQ (lesbian, gay, bisexual, transgender, and questioning) youth's access to information, resources, and equitable care.

Strategizing an Approach to Providing Comprehensive STI Services

During this panel, CHAC heard from programs in Mississippi, New York, and Minnesota that highlighted innovative strategies they are employing to increase access to testing and comprehensive STI services. These strategies included using the school space to increase access to health services for young people, leveraging technology, and the effort to align that with the COVID-19 pandemic response to: 1) innovate and modernize the public health infrastructure, which can serve as a good model moving forward in jurisdictions; and 2) determine how to secure and sustain funding to support these efforts moving forward in a post-COVID world.

Leveraging Policy to Advance HIV, VH, and STI Priorities

This panel focused on utilizing policy as a public health intervention as an approach to solving expansive issues in public health. The National Viral Hepatitis Roundtable presented on the state of Medicaid access with respect to Hepatitis C. The California Department of Public Health (CDPH) Office of AIDS provided an update on Senate Bill (SB) 159 pertaining to HIV pre-exposure and post-exposure prophylaxis (PrEP & PEP) for California pharmacists and the STD Control Branch presented on leveraging policy changes for STI and VH prevention, testing, and treatment. The Louisiana Office of Public Health STD/HIV/Hepatitis Program described Louisiana's *Hepatitis C Elimination Plan: 2019-2024*. The Transitions Clinic Network described issues pertaining to the Medicaid Inmate Exclusion Policy (MIEP) which reduces barriers to care for post-incarceration, reintegrating individuals.

Turning the Tide on Self-Testing and Sample Collection

This special presentation focused on self-testing and sample collection, highlighting the pipeline and approval process for self-collection kits. CHAC heard data on how impactful self-collection kits could be on communities that historically have not utilized traditional brick-and-mortar structures. The availability of self-collection kits has been demonstrated to increase testing practices in a number of communities. Discussion focused on how the Food and Drug

Administration (FDA) views HIV versus HCV and manufacturers' willingness to produce self-testing kits and seek FDA approval. Additionally, CHAC members discussed the differences in the criteria used for regulatory authorization of collection kits/methods domestically versus internationally and the potential for the review and revision of FDA process to increase access to and use of self-test kits.

Applied Syndemic Approach to HIV, VH, and STIs: Focusing on People

This panel focused on implementation of programmatic syndemic approaches, which underscored the need to take a "whole person" approach in terms of the issues that influence an individual's ability to access the resources that are being put forward, utilize them effectively, and achieve successful health outcomes. The New Mexico Department of Health (NMDOH) described its comprehensive harm reduction program focused on meeting people where they are to support HCV treatment and syphilis services. The North Dakota State Correctional Health Authority emphasized that corrections health is an important part of public health and represents a vulnerable and underserved population and can be an ideal setting for delivering comprehensive services. The San Francisco Unified School District (SFUSD) described policies and mandates, community partnerships, resources, training, and initiatives that help support comprehensive sexual health services to SFUSD youth. Finally, CDC's Division of HIV Prevention (DHP) provided an update focused on advancing syndemic approaches through cluster detection and response, emphasizing that cluster detection and response can guide tailored implementation of proven treatment and prevention strategies for HIV and other syndemic conditions where transmission is occurring most rapidly.

Telehealth/Telemedicine Working Group (WG)

The Telehealth/Telemedicine WG put forth several recommendations focused on enhancing routine screening through virtual services for all populations, health equity's relationship to telehealth service provision, and deployment of the Tele-PrEP initiative for Federally Qualified Health Centers (FHQCs).

Presidential Advisory Council on HIV/AIDS (PACHA)

CHAC was provided an update on PACHA's 73rd full council meeting that was convened virtually on March 14-15, 2022. This presentation emphasized the importance of hearing the voices of the community that will help guide PACHA in moving forward in terms of making recommendations to support EHE and in implementing the National HIV/AIDS Strategy (NHAS).

Business Session

The Business Session focused on CHAC actions and proposed future agenda topics. The next CHAC meeting is scheduled for November 1-3, 2022.

Future Agenda Topics Proposed

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

CHAC Actions

During this meeting, CHAC members voted unanimously to:

- Adopt the November 2021 CHAC meeting minutes, with no edits proposed.
 - Send the letter of recommendations presented by the Telehealth WG to the HHS Secretary, with a minor revision of repositioning the health equity recommendation as the first bullet.
 - Develop and send a letter to the HHS Secretary regarding LGBTQ youth.
 - Create a Self-Collection Self-Testing WG to consider issues related to self-testing, potentially including: 1) Differences in FDA risk classification of HCV and HIV; 2) Criteria required and data available for the FDA approval process; and 3) Downregulation to class II diagnostics. In addition, this WG will draft a letter to be presented to CHAC for a potential vote during the November 2022 meeting.
 - Establish a Workforce WG to liaise with PACHA on their efforts, to discuss the main issues CHAC is to consider on workforce including exploring the role of other professionals and community health workers (CHWs) in this space, and to discuss topics to potentially inform a panel for the November 2022 CHAC meeting.
-

**US DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
April 26-28, 2022**

Minutes of the Meeting

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

The CHAC is a committee chartered under the Federal Advisory Committee Act (FACA) to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies, and priorities for HIV, viral hepatitis, and STD prevention and treatment efforts for the nation. Information for the public to attend the CHAC meeting virtually was published in the *Federal Register*, in accordance with FACA rules and regulations. All sessions of the meeting were open to the public. Please see Appendix A for Membership Attendance.

Day 1: Opening of the Meeting and Roll Call

Marah E. Condit, MS

Public Health Analyst, Advisory Committee Management Lead
Office of Policy, Planning, and Partnerships
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Ms. Condit welcomed participants to the CHAC meeting, called the proceedings to order at 11:00 AM Eastern Time (ET), reviewed ground rules, and provided instructions for discussion periods. She indicated that members of the public would have an opportunity to provide oral comments at 3:30 PM ET during the second day, and that public comments would not be accepted at any other point during the meeting.

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

On behalf of CDC and HRSA, Dr. Mermin welcomed those present and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest (COIs) identified by the Committee Management Office (CMO) and recuse themselves from voting or participating in any discussions for which they could be conflicted. He then conducted a roll call to determine the CHAC voting and *Ex-Officio* members who were in attendance and establish quorum. Quorum was maintained during all 3 days of the meeting.

Conflict of Interest Disclosures

CHAC Voting Member Institution/Organization	Disclosure of Conflicts
Jean R. Anderson, MD Johns Hopkins Medical Institutions	Stocks: Apple, Amazon, Cisco, Alphabet, Splunk Research Funding: Merck, Gilead
Wendy Armstrong, MD Emory University School of Medicine	Research Funding: HRSA/Ryan White Parts A, B, D that supports part of her salary as well
Jodie Dionne-Odom, MD, MSPH University of Alabama, Birmingham	Research Funding: NIH
Shannon Brown Dowler, MD North Carolina Medicaid	None
Daniel Driffin, MPH D3 Consulting	None
Travis Gayles, MD, PhD Hazel Health	Self-recusal for Telehealth related topics
Meredith Greene, MD University of California, San Francisco	Research Funding: Gilead, NIH Works in a Ryan White-funded clinic
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN Duke University	Research Funding: NIH, ACF
Kali Lindsey amfAR, Foundation for AIDS Research	None
Christine Markham, PhD University of Texas Houston	Research Funding: NIH, ACF, OMH
Shruti Mehta, PhD, MPH Johns Hopkins Bloomberg School of Public Health	Research Funding: NIH, USAID Materials Support For Research Studies: Abbott
Johanne Morne, MSED AIDS Institute, New York State Department of Health	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program
Kneeshe Parkinson Washington University/Project ARK	Research Funding: HRSA/Ryan White HIV/AIDS Program Parts A, B, C, and D
Robert Riester Denver Element	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program, Part A
Leandro Rodriguez, MBA Latino Commission on AIDS	Research Funding: HRSA/Ryan White HIV/AIDS Program, CDC, SAMHSA, Gilead, ViiV
Samuel So, MD Stanford University	Research Funding: CDC, NIH

Ex-Officio members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA), Dr. Maureen Goodenow of the National Institutes of Health (NIH), Dr. Neerja Gandotra of the Substance Abuse and Mental Health Services Administration (SAMHSA), Ms. Kaye Hayes of the HHS Office of HIV/AIDS and Infections Disease Policy (OIDP), Mr. Rick Haverkate of the Indian Health Service (IHS), and Dr. Richard Wild of the Centers for Medicare and Medicaid Services (CMS). Liaison member Dr. Ada Steward of the

Presidential Advisory Council on HIV/AIDS (PACHA Liaison Representative) organization, Eau Claire Cooperative Health Centers, receives Ryan White Funding Parts B and D.

Dr. Mermin confirmed that a quorum of 22 was achieved and that CHAC could move forward with conducting its business on April 26, 2022.

Welcome and Agenda Review

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Gayles and Anderson welcomed everyone to the April 26-28, 2021 CHAC meeting. Dr. Gayles thanked CHAC members, federal officials, CDC and HRSA staff, and the general public for their attendance and commitment. He expressed particular gratitude to Dr. Stewart for her efforts to promote vaccination in the pediatric population, as well as her commitment across the full breadth of public health issues. He reviewed the agenda for the day, pointing out that it highlighted the continued need to be nimble and versatile in the ever-changing post-COVID world with the increased attention on public health issues and budget demands and supplies. He observed that many of the topics to be discussed during this meeting demonstrated how CHAC must continue to evolve in terms of considering what should be included in a comprehensive STI testing program in 2022, determining the types of policies that need to be put into place to impact service delivery in a more meaningful way, and examining how federal policies might influence the delivery of those services. As always, they looked forward to great presentations, robust discussions, and tangible action items.

CDC DFO Welcome and Updates

NCHHSTP Update

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

CHAC Designated Federal Officer

Dr. Mermin welcomed new CHAC Voting Members, Mr. Kali Lindsey and Dr. Christine Markham. He also welcomed Dr. Maureen Goodenow, Director of NIH's Office of AIDS Research, who is replacing Dr. Paul Gaist as the NIH *Ex-Officio* member.

To update CHAC correspondence, responses were sent on March 7, 2022, for the HIV and HCV classification letter; the Viral Hepatitis Workgroup (WG) letter; the Youth Engagement letter; and an interim response to the Perinatal Infection WG letter. CDC and HRSA are working on a detailed response currently and hope to have that finalized in the next couple of months.

In terms of COVID-19 pandemic, the number of deaths officially attributed to COVID-19 is close to 1 million in the US and there have been over 80 million total cases. Although mortality and hospitalizations decreased with the decreasing incidence of COVID-19 in the early part of 2022, cases and hospitalizations increased as the new subvariant began to spread. Challenges continue for all of public health and clinical care, as well as policies and other aspects of trying to keep America healthy in an environment where there are various other pressures

simultaneously. NCHHSTP continues to have multiple deployments for the COVID-19 response, with over 700 employees deployed since the beginning of the epidemic, over 1600 cumulative deployments, 53 people currently deployed, and 17 staff soon to deploy. NCHHSTP also is taking responsibility for several aspects of the incident management structure as CDC begins to reorganize its response to COVID-19, with the understanding that this is going to be a long-term effort.

NCHHSTP's Equity Initiative Strategy launched in 2021. This long-term strategy is intended to help achieve workplace equity and eliminate health disparities by addressing racism and other systems of oppression that hinder the center's mission. An implementation plan was developed that outlines the first steps of this process, though NCHHSTP already has been implementing many of the strategies. The overall goal is to help integrate health equity and equity in the workplace as core activities to which NCHHSTP is committed. NCHHSTP is focused on pervasive disparities associated with HIV, viral hepatitis, STDs, and TB, as well as adolescent health. The Equity Initiative involves all aspects of the center, with each division developing action plans that they have been implementing for some time.

An assessment was completed of external work for improving public health, internal workforce, organizational change, and analysis. Based on the analysis of the workforce, over 50% of NCHHSTP's staff are racial/ethnic minorities and close to 70% are women. The proportion of racial/ethnic minorities has increased at least 20% over the past decade. NCHHSTP also was the first group at CDC to conduct a survey of staff regarding sexual orientation and gender identity. Approximately 18% of NCHHSTP staff identified as LGBTQ (lesbian, gay, bisexual, transgender, questioning), with that proportion being the same in lower and higher General Schedule (GS) levels. NCHHSTP is committed to continue to perform these demographic analyses, develop fact sheets, and improve the inclusiveness of the day-to-day experience of staff within the center.

Part of the Equity Initiative is the development of an external public health dashboard that assesses the overarching measures of inequity in the diseases under NCHHSTP's purview. There are relative comparative measures and absolute measures, which follow current scientific practices for analyzing inequities. While these measures vary for each condition and population, the center is committed to reducing health inequity.

CDC's cross cutting strategic plan to reduce the infectious disease consequences among people who use drugs is complete. The mission is to decrease morbidity, mortality, and incidence of infectious diseases associated with injection drug use, as well as stigma experienced by people who use drugs. Several strategic priorities have been identified, including expanding the infrastructure of syringe services programs (SSPs) nationwide and integrating SSPs into the public health system, and establishing coordinated surveillance, monitoring, and program implementation. "Strengthening Syringe Services Programs" Notice of Funding Opportunity (NOFO) was issued recently that will expand SSP and support a network of SSPs across the country.

Additionally, this year CDC is implementing the 6th surveillance cycle among people who use drugs via the National HIV Behavioral Surveillance or NHBS which monitors prevalence and trends of HIV infection, risk behaviors, and prevention services among populations at increased risk for HIV, across 20-23 cities in the US. CDC is also launching the Microinfluencing project with the CDC Foundation and the Public Good Projects. This is a pilot to engage social media influencers to grow support for SSPs starting in West Virginia and other jurisdictions across the country. The campaign launched mid-April called "Appalachian Influencers," recruiting both paid

and volunteer influencers to begin posting messages, focusing on 4 audiences including law enforcement, health care, faith leaders, and community leaders.

Similar to what has been experienced in other infections, tuberculosis (TB) cases decreased in 2020 for a variety of reasons that are still under exploration and increased by 9% in 2021, however, not to the levels of 2019. Factors likely contributing to the observed decline include delayed or missed TB diagnosis due to disruptions in health care access, underdiagnosis, or a true decline from the reduced TB transmission due to pandemic mitigation efforts and fewer new arrivals from high TB incidence countries. TB incidence in the US continues to decrease over time, but not at the pace that would be necessary to achieve TB elimination goals.

Division of Adolescent and School Health (DASH) Update

Kathleen Ethier, PhD

Director, Division of Adolescent and School Health
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Ethier reminded everyone that DASH has been presenting to CHAC for a number of years about what has been observed through the Youth Risk Behavior Survey (YRBS) regarding the health and wellbeing of young people in the country. New data recently were released that were collected through the Adolescent Behaviors and Experiences Survey (ABES), a version of the YRBS that was implemented in Spring 2021. Students were recruited through schools, same as is done for the YRBS, but they were able to complete the survey online instead of in a classroom. This engagement allowed sample students who were learning virtually, as well as those who were learning in-person in school to participate.

These data reveal the magnitude of challenges that youth are experiencing, particularly related to mental health, experiences of abuse in the home during the pandemic, experience of racism in schools, and a variety of other issues. There is a continuing mental health crisis among youth, which was seen prior to the pandemic, particularly among female students and students who identify as being LGBTQ. These data show 26% of students who identify as LGBTQ attempted suicide in the year prior to the data collection during the pandemic and more than 50% of all students experienced emotional abuse in the home (e.g., verbal abuse by a parent or other adult), speaking to the level of stress experienced by students and families. Among respondents, 64% of Asian students and 55% of Black and Multiracial students reported having experienced racism in school not related to the pandemic.

Youth who identify as LGBTQ have been disproportionately impacted by the pandemic, experiencing higher levels of poor mental health, more than 3 times the likelihood to have attempted suicide in the past year, and more emotional abuse at home during the pandemic compared to their heterosexual peers. This data shows that access to schools and other places in the community where students can be supported is critical and was limited due to the pandemic. One of the hopeful findings was that connectedness mitigated mental health issues. Students who reported that they felt connected were less likely to experience mental health problems and were less likely to consider or attempt suicide. At the same time, students who identify as LGBTQ and students who experienced racism were less likely to feel connected to others at school. This sets up a challenge for those who work in schools in how to make schools safer and more supportive, particularly for those youth.

CDC's "What Works in Schools" approach improves adolescent health and wellbeing. This approach includes quality sex education, systems to connect youth to services, and a set of activities around improving school connectedness and providing support for LGBTQ students. In schools implementing this approach within CDC-funded districts, students were less likely to have ever had sex, have 4 or more sexual partners, be currently sexually active, miss school because of safety concerns, be forced to have sex, and/or use marijuana.¹ Sexual assault is known to be a predictor of lifelong trauma as well as posing STD and HIV risks.

Schools that put a set of policies and practices in place to support LGBTQ students such as identifying safe spaces, having professional development for educators, and having anti-harassment policies that are enforced leads to improvements in mental health outcomes and reductions in suicidal thoughts and behaviors. Improvements are observed in all students including LGBTQ in schools that put these policies and practices in place. The reverse is also the case—that when these policies and practices are not in place, mental health problems are exacerbated for students who identify as LGBTQ and also for heterosexual students. This has significant implications for the currently state of schools across the country. As schools are made less toxic for the most vulnerable students, schools are made less toxic for everyone and the reverse is also the case.²

Division of HIV Prevention (DHP) Update

Demetre Daskaliakis, MD, MPH

Director, Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Daskaliakis reminded everyone that has CDC requested \$310 million in the FY23 President's Budget in order to continue its focus on the 4 pillars of EHE, as well as to amplify these efforts by investing in key strategies to advance health equity. Some of the highlights are to focus efforts on increasing access to testing by scaling up self-testing, and to think specifically about the use of self-testing in high impact settings such as community-based organizations (CBOs), LGBTQ-focused clinics, correctional facilities, and SSPs. Syndemic approaches would be expanded to create efficiencies and broaden the reach to many key populations. Lessons learned during the COVID-19 pandemic will be assessed to identify ways to better improve capacity in small priority population-focused CBOs to increase the benefit of EHE prevention and care services. The focus on PrEP uptake would continue to be promoted and delivered, including a newly available injectable PrEP and working on increasing delivery of tele-PrEP. This funding also would support expanding implementation of innovative status neutral approaches to care delivery by providing peer-to-peer training and implementation support to health departments that currently are not providing such services. This all part of EHE and is one of the 5 equity interventions and is part of the focus to increase the reach of HIV prevention and care services to Black, Brown, and LGBTQ people as well as other priority populations.

¹ Robin L, Timpe Z, Suarez NA, Li J, Barrios L, Ethier KA. Local Education Agency Impact on School Environments to Reduce Health Risk Behaviors and Experiences Among High School Students. *J Adolesc Health*. 2022 Feb;70(2):313-321. doi: 10.1016/j.jadohealth.2021.08.004.

² Centers for Disease Control and Prevention, National Youth Risk Behavior Survey (YRBS), 2015 & 2017; Centers for Disease Control and Prevention, School Health Profiles (Profiles), 2014 & 2016

DHP is in the midst of a renaissance of community engagement with a focus on 3 types of engagement:

1. Information gathering, an example of which is a refresh of the domestic HIV program strategic plan
2. Topic-specific discussion, examples of which are cluster detection and response and status neutral approaches
3. Ongoing community-centered engagement. Community-centered engagement began in March when regional Town Halls were convened to educate, encourage, and focus on empowering local community implementation of the EHE Initiative. The goal is to work together to understand and address longstanding inequities and strategies that can be used to further nuance addressing those inequities.

At the beginning of April, CDC funded 36 CBO grantees in 18 states with \$400,000 in funding per grantee to focus on HIV prevention with young men of color who have sex with men and young transgender persons of color.³ Since the last group of grantees, 6 more organizations were identified, and each received an increased funding level. CDC also recently announced and received applications for a funding opportunity⁴ to support organizations that work in transgender clinics and partner with CBOs that focus on transgender populations to develop community-to-clinic models to integrate status-neutral HIV prevention and care services where people seek gender-affirming care. This takes advantage of navigation and other strategies that are designed to increase knowledge, confidence, and use of PrEP and other interventions.

One of the great innovations that came out of the COVID-19 pandemic was the self-testing program, which is being expanded and will be funded over the next 5 years to distribute 150,000 self-tests per year. Conversely, there were significant interruptions in care services due to the pandemic that have made surveillance data harder to interpret and more complex. The HIV Surveillance Data Tables will be released when the full reports are available and the commentary is able to guide how this is interpreted. Because of the disruptions, there are some derived estimates (incidence, knowledge of status, prevalence) that will not be possible to produce for 2020. Work is underway to update data collection to better capture these data, for which approval is expected by the end of 2022 from the Office of Management and Budget (OMB) and collection will begin in early 2023.

Division of Viral Hepatitis (DVH) Update

Carolyn Wester, MD MPH

Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Wester shared some of the work that the DVH has accomplished recently to address health disparities in viral hepatitis (VH). VH elimination has moved from risk-based to universal recommendations among adults. In November 2021, the Advisory Committee on Immunization Practices (ACIP) voted unanimously to update the hepatitis B vaccination recommendations to include the following recommendations:

1. All adults 19-59 years and adults ≥ 60 with risk factors should receive hepatitis B vaccines
2. Adults ≥ 60 without known risk factors may receive hepatitis B vaccines

³ <https://www.cdc.gov/hiv/funding/announcements/ps22-2203/index.html>

⁴ <https://www.cdc.gov/hiv/funding/announcements/ps22-2209/index.html>

CDC formally published these guidelines in the *Morbidity and Mortality Weekly Report (MMWR)* on April 1, 2022.⁵ The move away from risk-based recommendations will help reduce health disparities by eliminating the need for patients disclose potentially stigmatizing risk factors and also provide healthcare providers with a simplified vaccine decision-making process.

As reported during previous CHAC meetings, CDC is currently updating its hepatitis B screening recommendations from risk-based to universal recommendations as well. This will complement the vaccination approach, as well as the hepatitis C and HIV screening guidelines among adults. The proposed updated recommendations are 2-fold. The first recommendation is that screening be performed at least once in a lifetime for all adults ≥ 18 years of age and the second is to expand existing risk-based testing recommendations for ongoing testing for additional groups, including people who are currently or formerly incarcerated people with a history of STIs, and people with a history of hepatitis C virus infection. These recommendations are currently available on the *Federal Register*⁶ for public comments, which closes on June 3, 2022. Formal publication of this update is anticipated later in the year.

The prevalence of hepatitis C is increasing among reproduction aged individuals and pregnant persons, with approximately 6% of perinatally exposed children becoming infected.⁷ Of the recommendations currently available, the most consistent is to test exposed children with a hepatitis C antibody test at or after 18 months of age. There is no clear guidance regarding hepatitis C RNA testing beginning at 2 months of age despite the fact that this testing may possibly decrease loss to follow-up and misidentification. CDC is working to develop evidence-based hepatitis C testing recommendations for perinatally exposed children to ensure that exposed infants and children are appropriately tested and linked to care and curative treatments. Peer review and public comments for these recommendations are expected to take place in Fall 2022, with publication anticipated in early 2023.

Viral hepatitis cannot be eliminated without also addressing the challenges posed by the national opioid crisis. People who inject drugs (PWID) are at high risk for viral hepatitis, HIV, and other infections. They also experience unique barriers to testing and treatments. Harm reduction service programs are a proven effective component of community-based programs to prevent the spread of infectious consequences from injection drug use. In 2019, the DVH established the National Harm Reduction Technical Assistance Center (NHRTAC) to strengthen the capacity of SSPs.⁸ DVH first partnered with the National Alliance of State and Territorial AIDS Directors (NASTAD) to build the infrastructure of this center. As the program grew, partnerships were expanded to include the National Harm Reduction Coalition (NHRC) and the University of Washington. Now in Year 3, the center has broadened involvement of the NHRTAC to include CDC's Injury Center and SAMHSA and National Association of County and City Health Officials (NACCHO) and 6 additional TA-providing organizations are joining for bridging expanded expertise and offering harm reduction from health departments and recovery communities, as well as experts from SAMHSA's Addiction and Prevention Technical Training Centers.

As part of the effort to build up comprehensive programs to support the needs of PWID, CDC released a NOFO in March 2002, Strengthening Syringe Services Programs (CDC-RFA-PS22-2208), with 2 key components that will increase access to harm reduction services for PWID. Component 1 will support the development of a national network of SSPs to facilitate

⁵ <https://stacks.cdc.gov/view/cdc/115806>

⁶ <https://www.federalregister.gov/d/2022-07050>

⁷ Centers for Disease Control and Prevention. 2019 Viral Hepatitis Surveillance Report. <https://www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm>

⁸ harmreductionhelp.cdc.gov

communication among SSPs and other harm reduction programs and health organizations trusted by the PWID community and improve data about SSPs by conducting an annual national survey of SSPs to document capacity, needs, access, and service gaps. Component 2 will increase support and resources to SSPs for implementation of these programs, including syringe distribution and disposal, testing, treatment, and prevention of the infectious complications of infections of injection drug use. This program will enhance and expand harm reduction services leading to reductions in new viral hepatitis infections.

In conclusion, the DVH will continue to promote innovative and holistic approaches to reduce health disparities and meet the needs of people living with or vulnerable to viral hepatitis.

Division of STD Prevention (DSTDP) Update

Leandro Mena, MD, MPH, FIDSA

Director, Division of Viral Hepatitis

National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Mena reported that DSTDP is in the process of developing a new division strategic plan for 2022-2025. This effort will include alignment with the Sexually Transmitted Infections National Strategic Plan for the United States | 2021–2025.⁹ The new proposed goals will be to:

1. Prevent new STIs
2. Improve the health of people by reducing adverse (harmful) outcomes of STIs
3. Accelerate progress in STI research, technology, and innovation
4. Reduce STI-related health disparities and health inequities
5. Achieve integrated, coordinated efforts that address the STI epidemic

The new plan is projected to be finalized in early Fall 2022. DSTDP envisions a whole nation response to preventing and controlling STIs in the US that goes beyond disease to address the health and wellbeing of the individual, recognizing that this will require support of partners and collaborators.

The National Strategic Plan and the DSTDP strategy call for reductions in disparities and health inequities. This key approach will be reflected in NOFOs and activities to ensure that there is high population-level impact. The strengthening of STD prevention and control for health departments has had a tremendous response, with an additional \$200 million going to recipients each year for the next 5 years for which there is an emphasis on expansion of the workforce and to strengthen disease outbreak and response capacity by bringing on an additional 1800 staff members. DSTDP continues to strengthen its supplemental surveillance projects, including strengthening US surveillance of drug-resistant gonorrhea with the use of whole genome sequencing (WGS) to better understand the epidemiology of gonorrhea. Investments are being made in innovation, particularly in syphilis diagnostics and in training of Disease Intervention Specialists (DIS). Some of these innovations and trainings will be funded from the \$1.13 billion that was allocated to DSTDP last year through the America Rescue Plan Act.

⁹ <https://www.hhs.gov/sites/default/files/STI-National-Strategic-Plan-2021-2025.pdf>

The 2020 STD Surveillance Report¹⁰ was released in early April 2022 along with preliminary 2021 syphilis data. In 2020, there were increases in gonorrhea, syphilis, and congenital syphilis. Increases are being seen in syphilis and congenital syphilis for 2021 as well. Conversely, there was a 12.7% decline in cases of chlamydia from 2019. This decline is likely due to decreasing STD screening and diagnosis during the pandemic rather than a reduction in new infections since chlamydia is usually asymptomatic. While syphilis cases are increasing, they do present an opportunity for HIV prevention. Since 2015, the number of primary and secondary syphilis cases reported among HIV-negative MSM has surpassed the number of cases reported among HIV-positive MSM. While overall cases reported among HIV-positive MSM may be leveling off, there are no signs of syphilis slowing down among heterosexuals. Reported cases of primary and secondary syphilis cases increased 420% among women from 2011-2022. The intersection of HIV and syphilis presents a clear opportunity in which syndemic approaches can be beneficial to addressing these infections, as well as the conditions that contribute to their occurrence.

Along with the new plans, some key actions DSTDP is taking include identifying opportunities for collaboration and integration of services, increasing access to stigma-free healthcare, expanding partner services and DIS programs, improving STI diagnostics and therapeutics, and enhancing surveillance systems to inform public health actions and better understand root causes of increasing STIs at the national and local levels. For each of these activities, DSTDP is committed to a process that prioritizes access to and extension of services that address disparities and inequities. Social health services can be a gateway for overall health and wellness. DSTDP will move from a disease-focused approach to a social health promotion and wellbeing framework.

HRSA DFO Welcome and Update

Laura Cheever, MD, ScM

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
CHAC Designated Federal Officer

Dr. Laura Cheever extended her welcome to new CHAC Voting Members, Mr. Lindsey and Dr. Markham. She also welcomed new NIH *Ex-Officio* member, Dr. Goodenow, and expressed her gratitude to Dr. Gaist for his years of service to CHAC as the NIH *Ex-Officio* member.

Dr. Cheever announced that Carole Johnson was named the HRSA Administrator in January 2022. Before coming to HRSA, Ms. Johnson served as the Testing Coordinator on the White House COVID-19 Response Team. She also served as the Commissioner of the New Jersey Department of Human Services, leading the state's largest agency and providing healthcare and social services to 1 in 5 New Jerseyans. During her tenure as Commissioner, the Department expanded Medicaid coverage of mental health and substance use disorder (SUD) services, created new Medicaid benefits to improve maternal health outcomes, and integrated Medicaid into the newly launched state-based Affordable Care Act (ACA) marketplace. Ms. Johnson served for more than 5 years as the Domestic Policy Council public health lead in the Obama White House, working on the Ebola and Zika responses, implementation of the ACA, and combatting the opioid epidemic. In addition to several key positions on Capitol Hill, Ms. Johnson was Policy Director for the Alliance of Community Health Plans, Program Officer with the Pew Charitable Trust health program, and Senior Government Relations Manager with the American Heart Association (AHA). Dr. Cheever welcomed Ms. Johnson back to HRSA where

¹⁰ <https://www.cdc.gov/std/statistics/2020/default.htm>

she previously worked in workforce policy, and she thanked Diana Espinosa for leading the agency as the Acting Administrator for the last year and a half. HRSA is fortunate to have someone with Ms. Johnson's experience and deep knowledge of HRSA's programs, as well as her passion about health equity in the work the agency does.

HRSA's HAB vision is optimal HIV care and treatment for all to end the HIV epidemic in the US. The mission is to provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities. Health equity is a core concept of the RWHAP, which has been working many years to reduce disparities. It is very exciting to have a new environment in which health equity is in the forefront across the entire federal government.

HRSA is excited that the HAB website has been officially relaunched with a new look and the new URL of <https://ryanwhite.hrsa.gov/>, which should help people searching for information on the Ryan White HIV/AIDS Program (RWHAP). The website navigation has been updated and the content has been reorganized to help visitors find information and resources more efficiently.

Since the last CHAC meeting on December 1, 2021, the *National HIV/AIDS Strategy (NHAS, the Strategy)*¹¹ was released and provides stakeholders across the nation with a roadmap to accelerate efforts to end the HIV epidemic in the US by 2030. In order to guide the nation toward realizing the vision, the strategy includes 4 overall goals, which are to:

1. Prevent new HIV infections
2. Improve HIV-related health outcomes of people with HIV
3. Reduce HIV-related disparities and health inequities
4. Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and stakeholders

The strategy has been used across HRSA and government to help focus efforts and refine the work that is being done in this area.

HRSA is developing an NHAS Implementation Plan that outlines specific actions to achieve the Strategy's goals and objectives. Representatives from across HAB and HRSA have been working to identify strategic policies, programmatic activities, and initiatives to leverage support of the goals, objectives, and strategies outlined in the plan as part of the Strategy implementation. Partnering across the federal agencies is a very important part of this step in the work. HRSA has actively engaged CDC, Administration for Community Living (ACL), Housing and Urban Development (HUD), and others in thinking about the work that needs to be done in order to achieve the goals. Given the Strategy's whole of society approach, HAB leadership conducted a series of listening sessions to engage directly with the RWHAP stakeholder community to hear thoughts and ideas on ways HRSA can support the goals and objectives outlined in the NHAS in the effort toward EHE. Key stakeholder groups included patient advocacy organizations, HIV provider organizations, constituency-based organizations, and coalition groups. Dr. Cheever expressed gratitude for the contributions of the many divisions and offices that took part in this collaborative effort, including HRSA's regional offices and CDC that were part of all sessions.

¹¹ <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>

The NHAS also calls for the development of a quality of life (QOL) indicator. The White House Office of National AIDS Policy (ONAP) asked CDC and HRSA to Co-Chair a federal WG to make recommendations. The WG's charge from the White House was to use existing federal datasets that include measures of QOL or measures that can assist in gauging QOL. ONAP held a community listening session to receive input on these datasets. The WG was asked to complete its work by May 2021. QOL has been part of the fabric of the RWHAP over many years. In the absence of a method to measure QOL, HRSA has been addressing it through various domains, such as housing instability, employment, and food insecurity. Critical thought also is being given to domains around health, wellbeing, and psychological factors and work has begun on a framework to conceptualize the efforts and identify work that still needs to be undertaken.

HAB has a relatively new and productive partnership with ACL. ACL's mission is to foster safe, high quality health care for the aging population. This is particularly important for the RWHAP where many clients are aging with HIV. In 2020, about 48% of clients in the RWHAP were over 50 years of age. The goal of this partnerships is to work together to share resources among recipients and cultivate partnerships with other federal and non-federal partners. HAB and ACL have collaborated on several webinars to share information about the RWHAP and to hear from ACL about their programs and services. HAB and ACL also have teamed up with training for ACL grantees and Ryan White recipients on the Older Americans Act (OAA) and Area Agency on Aging (AAA). There is a tremendous amount of expertise in the community on aging, which should be leveraged in the efforts to expand the work in the RWHAP in order to improve services for older people with HIV quickly.

HAB also has a longstanding committed partnerships with HUD. HAB is currently assessing how the RWHAP can better address the housing needs of people with HIV. Because HAB is not primarily a housing provider, they are grateful for the partnership with HUD. The focus traditionally has been on the federal Housing Opportunities for People with AIDS (HOWPA) program. HAB also is working to expand its efforts with HUD beyond the HOWPA program and to continue to work together to address the needs of RWHAP clients. HAB and HUD will continue to partner on educational events at the intersection of housing and HIV and other opportunities broadly across HUD programming.

The 2022 National Ryan White Conference (NRWC) on HIV Care & Treatment will be convened August 23-26, 2022. Dr. Cheever thanked the RWHAP community providers, recipients, and partner organizations who submitted a total of nearly 400 abstracts for consideration in the 2022 conference. Abstract approvals were sent out the week of April 12, 2022. In light of the constantly evolving COVID-19 pandemic, HAB has made the decision to host the 2022 NRWC virtually. This is a shift from the initially proposed hybrid format that included both virtual and in-person components. The conference dates will remain the same, but times will be adjusted to accommodate the different time zones. Recognizing the unpredictability of the COVID-19 pandemic over the last several years, HAB holds true to its commitment to providers, recipients, stakeholders, partner organizations, planning council members, and more than the half million people they serve every day to reduce any risk of potential COVID-19 transmission. All of the recipients, providers, stakeholders, and people with HIV who are a part of the RWHAP will have an opportunity to attend the conference and not be taken away from the communities HAB serves. This means that the RWHAP part-specific caps that were applied to the hybrid format no longer apply. The virtual format will utilize the same platform as the 2020 conference that had incredible engagement during the chat as sessions were occurring. All breakout sessions will be pre-recorded.

Turning to policy updates, transgender people with HIV continue to be a priority for HAB. There are tremendous disparities for this particular population. In December 2021, HAB released a letter to RWHAP service providers reaffirming the importance of providing culturally-affirming health care and social services to the transgender community as a key component of improving the lives of transgender people with HIV and eliminating health disparities. The letter is not a new policy or approach to the services delivered by the RWHAP, but builds upon HAB-funded initiatives that support patient-centered, trauma-informed, and inclusive environments of healthcare for people with HIV to help reduce medical mistrust and other barriers to adherence from transgender populations.¹²

To highlight a few RWHAP updates, 2 new Executive Summary documents have been published that are on the RWHAP website. The first is a high-level summary of what was learned during the 2021 EHE in the US listening sessions with public health leaders and communities mentioned earlier. This document discusses the key themes from those sessions and provides a high-level look at how HAB is moving forward to build on what has been learned. The second Executive Summary is based on the telehealth white paper that shares how RWHAP have been leveraging telehealth during the COVID-19 pandemic. Both of these publications should be useful to RWHAP.¹³

Moving to data updates, all states showed improvements in viral suppression among RWHAP clients by state from 2010 to 2020. However, some states continue to have room for improvement—particularly in the Southeast US. Also notable was a significant improvement in viral suppression in 2020 even though at that time, states and recipients were responding to the COVID-19 pandemic. Among key populations served by the RWHAP, viral suppression of all RWHAP clients was 69.5% in 2010 and 89.4% in 2020. The improvement in suppression occurred across all key populations. However, it is important to note that challenges remain in achieving viral suppression for certain populations. Most notably in 2020, there were disparities in viral suppression overall for African Americans and Blacks at 86.7%, transgender clients of 84.5%, youth 12-24 years of age at 81.5%, and clients with unstable housing at 76%. This illustrates that more work needs to be done.

Viral suppression increased for all RWHAP clients nationally by about 19.9 percentage points from 2010-2019. Key populations had even greater improvements in viral suppression. For example, viral suppression increased by 23.4 percentage points among African Americans. This demonstrates that while disparities remain, the disparity gap has been decreased. Among youth transgender populations and people who are homeless, larger disparities remain with significant work to do.

The inaugural *2020 HRSA HAB Ending the HIV Epidemic in the U.S. Data Report* was released and is posted on the HRSA HAB website. This is the first publication to highlight data submitted through the EHE Triannual Module data system. This module collected aggregate-level data 3 times a year on the number of new and existing clients receiving services and the number of clients prescribed antiretroviral therapy from EHE-funded providers. EHE recipients, sub-recipients, and stakeholders have been doing important work in response to the COVID-19 public health emergency to meet the needs of clients during that emergency while simultaneously doing incredible work in this new EHE Initiative that launched in March 2020 simultaneously with the COVID-19 pandemic nationally and submitting high-quality, complete EHE triannual data to HRSA HAB.

¹² <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/hiv-care/gender-affirming-care-rwhap.pdf>

¹³ <https://targethiv.org/library/innovation-rwhap-telehealth>

Many EHE recipients used their EHE funding to expand and innovate the delivery of existing RWHAP service categories. For example, RWHAP EHE recipients focused on what could safely be accomplished during the pandemic such as emphasizing self-care within the community, leveraging virtual spaces, and staggering or scaling back activities in order to provide them safely. Recipients also introduced flexibilities that prioritize health and safety, such as offering telehealth and remote work for staff, contactless prescription delivery, e-prescribing, providing 90-day supplies of antiretrovirals, and delivering socially distant case management and navigation—something most providers had not done previously.

EHE recipients scaled up services to address new activities or activities where there was greater demand, such as transportation, rental assistance, emergency financial assistance, and food or delivered meals. Recipients also worked to streamline the client experience, including consolidating services in clinics and creating policies and procedures to simplify future client interactions. Beyond EHE, recipients were able to leverage their existing RWHAP knowledge, partnerships, experiences, and resources so their jurisdictions could respond to the COVID-19 pandemic. It is amazing what recipients have been able to achieve throughout this pandemic.

CHAC Member Discussion On CDC & HRSA Updates

The following questions, observations, and suggestions were raised:

- Dr. Gayles observed that all of the teams demonstrated the ability to be flexible in pivoting to new ways to deliver services to meet the needs of those who utilize CDC and HRSA services. Mental health crisis in children was significant before COVID-19 and is further exacerbated. This is a key moment in terms of responding to this need in terms of building infrastructure. Equity remains important as disparities continue to be seen in incidence across populations and continued gaps in access to services such as PrEP. There are exciting new funding opportunities from CDC and HRSA and continued inclusion of the SDOH and the impact that those play on service delivery. It also was affirming to hear the continuing commitment from both agencies in providing affirming services to different communities, given the political environment in many places across the country that potentially affect the way services are delivered. Given the increased attention on mental health in young people and the impact that mental health issues can play on risk-taking behaviors, he inquired as to how services are being implemented across the board in various divisions in thinking about rolling out new projects.
- Dr. Ethier said that from a school health perspective, DASH has layered in additional resources received from Coronavirus Aid, Relief, and Economic Security (CARES) Act dollars to transition some of the school services into the virtual setting and to help support the infrastructure that already had been created to connect youth to sexual health services and to mental health services. Schools received an influx of funds and an array of additional resources, but it is not clear whether they were able to use those funds effectively toward these efforts. There have been discussions with partner organizations to establish services outside of schools and determine the best way to connect with school districts. As often is the case with community-based services, a 2-pronged approach is needed. Something is needed to motivate the school district to create infrastructure to connect to services in the community, but that is not sufficient. It is also important to make a connection to the community to help them establish connections in schools. They have consistently seen that it is not going to be possible to “mental health professional” our way out of this. There are not sufficient trained mental health providers to be able to deal with the influx. Mental health services are just not available for adolescents. This also speaks to the pipeline issues. In

order to convince providers to train or retrain to work with youth, the mental health professional pipeline has to be made possible, affordable, and attractive.

- Based on the data Dr. Cheever presented, Mr. Driffin noted that close to 90% of people living with HIV return back to care. He wondered whether the data team would pose additional inquiries to determine why those individuals decided to stop care and ultimately return to care during the pandemic or connected to EHE activities, and how those findings could be incorporated into better healthcare delivery for people living HIV.
- Dr. Cheever indicated that they are not collecting this from the recipients. The reporting is kept high-level because of the burden on recipients. Many EHE programs do inquire about what keeps people out of care so that they can better respond in the future. A challenge over time has been the difficulty in finding people who are out of care, understanding who they are and the challenges they face. Dr. Cheever will take this idea back to the Project Officers.
- Dr. Mermin observed that the viral load suppression data highlighted by Dr. Cheever showed remarkable increases in viral load suppression with a 30-point absolute increase in 10 years and an almost elimination of racial and ethnic disparities in viral suppression. He wondered what the most important factors were that led to that increase, as well as how to get to the next 10% to achieve 100%. He also requested an update on the HRSA-initiated hepatitis C program that screened, diagnosed, and cured people in RWHAP of hepatitis C.
- Dr. Cheever noted that HAB has been focused on data quality and quality improvement. There have been several large collaboratives with hundreds of thousands of patients in which individual recipients assess their data and then experts, including people with lived experience, to help figure out what works through a quality improvement rapid cycle. A number of these over the years have been successful and the rates of improvement in these initiatives have been remarkable. That is why they are adamant about developing best practices communication so people can demonstrate improvements by publishing what works in this key population so others are able to replicate. There is some improvement with easier drugs to take, but overall improvement is due partly to specific quality improvement activities. The hepatitis C chart abstraction work slowed down during the pandemic because it is difficult to collect data at the national level, especially regarding treatment and sustained viral response. HAB has a chart abstraction contract through which these data were going to be collected in individual clinics, but that was delayed significantly by the pandemic. All they have at this point are anecdotal inputs.
- Given that many cities are experiencing increasing problems with homeless populations, Dr. So inquired as to whether CDC has programs to try to improve prevention, testing, and treatment for HIV and hepatitis in homeless populations and whether SSPs across the country are experiencing any pushback by states.
- Dr. Mermin indicated that there is a lot of interest in homeless populations at CDC. They have been engaging with HOPWA and HUD in general, and DDID has taken on a role of looking across the agency to determine whether there are ways to work at the more fundamental social determinants side. Housing and homelessness affect almost all aspects of public health, so CDC is increasingly trying to work in that field. In terms of SSPs, it is a project that takes concerted effort and continual monitoring and support over time. In some places, SSPs have been initiated and expanded and sometimes there is not a lot of pushback. SSPs become normalized with engagement with the community and law

enforcement, and when there is supportive legislation in the state or local areas that enable SSPs to continue over time. There are other places where SSPs are going well and then there is pushback for a variety of reasons (e.g., political conflict in the community, certain events that result in loss of trust with law enforcement or politicians, et cetera). There are a lot of services that cannot be offered now due to minimal resources, lack of technical capacity, and or lack of infrastructure.

- Dr. Daskalakis added that really great work is occurring with HUD beyond HOPWA in a more status-neutral space. One exciting area is the work with HOPWA to think about housing as an outbreak intervention which is moving in a great direction. They are looking at ways testing interventions can be deployed specifically in those environments as social determinants are also being addressed. DHP's most recent NOFO for young MSM and transgender women of color has a component that asks the grantees to select areas of social determinants to pursue, one of which is housing.
- Dr. Wester added that people who use drugs, injection and non-injection, and people experiencing homelessness are some of the populations most heavily impacted by the multistate outbreaks of hepatitis A, which now include 37 states and over 44,000 cases. The TA efforts that have been provided to states and other jurisdictions experiencing that have made a lot of inroads into those communities.
- Dr. Anderson emphasized how impressive the increases in viral load suppression and reduction in disparities were that Dr. Cheever presented. She asked how DASH plans to follow up on the data regarding mental health issues among adolescents, particularly the data on LGBTQ adolescents and the outsized concerns in these issues. This includes more than individuals who are HIV-affected. She asked whether the data on LGBTQ includes transgender and lesbian, gay, bisexual or if they were separated out. The issues are probably slightly different.
- Dr. Ethier indicated that for the ABES data, they were not able to include a question on transgender identify. At this point, that question is on the state optional list. However, they were able to include the transgender identify question on the ballot process for the questions to be included in the 2023 YRBS. They are optimistic that this question will be included on the national survey. Hopefully for the next CHAC meeting, she will be able to provide an update on some of the improvements they will be able to make for the 2023 survey. ABES was done in Spring 2021 and the regular YRBS was moved to Fall 2021. Approximately 30 states and locals included the transgender identify question on the state YRBS. This allows them to group those data together to look in more depth at those students.
- Mr. Lindsey noted that substance use is an area that has not had as much data to contribute to prevention efforts and healthcare engagement efforts, and that he was happy to hear about the marijuana data in Dr. Ethier's presentation. Particularly given the increase in stimulant use over the past couple of years due to isolation and other social dynamics that have arisen, especially in urban communities. He wondered if they have been able to or plan to collect those data.

- Dr. Ethier indicated that they do assess stimulant use as one of the substances. They did not find an impact of the program on stimulant use, but that could be because it was relatively low for young people—at least when those data have been collected. Prior to the pandemic, all substance use apart from alcohol and marijuana had been decreasing. They have not collected opioid data for long enough to know whether there has been an increase or decrease.
- Dr. Daskalakis added that the National HIV Behavioral Surveillance (NHBS) survey is able to tease out stimulant use, which is something that DHP is following.
- Dr. Cheever added that they are taking a deeper dive into SUD and what people are actively using in their chart abstraction survey, so that will be a topic every other year.
- With the current political climate regarding LGBTQ in Florida, Dr. So asked Dr. Ethier whether she is worried about the coming year in terms of how much progress can be made. Already there are mental health issues. He wondered whether the politicians know how much harm they are doing. He also asked whether it would be appropriate for them to raise this concern through a CHAC statement, perhaps.
- Dr. Ethier responded that as a federal employee, she was unable to comment on any particular state law or policy. She said that she is extremely concerned about whether the gains made over time in implementing the policies and practices that she mentioned are effective for all youth with respect to mental health and wellbeing. In 2018, close to 80% of schools had safe spaces for LGBTQ students, more than 90% had anti-harassment laws, and about 75% had professional development on inclusivity for teachers. That had improved dramatically over time, but now changes have been made to directly take some of those important practices out of schools. She is extremely worried about the mental health crisis for young people. Taking away those supports will be threatening not only for LGBTQ students, but also for other students. As she mentioned earlier, making schools more toxic for anyone makes them more toxic for all students.
- In terms of whether there is something CHAC can do, Drs. Gayles and Anderson will discuss this offline and will get back to the group about what is/is not within CHAC's purview as a committee.
- Mr. Riester noted that a bill recently passed the House that would criminalize certain amounts of fentanyl, which could increase the number of people who are incarcerated and also would require mandated substance use counseling. There is a very large problem with fentanyl across the country, so this is something to think about in the future. Regarding mental health status and LGBTQ youth, he asked whether there is a correlation to visibility, inclusion, awareness, and/or a specific geographic prevalence.
- Dr. Ethier responded that the ABES data is nationally representative, so it does not tie back to specific geographic areas. They do not ask about visibility, inclusion, and awareness in this survey. Therefore, they do not know whether the more "out" someone is increases the reaction and stigma associated with their identity. However, this is a very important question. It might be possible to look at some of these difference by state in the 2021 YRBS data. This did come up to some extent with regard to parental abuse questions related to

issues around whether healthcare providers and school personnel are required to report back to parents if they have conversations with young people about their sexual identity. They do not ask these questions, but it is difficult to imagine that there is not some aspect of being out to one's family and then experiencing abuse, otherwise they would not see the difference between students who identify as heterosexual and those who identify as LGBTQ.

- Dr. Markham added that as a youth sexual health researcher in Texas, she echoed Dr. Ethier's concerns. They hear a lot from school-based personnel and clinicians that the climate in Texas is definitely a concern in terms of the mental health of youth and also their families trying to be supportive of them. With the abuse cases and reporting cases, it is getting quite dire. Whatever CHAC might be able to do, she would love to be part of that. She also expressed interest in information about additional initiatives for provider training, influences, and other programs to address rises in congenital syphilis, for which Texas may be #1. There also is an overlap with teen STI rates in Texas.

Panel 1: Strategizing an Approach to Providing Comprehensive STI Services

Moderator: Robert McDonald, MD, MPH, LCRD, USPHS; Medical Officer, Division of STD Prevention, NCHHSTP, CDC

Addressing STIs in Mississippi

Thomas E. Dobbs, MD

State Health Officer

Mississippi Department of Health

Dr. Dobbs first shared a photograph from an 1881 photograph atlas on cutaneous syphilis to illustrate that history is reality and that a lot of work remains to be done. For instance, based on the 2020 published STD rates, Mississippi ranked first in chlamydia per capita by a substantial margin of almost 100/100,000 population higher than Louisiana, ranked second highest for gonorrhea, and tied for first place in primary and secondary syphilis rates. This is the worst STI performance he has seen during his tenure at the State of Mississippi. While that is awful and embarrassing, there are interventions for improvement.

There has been a transition in the landscape of care. The health department and its STD clinics traditionally have been thought of as a go-to location for STD treatment and diagnostics in Mississippi. However, data by ordering facility type in 2020 showed that the majority of STD cases were being identified primarily in private physician offices and other health clinics. Some reasons for this are the general transition away from public health services for clinical care and funding issues. Compared to 10 years ago, they have half of the nurses they had in 2010. They have less nurses now in 2022 than in 2019—even with the COVID-19 pandemic funds. While there is a paucity of providers in general, nurses are responsible for much of the frontline work in STI treatment. If the Mississippi Department of Health is addressing only 10% of the pie, they are missing 90% of the opportunity and must rethink how to address STIs in Mississippi.

To demonstrate a parallel lesson, the fertility rate in Mississippi has been declining gradually since 2001 other than an interesting increase from 2006 to 2008 that was observed across the country for unknown reasons. There also has been a decline in teen births in Mississippi, with the exception of an increase in 2007. Although fertility and teen birth rates have been

decreasing, the health department has been losing ground in providing reproductive health services. This suggests that there are solutions to the problem that transcend what a county health department or STD division can do, but depending upon third parties who do not have the same authorities or a more holistic view of STI intervention also raises a number of challenges in addressing STIs and HIV.

Community health centers offer an opportunity for interventions in Mississippi where there are 11 Federally Qualified Health Centers (FQHCs) that operate 69 school-based clinics. This presents an excellent opportunity to provide sexual health resources to young people who are at risk. The majority of chlamydia and gonorrhea cases occur among older teens and young adults in their early 20s. While there are only 69 school-based clinics currently, there are 530 high schools in Mississippi. This means that there are many uncovered locations that could be served.

As pointed out in Healthy People 2020, one of the correlates associated with STD transmission is social determinants of health (SDOH). Mississippi Department of Health has struggled to expand its role beyond just STDs. While they can get shots in people's arms, test for chlamydia, et cetera, they must address SDOH—most of which pertains to racial and ethnic disparities. Otherwise, they will continue to try to “bail water from a sinking ship.” The majority of STD cases are now among African Americans, which are a minority population. SDOH issues must be addressed to get ahead of the problem. These include racial and ethnic disparities, structural issues (including structural racism), poverty and marginalization, access to healthcare, substance abuse, stigma pertaining to sexuality and secrecy and/or HIV transmission, risky sexual network, and so forth.

Most adults and the vast majority of children in Mississippi have health insurance. However, about 24% of adults are uninsured. Mississippi adults 19-25 years of age represent a high-risk group who do not have access to care and impoverished communities are over-represented. There are multiple difficulties in Mississippi. They do not have contact tracing and treatment, especially within private clinic settings. If someone is diagnosed within the health department, they will be given a referral card. While Mississippi does not yet have partner expedited therapy, an effort to offer this option is underway. The private clinic setting does not have the same public health focus that county health departments and STD-focused clinics have. Stigma and reluctance to discuss sexual health among patients and providers is a major problem, especially in the era of a 15-minute medical visit—10 minutes of which are spent on a computer. Ensuring that clinicians are up front diagnosing people with STIs and that there is access to care are critical issues. Mississippi is a non-expansion state with no anticipation of that changing in the near future. This state also has a very high poverty rate, is a rural location, and has a low provider to population ratio. People with STIs or symptoms do not want to go to a local clinic for various reasons, which results in major delays in care.

There are many potential opportunities, such as using some of the lessons learned from the COVID-19 pandemic to move forward. COVID-19 provided an opportunity to build remarkable new partnerships that included making remarkable inroads with the Spanish-speaking community, faith communities, local leaders, and others. These partnerships should be fostered and translated into successes in sexual health and STI prevention, treatment, and diagnosis. Continued work must be done to advance partner expedited therapy, though it is going to be challenging to move that outside of the health department to places where the majority of people are being seen. Mississippi plans to perform targeted contact tracing. For a small state with a shrinking workforce and 30,000 cases of chlamydia, comprehensive contact tracing poses a major challenge, but an effort must be made to try to interrupt some high-risk sexual networks.

Telehealth offers a major opportunity. While Mississippi Department of Health already offers universal PrEP through free telehealth, it is currently underutilized. It also is important to break down silos such that all services are providing comprehensive care that are not focused only on STIs or HIV. Mississippi has a major challenge within its epidemiology infrastructure and is underfunding its workforce. Mississippi has one epidemiologist for HIV/STDs. The state also is traditionally unfriendly to government employees and tries to keep the wages artificially low. Hence, people who complete top-notch training programs are not flocking to the Mississippi workforce. Despite the challenges, Mississippi will continue to seek opportunities for improvement.

Innovative Models to Support New York City (NYC) Sexual Health Clinics

Joaquin Aracena, MA

Assistant Commissioner, Division of Disease Control
New York City Department of Health and Mental Hygiene

Christine M. Borges, MPH

Director of Program Implementation and Evaluation
New York City Department of Health and Mental Hygiene

Dr. Aracena described innovative models that the NYC Department of Health and Mental Hygiene (NYC Health) have incorporated during the COVID-19 pandemic to reach and continue to serve New Yorkers with sexual health services. NYC Department of Health went through a reorganization during the pandemic, so the Bureau of STI no longer exists and the clinics have been folded into the Bureau of Public Health Clinics (BPHC). Bringing innovative services to the community was done through innovative approaches such as telemedicine, an STI Hotline, STI Quickie, and a COVID-19 Pivoting Model.

The BPHC was created on July 1, 2021 and oversees the health department's clinics that offer direct services to New Yorkers. This includes 8 Sexual Health Clinics (SHCs), 4 Tuberculosis Chest Centers, and 9 COVID Express Testing and Vaccination Clinics. The rationale behind this reorganization was that under centralized clinical operations, they are in a better position as a bureau and agency to achieve their goals to integrate services where common interventions are effective; create new pathways to expand services, especially telehealth services that are new for NYC Health; implement innovative approaches; and improve resilience to budget challenges.

Pre-pandemic in 2017, NYC Health serviced close to 80,000 patients. Among them, 53% are MSM and 47% percent are men who have sex with women (MSW). The 4 clinics operating in 2021 saw less than 50,000 patients, the demographics continued to narrow, and they were still reaching similar populations. Interestingly, there was an increase in MSW presenting for services or who received services via telemedicine. In terms of the SHCs' annual volume, there was a peak in 2019 and a major decline in 2020 during the height of the COVID-19 pandemic. Clinic visits and telemedicine visits began trending back up in 2021. In terms of efforts to reduce sexual health disparities, the clinics offer same-day HIV testing and PrEP and post-exposure prophylaxis (PEP) and PrEP Jumpstart. Other services include STI screening and treatment, condoms, partner services, emergency contraception, QuickStart contraception, crisis counseling, and substance use services.

In terms of the impact of COVID-19 on SHCs, the BPHC is within the Division of Disease Control. Therefore, many NYC Health staff were deployed to the pandemic response and 7 of 8 clinics had to be closed as part of the deployment and lockdown. The Chelsea clinic in Manhattan remained open and NYC Health quickly had to identify a model on how to continue to serve New Yorkers during this time in the absence of the clinics. The telemedicine operation was launched by the end of March 2020 to provide all EHE services. Not only were they able to assess individuals during this time, but also they were able to prescribe. They quickly published an RFP to contract with a pharmacy to deliver medications to individuals' homes at no cost to the patient. An additional layer was added to the pharmacy delivery that included home HIV test kits.

In May 2020, they were able to reopen the Fort Greene Clinic with limited services, given that many staff were still deployed to the COVID response. In June 2020, express visits resumed, and long-acting reversible contraception (LARC) services resumed at one clinic. Express visits and LARC services resumed in the 4 currently operating SHCs in July 2020. The Jamaica clinic reopened in July 2020 with limited services and telemedicine was expanded as staff came off of deployment. By August 2020, COVID Express Clinics were opened in SHCs and Tele-PrEP began. They had about 12 weeks to convert spaces that were not previously laboratories into laboratories to be able to respond to COVID testing. Morrisania opened in November 2020 for limited services, so now there is representation in 4 of 5 boroughs. They do not have a presence in Staten Island. In July 2020, they were able to pivot one of the instruments being used for COVID testing to be able to do STI testing in parallel.

Telemedicine services included management of positive/abnormal STI tests results, with HIV treatment initiation for those diagnosed with HIV who wished to start HIV treatment for the first time; consultation for PrEP initiation for NYC residents ≥ 13 years of age, including daily PrEP and PrEP on demand; medical evaluation for those who think they have signs or symptoms of HIV; medical evaluation for those who might have or have been exposed to a HIV; contraception services, including emergency contraception and consultations for other contraceptive methods (e.g., pills, ring, patch, shot, LARC); and prescriptions for STI treatment and HIV home test kits. To highlight telemed trends, there was an increase in the volume of calls during the peak of the pandemic. However, this declined when clinics began to reopen and it was possible to work with community partners to link individuals to services. There were 523 Tele-PrEP visits in 2021. Among these, 376 (72%) patients visited a SHC post-telehealth visit within 14 days of the telehealth visit and 332 (88%) patients received PrEP medication on the day of their visit.

Services offered at STI Quickie Clinics include provision of services such that individuals are in and out of a clinic within a cycle time of under 30 minutes compared to 1.5 hours in regular SHC. Services offered include HIV testing with 1-minute results; and CT/NG testing with 24-hour or less results; syphilis serology testing and hepatitis serology testing for HEP A-B-C with results in 3-5 days. There continues to be an increase in STI Quickie Clinic visits that now reach capacity each day. The positivity rate of either gonorrhea or chlamydia is over 13%, which provides an opportunity to test/diagnose someone who is asymptomatic and engage in conversations with them on PrEP and additional services they may need. BPHC now operates 8 Covid Express clinics across Bronx, Brooklyn, Manhattan, and Queens within existing SHCs.

To highlight some expansion plans, STI Quickie Services will be scaled up in the outer boroughs with Fort Greene anticipated to come online in Summer 2022. A patient-facing scheduling platform will be implemented. A PrEP Continuity Clinic will open in Summer 2022. There are plans to build up an Emergency Response Unit to allow for pivoting between COVID

Express Clinics and STI services as needed, and future reagent cartridges will be explored for implementation as they are FDA-approved.

Minnesota Community Care

Erica Drake APRN, CNP

Medical Director, Health Start Clinics-School Based Health Clinics
Minnesota Community Care

Sandy Naughton, BA, CCE

Health Education, Health Start Clinics-School Based Health Clinics
Minnesota Community Care

Ms. Drake and Ms. Naughton described Minnesota Community Care's Health Start Clinics-School Based Health Clinics in St. Paul Public Schools (SPPS) and their comprehensive STI outreach. The Health Start School-Based Clinics began as a maternal and child health (MCH) organization housed in a hospital across the street from a high school. They realized quickly that teens, especially pregnant teens, were not keeping their appointments, even though the organization and school were across the street from each other. They were then given space within the school and now have 10 school-based clinics. Young people who have access to school-based care have much better health outcomes, and the mantra at the time was to make those clinics acceptable, accessible, and available and they still view their provision of services this way.

The clinics are designed with an integrated team approach that includes an Advanced Practice Provider, Mental Health Provider, Health Educator, Registered Dietician, Medical Assistant, and Clinic Coordinator. One of the school-based clinics is open to adolescents 13-22 years of age regardless of ability to pay. Confidential care is provided under the Minnesota Minors Consent Law, without notification to adolescents' families. Given that the Health Start School-Based Clinics can help to provide this care for free, it overcomes a barrier in other types of clinics that may bill insurance and send home an explanation of benefits (EOB). The 10 clinics within the SPPS see an average 4,000 unique patients a year between the 4 disciplines and have a total of approximately 25,000 visits.

In addition to the 4,000 students seen in the clinics, about 100,000 students are seen through classroom visits provided all year. They are often invited to Health and Social Studies classes to talk about a variety of topics (e.g., hygiene, risk reduction, risk management et cetera). Each year, CRUSH (Community, Restoring, Urban Youth, Sexual, Health),¹⁴ a partnership of youth serving organizations and community members, holds a statewide STI Day in June. CRUSH focuses only on chlamydia and gonorrhea on the day that youth come in. During the summer, 3 clinics are kept open so that young people never lose their access to health care. Even though the focus is on chlamydia and gonorrhea on the testing day, adolescents are invited back for a fuller panel of testing. On the CRUSH testing day, clinics can see as many as 50 to 70 young people in this stigma-free situation. When this began, the idea was to do testing for students who felt they might need testing. That felt very stigmatizing, so now it is presented as visiting the clinic to talk about staying safe for life.

¹⁴ <https://www.health.state.mn.us/diseases/chlamydia/crush.html>

This teen-friendly, stigma-free introduction to the clinics that focuses on outreach into the classrooms and beyond the clinic walls, offers walk-in testing and basic sexual health screening, and makes it fun and exciting (e.g., decorate the clinic, play music, have a raffle for attendees, provide treats, incentives, et cetera). These testing days are the first time some young people visit the clinic. This is the first time that they have visited the clinic, so there is visibility. While this was the first clinic to open in a school building, there are now thousands of school clinics. This is a wonderful way to provide adolescent healthcare. The SPPS school-based clinics are holistic in that they teach, test, and treat in a stigma-free manner. A longer screening form has been shortened just for CRUSH STI Day. Every adolescent who attends completes the screening form, which helps to determine what kind of care they need and provides contact information so that they can be reached for follow-up care if needed. They do make it clear that adolescents do not have to have had sex to attend a CRUSH STI Day, because it also includes education and outreach.

For ease of flow, only a urine screen is done for chlamydia and gonorrhea. The screening tool is used to schedule further education and screening for additional STI testing, including blood draws and throat and rectal screening. Condoms are provided to all students and as noted, the clinics can provide care for all students regardless of parental consent under the Minnesota Minor Consent law. The clinics within SPPS require parental consent for all services except reproductive healthcare. Clinic staff can help uninsured students apply for the Minnesota Family Planning Program (MFPP)¹⁵ to help assist with reimbursement rates for the services the clinic is able to provide.

The last CRUSH STI Day event was in Spring 2019 because SPPS did not return students to in-person education until the middle of April 2021. CRUSH STI Day 2022 is now being kicked off. During these events, approximately 400 teens are seen and about half of them are screened based on their sexual history and risk factors. There is about a 10% positivity rate.

CHAC Member Discussion on Panel 1

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. How can CDC/HRSA support the expansion of STI care to include ART and PrEP services in clinical care sites and service areas?
2. How can CDC/HRSA support the integration of comprehensive care into school health clinics?
3. How do we equip school districts with a means to improve the linkage of healthcare in communities?
4. What else does CDC/HRSA need to consider when expanding STI care?

The following questions, observations, and suggestions were raised:

- Dr. Gayles noted that during COVID times, health department directors often have been met with surprise and confusion from political and community leaders for not having tons of contact tracers or a sophisticated surveillance system to follow COVID cases, which health department directors frequently pointed out that this was a side effect of years of budget cuts due to under development/underfunding of public health infrastructure. He asked how NYC was able to leverage CARES Act funding to support their rebranding and if they were

¹⁵ https://www.dhs.state.mn.us/dhs16_137813

able to identify new potential funding streams for other public health programs to support their work.

- Mr. Aracena indicated that there was a lot of cross-collaboration among agencies and hospitals throughout the city leveraging any current infrastructure.
- Dr. Dowler reported that North Carolina also is a non-expansion state, and they experienced a lot of the same issues as Mississippi. She has worked very hard over the last couple of years to expand PrEP access within the Medicaid family planning benefits. While this is a much smaller benefit, she encouraged Mississippi to reach out to their Medicaid partners. North Carolina was able to get everything within that program except for the drug, which can be obtained through HRSA's program to make it reimbursable for folks and to encourage health departments and FQHCs to reach out to that population that is essentially uninsured. An important part of North Carolina's initiative was that men need family planning as well.
- Dr. Dobbs indicated that Mississippi does have a full benefit for a family planning waiver for PrEP and they pay for the medicine as well. The problem is that it is underused.
- In terms of EOBs, Dr. Dowler indicated that North Carolina has viewed the EOBs being suppressed as a requirement for any Medicaid Claim. Particularly for managed care companies, EOBs cannot go out to the homes because North Carolina Medicaid does not want that to be a barrier for care. They want school-based health clinics or health departments to bill Medicaid as a payer source whenever possible so they can save their dollars for the uninsured. Some areas of the country experience barriers with school boards as well.
- Ms. Drake clarified that the public assistance program does not send home EOB, but private insurance does. Minnesota has only a handful of Planned Parenthood and other types of clinics left since so many have been closed over the last 10 years. Adolescents without access to school-based clinics suffer even more without access to other types of clinics. They are able to have a pharmacy in their school-based clinics through their 340B funding that permits them to provide various types of oral contraceptives, and they work with their obstetrics team to get IUDs placed.
- In terms of CHAC's role on advising CDC and HRSA, Dr. Greene inquired as to how the committee could support expansion and perhaps advise on how federal support could help with the interplay with local or state policies that are more restrictive. Given that the workforce is a challenge across all sectors right now, she also wondered what would help to increase the workforce or work in Mississippi or other areas that perhaps are not as desirable.
- Dr. Dobbs said that while he knew it was a pipe dream, the most beautiful thing that happened during COVID-19 was the HRSA portal. People used that like it was a de facto way for things to happen. His dream would be to have a HRSA portal for these other needs. In a non-expansion state, there are still major financial barriers for people to get access even to FQHCs. People who are undocumented are really in trouble because they do not have proof of income and are paying market rates for healthcare in a community health center. It would be helpful to find a way to have no cost visits for community health centers. The health department is the only place with no cost care, except for a few free clinics that do not provide reproductive health services. A lot of activities must happen, but there often are not enough people to get to the desired depth. Part of the issue pertains to deciding

what to do and handing off other activities to partners who are better suited for them. The issues with the epidemiology component involve low pay and the need to create a training program locally since people in Mississippi tend to stay there. Some strides have been made in pay, but now they do not have enough human resources (HR) staff to bring on new people. It is literally like trying to build a sandcastle in a hurricane.

- Dr. So commended NYC Health for thinking about expanding the usage of the laboratory capacity they built for COVID-19 to test for other diseases. He asked whether hepatitis A, B, and C testing is offered to all the patients who have no history of previous testing, infections, and/or who have not been vaccinated. CDC recently published a study that showed that in addition to the current recommendation, offering people a one-time hepatitis B test also would identify an estimated 1000 people every year who acquire hepatitis B from sexual activities and will save vaccine doses if they already have been infected or have immunity.
- Mr. Aracena said it was based on certain categories originally. Recently, they began offering testing and vaccination to all patients.
- Mr. Lindsey pointed out that while there is discussion about “risky sexual networks” and “social sexual networks” in the HIV area, he had not heard that as much in terms of STIs. He wondered whether there were opportunities to evolve the language to talk about “open sexual networks” instead of “risky sexual networks” in the future in terms of engaging communities in thinking about getting tested for STIs. He asked whether prophylactic interventions are a dead conversation in terms of STIs, even after the success of COVID-19 vaccines and some promising thoughts about the potential for an mRNA HIV vaccine. Consideration also should be given to work that is being done at the global level and whether that might make sense for local communities, such as the Dean Street Clinic in Atlanta that used some of the resources from the EHE planning. There are a lot of advantages to 24/7 online access to schedule STI screening and treatment, order HIV self-tests, order condoms and lubricants, obtain information to connect with health literacy training online or in-person, et cetera.
- Dr. Dobbs noted that Mississippi is making an effort to implement interventions in the community at the highest impact points. Part of that involves targeted contacts investigation and work with community partners to find the engagements that can pay the most dividends. When there are many bottlenecks, it creates “inverse energy” and more bottlenecks. Mississippi cannot even do GIS mapping because they cannot assemble staff. There is a lot of infrastructure to build out, but this is hard, laborious, boring, and no one wants to fund generalized infrastructure that is self-sustaining and builds on each piece.
- Mr. Aracena noted that like the Dean Street Clinic, the Quickie model was born out of being so busy during that pandemic that there were no opportunities for static. They were able to innovate and continue to evolve to try to stay ahead of the curve of not just the pandemic, but also in order not to lose sight of EHE as well. They were fortunate at NYC Health to have one STI Quickie model at Chelsea that they were quickly able to mirror and convert to a COVID-19 express testing model, which gave them the opportunity to expand out and extend their vision. It would have taken decades to stand up laboratories at all of the SHCs. Due to the pandemic, all sites have them. Now it is a matter of finding the funding to be able to turn them on and pivot them to extend the service.

- Dr. Gayles emphasized that with the pandemic funding streams drying up, consideration must be given on how to sustain the work that everyone has put in place. This is likely to be an ongoing conversation. As Mr. Lindsey raised earlier, what happened to creative science and technology to improve and prevent STDs and HIV (e.g., better diagnostics, point-of-care self-tests, better vaccines and more of them for a lot of infections, better treatments, et cetera)? These are all areas that respective parts of NCHHSTP have been exploring in terms of their role in moving these efforts forward, including working with NIH, FDA, and industry partners. This is a nascent topic that is ripe for growth, and it is possible that in the next CHAC or the one after that, it may be possible to talk more practically about what can be done about it. CDC is going to be funding new diagnostic research into syphilis testing.
- Dr. Mermin observed that telemedicine is a great opportunity to provide services and reduce inequities. One of the biggest obstacles for Tele-PrEP is the diagnostics. That is also true for STD diagnosis. There are good scientific data showing that the OraQuick® HIV test is insensitive compared to other tests in early infection and that it can be problematic particularly in regard to PrEP. Some anecdotal cases have reported several months before seroconversion with OraQuick®. He asked whether NYC Health has capacity to use surveillance and/or other data sources to look back at all of the people who participated in Tele-PrEP and use some form of person years of PrEP use and then HIV seroconversion rates. If it is low, that could be very useful for other jurisdictions that are considering this kind of programming and it could be compared to people who are taking PrEP in-person.
- Mr. Aracena clarified that their Tele-PrEP was more of a consult in which everything would be started for the individual, but it would not be initiated until the first day at the clinic. The at-home test kits were provided with a prescription for any STI treatment. They are still considering ways to evolve their Tele-PrEP initiative.
- Ms. Borges added that they did perform a surveillance match with their colleagues in HIV to assess HIV seroconversion.
- Dr. Anderson observed that the presentations offered nice snapshots of the urban, rural, and school-based settings. She asked whether the individuals presenting the Quickie Clinics differ from those who are accessing different services, and whether they were advertised differently. She asked to what extent each group was using peers or community-based workers in all settings, which could be enormously helpful in extending health services, reducing stigma, education, and using a task-sharing and task-shifting model.
- Mr. Aracena indicated that the demographics of the people accessing the Quickie and COVID Express services were very similar. When they expand to Fort Greene in the summer, they will be able to do further comparisons. NYC Health funds a lot of community organizations, FQHCs, and various institutions, so there is a lot of cross collaboration in NYC and they also have CBO liaisons within the BPHC who work closely with community partners. During this pandemic, they have been able to expand their reach and collaboration in different settings that they did not work closely with previously, so they want to continue to leverage those partnerships going forward as they begin to pivot their instruments as well.
- Ms. Naughton indicated that Minnesota Community Care was partnering with a college in St. Paul on a Youth Advisory Board (YAB) that was taking off and doing well until COVID hit, so it all has been very distanced. Before COVID, they had representatives in each of the schools working with these college students who helped develop materials that are used in

the clinics, as well as advising them on activities they can host, distance learning, et cetera. They plan to continue this YAB work as COVID restrictions are lifting.

- Dr. Anderson asked whether anyone was using Peer Navigators (PN) as part of a telehealth system for education, counseling, linkage to care, et cetera.
- Ms. Naughton said that they have done a great deal of peer education around issues of sexual safety, especially in terms of HIV. They have not done this in telehealth, partly because of the need to be careful about not providing incorrect information. In previous peer education, a professional staff member went with peer educators to assist them with answering questions.
- Dr. Akolkar asked if/how compliance is being monitored of those people who are receiving PrEP via telehealth.
- Dr. Dobbs said it is early and they do not have enough data to support it, but it is challenging for them to keep folks on PrEP regardless. Telehealth is no different.
- Ms. Borges said that in New York they are not currently retaining patients who they start on PrEP. They start it and then refer to a community provider. The most they do is make sure the patient attends the appointment made for them. They are given a prescription for the first month, except during COVID-19 it was 3 months because it was a lot harder to get a quick appointment in most places. Once they are connected to their community provider, they are no longer a patient.
- In terms of funding streams, Dr. Mermin pointed out that they are interested in becoming as efficient as possible with providing holistic services to certain people and in certain venues. That applies to STIs at STI clinics, community health clinics, or student health clinics. Yet the funding streams tend to come from multiple sources. With that in mind, he asked what could be done better.
- Dr. Dobbs suggested finding a clearer way to braid funding. Project Officers see things very black and white, it is almost impossible to blend multiple streams of funding.
- Ms. Naughton added that something that makes school-based clinics work so well and have such good outcomes is that the team is very integrated. That is always hard to find support for, especially considering the effects of SDOH on every kind of behavior and health outcome. They are very attached to their integrated program and when they have had a chance to do that in their larger ambulatory care sites, they find better outcomes as well.
- Mr. Aracena noted that because things are so selective in these buckets, they have to continuously seek additional funding to complete the wheel on the vision and the pathway they are trying to reach.
- Ms. Borges agreed, emphasizing that they all do their best to piece together different funding sources. That can be complicated in terms of reporting and justifying/explaining to Project Officers the best they can.

- Dr. Gayles asked Ms. Drake and Ms. Naughton to speak more about having achieved a higher level of integration of services in the school-based program comparable to community services and to share more about how within that integration, how they have tapped into the community resources to improve and enhance linkage to care services and any particular best practices that could be scaled up into a community model that CDC and HRSA could support.
- Ms. Naughton indicated that within their own system, they have a very comprehensive health history and they are very careful about linking within their own system to all the disciplines and they have developed community resources that go beyond what they can do within their clinics, which are widely available to everyone within their full organization. That is a constant build and a constant nurturing of those resources.
- Ms. Drake added that having the services that are most needed for adolescents within the school-based program results in easy access to care (mental health, nutrition, therapist for counseling, et cetera) and students do not have to leave school to go outside for services. While the mental health team is able to bill and get reimbursed, health educators and registered dietitians cannot except through private insurance. There is a lot of frustration with medical assistance and public funding in terms of not getting reimbursement for those services. Seeking funding for these services is a never-ending process.
- Mr. Lindsey asked whether the NCHHSTP retired program coordination and service integration (PCSI) in the reorganization.
- Dr. Mermin indicated that PCSI is not retired and is a core part of the center's strategy. They prioritized certain aspects of PCSI that they thought would make the biggest difference, but then COVID hit, and people were shifted in general. They have a new reinvigorated conceptual framework that initially was called PCSI 2.0, but now they are thinking of pulling in the conceptual framework of syndemics because it is very similar but more cutting-edge and pulls in a slightly different concept of population health and holistically valuing people, groups of people, and populations. PCSI was focused more on structured service provision. There is a lot of support from the Division Directors, but NCHHSTP recognizes the difficulty in identifying the specific interventions, research areas, programmatic areas, and policy areas that will make the biggest difference. That was part of the reason he asked the question about just funding streams, because that comes up a lot and has been insoluble at times. Congress allocates funds by diseases and conditions, but public health thinks about health by individuals, populations, and sometimes geography. COVID showed the importance of the skills, energy, and smarts of DISs. The new resources CDC has for DISs which Dr. Mena discussed is a comprehensive approach to COVID, infectious diseases, and STIs. Regardless of size, most health departments focus on at least HIV and STDs and sometimes venture into hepatitis and TB. They might be able to build on that.
- Dr. Anderson encouraged everyone to think about the advice that has been requested from CHAC by CDC and HRSA and potential motion, action items, suggested WGs, et cetera that they might discuss during the business meeting.
- Dr. Dowler emphasized the importance of standardizing payment for testing more broadly. Right now, this is very limited. She is in a state with 100 counties and every health department has its own funding stream that is different from the one next, none of which is patient-centered. A gold standard is needed for screening availability and provision of tests

for everybody regardless of where the testing is done (e.g., home, laboratory, clinic), geographies, political issues, or financial status.

- Dr. Gayles summarized that this panel discussion highlighted significant continued funding needs, the need to be flexible and nimble in services provision, reimbursement issues, the need to define what is included in a post-COVID approach, et cetera. Just as a zip code should not determine life expectancy, it also should not determine what type of STI services, testing, et cetera are available. Consideration should be given to the potential impact on the incidence of new cases that could be arrested and curved if services were readily available.

Panel 2: Leveraging Policy to Advance HIV, VH, and STI Priorities

Moderator: Michael Williams, MPH; Office of Policy, Planning, and Partnerships, NCHHSPT, CD

Hepatitis C: State of Medicaid Access

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP
Director of Programs National Viral Hepatitis Roundtable

Julia Harvey, JD
Clinical Fellow, Center for Health Law and Policy Innovation
Harvard Law School

Dr. Simmons and Ms. Harvey provided an overview of a 5-year project called *Hepatitis C: State of Medicaid Access*,¹⁶ recent progress and the current state of hepatitis C treatment access in Medicaid programs; remaining barriers to care; and next steps for this project. To provide a brief history of hepatitis C treatment access in Medicaid, the first direct-acting antiviral (DAA) Sovaldi came to market in 2013. It was commonly known as the “thousand dollars a day pill.” Due to the high cost of treatment, most payers imposed restrictions on access to treatment. In 2014, a group of researchers published a preliminary review of Medicaid coverage policies, which showed that restrictions to hepatitis C treatment were common and commonly enforced by prior authorizations. In 2015, CMS issued guidance to states that Medicaid must cover medically necessary DAAs in the hope that Medicaid programs would voluntarily loosen their restrictions. Following little voluntary progress, in 2016 Washington Medicaid was sued for requiring severe liver damage in order to access hepatitis C treatment. In 2017, the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) launched *Hepatitis C: State of Medicaid Access*, which detailed Medicaid restrictions by state.

At its core, the *Hepatitis C: State of Medicaid Access* project was developed in direct response to treatment restrictions occurring in the Medicaid Program. The project conducts individual state-by-state assessments of treatment access policy and tracks national trends in treatment access over time. This project is meant to serve as a resource to state officials and advocates to help provide a comparative lens across Medicaid programs as to the state of hepatitis C treatment access, and to identify clear opportunities for policy improvement within state Medicaid programs. Historically, this project has tracked 3 primary types of treatment restrictions in hepatitis C treatment Medicaid programs. The first type is restrictions based on fibrosis score or the amount of liver damage a patient would have to have before they were eligible for treatment. The second type is restrictions based on patient abstinence from alcohol

¹⁶ www.stateofhepc.org

and drugs, most often implemented as a required sobriety period of 1, 3, or 6 months to access treatment. The third type is restrictions based on which providers are eligible to prescribe treatment. In some cases, states would narrow the pool of providers eligible to prescribe (e.g., hepatologist, gastroenterologist, infectious disease doctors). These restrictions have been tracked because federal agencies and courts have declared that they are incompatible with federal law, and it is known that these types of restrictions have had severe impacts on individuals who are trying to access care who otherwise certainly would benefit from treatment.

In terms of progress over the last 5 years, there continue to be severe restrictions and states that have been hard-hit by hepatitis C. In terms of prior authorization (PA), 12 states now allow access to hepatitis C treatment without requiring a PA for most patients. Those states include: Washington, Louisiana, New York, California, Indiana, Wisconsin, Missouri, Michigan, Rhode Island, Virginia, Alaska, and Massachusetts. Oregon will soon be the 13 state to join this list. The majority (67%) of these states removed PA without using a subscription or what is called a “Netflix model.” This is a tremendous improvement that will help streamline access to treatment by eliminating burdensome paperwork.

Moving to fibrosis, the most progress made to date has been removing this barrier, with 33 states having either eliminated or reduced their fibrosis restrictions. Only 2 states have restrictions remaining. Regarding sobriety, many states have required patients to abstain from substances or alcohol for a specific period of time before approving hepatitis C treatment despite injection drug use driving new infections. Fortunately, 29 states have loosened their sobriety restrictions and the majority of states no longer require a minimum period of abstinence. While many improvements have been seen with restrictions related to substance use, this remains the most widespread barrier of the barriers that are currently tracked. Important improvements have been seen in removing prescriber restrictions, with 28 states having scaled back on prescriber restrictions. However, barriers remain in 18 states that require specialist involvement to prescribe hepatitis C treatment and 1 state that requires prescriptions to be written by a specialist.

Despite the progress that has been made in terms of access to hepatitis C treatment within Medicaid programs, it also is known that fibrosis, sobriety, and caregiver restrictions are not the complete universe of barriers to hepatitis C treatment. Over the last few months, in an effort to understand what some of these barriers are and specifically how they impact patients, the project team has been soliciting input from patients, providers, policy-makers, and others with the goal of understanding how to improve tracking and reporting out on state Medicaid programs to best meet the needs of individuals seeking access to hepatitis C treatment. Over the last few months, the team hosted a public listening session, disseminated a public survey, and convened a provider-led steering committee to identify the most pressing barriers. In terms of the breakdown of the 275 individuals who participated in the survey, the majority (~52%) of responses were from providers and other members of the healthcare team, followed by government staff (~23%), advocates (~11%), individuals personally impacted by hepatitis C and others (~6%).

What was learned from these conversations was that there are many key barriers to hepatitis C treatment and access beyond what has been tracked to date. Many of these have not previously been comprehensively tracked across Medicaid programs. This is not a complete list of everything that was identified, but barriers include the PA process, chronic infection diagnosis, time-based laboratory values, genotype reporting requirements, adherence assessments, retreatment restrictions, specialty pharmacy requirements, and differences in requirements between Medicaid fee-for-service and managed care. Responders indicated that all of these really play a role in meaningfully inhibiting access.

In terms of the impact of these barriers, they have heard anecdotally and objectively that these barriers result in delays, denials, and interruptions to care and ultimately impede the ability to eliminate hepatitis C by 2030, particularly among communities who are disproportionately impacted by hepatitis C. Rhode Island estimated that PA can take between 45 to 120 minutes per patient, not including time addressing denials and appeals. Patients are frequently lost to follow-up due to administrative barriers at every step of this process. The following quotes from the survey describe the impact of these barriers:

“In my state, there is actually investigation into adherence for other medications for the patient. For instance, if a person has picked up their diabetes meds late before, [Medicaid] will deny [hepatitis C] treatment.”

“The burdens include the wasteful cost of repeat labs and negative impact on patients regarding cost and access to transportation. Genotype results have a long turnaround time, sometimes creating delays.”

“Some of the specialty pharmacies have requirements to speak with the patient before mailing the medication. It becomes a barrier, and possibly even a delay in treatment.”

The impact of these barriers also is evident in data recently published by CDC, which shows that the number of people who initiated hepatitis C treatment in the US declined from 2015 to 2020.¹⁷ The National Academies of Sciences, Engineering, and Medicine (NASEM) has estimated that at least 260,000 people must be treated each year to eliminate hepatitis C by 2030. However, only 120,000 people on average are treated each year and that number continues to decline in the context of the COVID-19 pandemic.

In terms of next steps, the project team is currently in the process of updating *Hepatitis C: State of Medicaid Access* project to reflect what has been learned about these other barriers to care and to include many of them in the assessment process moving forward. Based on the stakeholder input received, the state evaluation criteria have been updated and the project team is in deep data collection mode. The release of the updated report cards and full report is targeted for late May 2022.

Senate Bill 159 (SB 159) HIV PrEP & PEP For California Pharmacists Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment

Marisa Ramos, PhD

Chief, Office of AIDS

California Department of Public Health

Dr. Ramos presented on Senate Bill 159 (SB 159), HIV Pre-Exposure and Post-Exposure Prophylaxis (PrEP & PEP) For California Pharmacists. As a reminder, oral PrEP is a once-a-day pill (Truvada/Descovy) that can reduce a person’s risk of acquiring HIV by up to 99% from sexual contact. Among individuals who inject drugs, there is a 70% reduction in acquisition of HIV. PrEP provides maximum protection when taken daily for 7 days after engaging in anal sex and 20 days for vaginal sex or injection drug use. It is important to note that while an injectable version of PrEP given once every 8 weeks has been approved by the FDA, it is not relevant for SB159. Pep is a regimen to reduce the risk of contracting HIV after an exposure. PEP is the

¹⁷ Eyasu H Teshale, MD, Henry Roberts, PhD, Neil Gupta, MD, MPH, Ruth Jiles, MS, MPH, PhD, Characteristics of persons treated for hepatitis C using national pharmacy claims data, United States, 2014–2020, Clinical Infectious Diseases, 2022; ciac139, <https://doi.org/10.1093/cid/ciac139>

“Plan B” of HIV that reduces the risk of contracting HIV if taken in the 72-hour window from the moment of possible exposure. PEP is most effective when started as soon as possible and typically consists of Truvada or Descovy plus another agent, which is usually an HIV integrase inhibitor. Unlike PrEP, PEP is a complete antiretroviral regimen against HIV. Once prescribed, it must be taken for 28 days.

SB 159 was introduced by State Senator Weiner and was signed into law on October 7, 2019. SB 159 provides authority for pharmacists to determine if patients meet clinical criteria for PEP or PrEP and allows them to furnish 30 or 60 days of PrEP once every 2 years or furnish 28 days of PEP. The pharmacist must inform the patient’s primary care provider (PCP) or provide the patient with a similar report to give to their provider themselves. The law also requires that before providing PrEP or PEP, pharmacists have to complete training that is approved by the California Board of Pharmacy or that is delivered by an accredited provider. Free training is available.¹⁸ Participants must pass a quiz with a 70% score, maintain the record of training for 4 years, and retrain every 4 years. There is a website¹⁹ to find pharmacists who are permitted to provide PrEP/PEP and who have signed up for the website. It is important to note that pharmacists are not automatically enrolled in this website.

Patients must meet certain conditions to qualify for pharmacist-furnished PEP. The pharmacist must screen the patient and determine that exposure occurred within the previous 72 hours. The patient must meet the clinical criteria for PEP consistent with CDC guidelines, and there must not have been any signs or symptoms associated with acute HIV. Given that education must be provided, the patient may not waive the consultation with the pharmacist. The pharmacist is required to provide information to the patient’s PCP or provide the patient with a list of where to seek care or start PrEP if they do not have a PCP. PEP initiation should not be delayed for baseline laboratory testing, but the patient should follow-up with a provider for laboratory testing.

To qualify for PrEP, the patient must have a negative HIV test in the previous 7 days (negative antigen/antibody test or negative rapid test) and no signs or symptoms associated with HIV infection. The patient must not be taking any contraindicated medication. As with PEP, the patient must receive education and may not waive the consultation. The patient must consent to follow-up with a PCP for additional prescriptions. The pharmacist must maintain a record of the prescription provided and provide information either to the PCP if the patient has one or provide a list where the patient may seek additional care for PrEP.

In summary, pharmacists have played an important role in HIV prevention for decades. They provide condoms, sterile syringes, and supporting adherence to HIV treatment. The notion behind SB 159 is that pharmacists are uniquely situated to improve access to new preventive tools, PrEP, and PEP—especially for patients who are underserved. There are typically pharmacies within walking distance or nearby. Pharmacists also have relationships with prescribers and can support linkage to care for ongoing PrEP prescriptions, HIV testing, and laboratory monitoring. Financial assistance is available on the PrEP-AP Webpage.²⁰ Evaluation of implementation of this program begins this year to assess use, barriers, and facilitators.

¹⁸ https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml

¹⁹ https://www.dca.ca.gov/webapps/pharmacy/services_search.php

²⁰ <https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAadap.aspx#prep>

Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment

Rachel McLean, MPH

Chief, Policy and Viral Hepatitis Prevention
Sexually Transmitted Diseases (STD) Control Branch
California Department of Public Health

Ms. McLean reported on additional policies and laws passed in California, as well as their implications. In terms of background, STD rates increased significantly in California between 1990-2019. As syphilis rates increased among people of childbearing age, congenital syphilis cases increased as well to an alarming 446 cases in 2019. This is included cases of fetal demise and stillbirths, which are preventable and should never have happened. California also bears a significant burden of chronic hepatitis B and C based on the most recent data. From 1989 to 2016, the cumulative total of chronic hepatitis B cases newly reported to CDPH was 287,087. From 1994 to 2018, the cumulative number of chronic hepatitis C cases reported to CDPH was over 700,000. This does not take into account the many people living with hepatitis B or C who remain unaware of their infection, meaning that these are probably under-estimates. STI testing volume decreased during the COVID-19 pandemic, which highlighted the need for alternative testing options.

Within that context, there has been interest in creative strategies that can be used to increase all hepatitis testing. Two bills were signed into law, Senate Bill (SB) 306 (Pan, Chapter 486, Statutes of 2021)²¹ and Assembly Bill (AB) 789 (Low, Chapter 470, Statutes of 2021)²² that healthcare providers (HCP) in California are now required by law to follow. Effective January 2, 2021, California law now requires syphilis screening in pregnancy per CDPH guidelines. This includes third trimester screening in pregnancy. SB 306 also provides liability protections for prescribers and pharmacists dispensing expedited partner therapy (EPT) for chlamydia and gonorrhea. This is very exciting, given that prescriber concerns about liability have been a barrier for a number of years. California also had stricter laws related to the use of Clinical Laboratory Improvement Amendments (CLIA)-waived rapid tests. SB 306 now will allow HIV test counselors who are trained and certified to use CLIA-waived rapid tests. AB 789 requires primary care facilities to screen adults for hepatitis B and C, which was modeled after the law in New York and appears to be the first law that requires screening for both.

SB 306 also requires health plans to cover at-home STD tests, which is particularly important due to the increased use and comfort that arose with home tests for COVID-19 that could help pave the way for at-home tests for other diseases. The SB 306 definition of at-home STD tests is, "A product used for a test recommended by CDC guidelines or USPSTF that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting." CDPH has spent a lot of time examining each word in this definition, given that it is somewhat cryptic. It has been reported that FDA is working closely with companies to help them achieve FDA approval standards for at-home tests. The SB 306 at-home STD testing coverage requirement is complicated. Specific coverage requirements vary by payer depending on which state agency regulates their products. Medicaid (Medi-Cal) does not have to reimburse for at-home STD tests until specific billing codes are created, including American Medical Association (AMA) Common Procedural Terminology (CPT) Codes and CMS Healthcare Common Procedure Coding System (HCPCS) Codes.

²¹ SB 306 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB306

²² AB 789 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB789

In terms of next steps, CDPH is in the process of developing fact sheets to summarize various aspects of SB 306 and AB 789 for dissemination to HCP, payers, local health departments, and CBOs. The fact sheets are now going through the clearance process. They also are monitoring testing company efforts to request new CPT and HCPCS codes that will be needed for at-home test reimbursement. CDPH has a formal evaluation plan in place and is exploring options for how to evaluate the impact of these bills.

Louisiana's HCV Elimination Plan

Anthony James, MS, MA, MSHCM

Deputy Director of Programs
STD/HIV/Hepatitis Program
Louisiana Department of Health

Mr. James reported on the progress that has been made on Louisiana's HVCV Elimination Plan that was launched in July 2019 and is rooted in several strategies. One of the primary strategies is the establishment of an innovative payment model. The plan also seeks to expand provider capacity to treat hepatitis C; educate the public related to the availability of a cure; expand screening and expedite linkage to HCV treatment; strengthen surveillance systems to identify and diagnosis; and link those who are identified to care and treatment as part of Louisiana's "Big Bet." As part of the Big Bet, Louisiana Department of Health (LDH) has undertaken several large-scale projects to improve health conditions within Louisiana. Since the launch of the Big Bet in 2019, a total of 10,759 persons have access to treatment for hepatitis C. That includes 9,302 persons within the Medicaid population and 1,457 persons who are incarcerated.

In terms of the breakdown of characteristics of Louisiana's Medicaid and corrections populations, the majority of folks (60%) who have access within the Medicaid population are male and 40% are female. In the incarcerated population, 96% have been male and only 4% have been female. While there is a fairly good distribution race and ethnicity, approximately 59% of those accessing Medicaid treatment are white and 60% of those within the incarcerated population are Black. It is important to have that historical context to understand that a disproportionate number of persons of color are incarcerated compared to those who identify as White. The largest distribution of those accessing treatment within the Medicaid population are between 30-59 years of age, with a similar trend within the corrections population.

As everyone knows, even the best laid plans have hiccups. Since the launch of the plan in 2019, one of the biggest hiccups has been COVID-19. Being a Southern Gulf state, hurricanes also impact Louisiana significantly. Hurricanes Ida, Laura, and Zeta and an ice storm all had major impact on the Southwestern portion of the state in 2020 and 2021. Prior to this prescription model, about 61 persons on average were accessing a hepatitis C treatment. That number increased significantly to about 390 persons on average. Due to COVID-19 spikes, that average decreased to about 290. It is important to note that for persons on Medicaid, treatment is calculated using DAA claims data. Due to delays in reporting of claims data, numbers from recent months are preliminary and are an undercount.

Since July 15, 2019 over 9,300 persons have accessed treatment for HCV through Medicaid; 9,133 persons have started treatment for HCV through Medicaid for the first time; 7,930 persons who have accessed treatment have completed it; 6,394 persons have accessed treatment because of Medicaid Expansion; 612 providers have written prescriptions for DAAs for the first time; and last HCV RNA was positive for 585 persons who did not complete treatment. In order for all of this to work, it was necessary to examine some policy changes.

Several of those dealt with Medicaid in terms of lifting provider restrictions and the sobriety and fibrosis requirements.

It is important to understand that while over 9,300 individuals have been treated, others have been identified who are currently enrolled within the Medicaid group who are accessing one of the 5 managed care organizations (MCOs), which helps fulfil Medicaid's charge. Close to 16,000 persons with a positive RNA have been identified who are currently enrolled but who have not been treated. In terms of the last 2 years of this iteration of the statewide elimination plan, a lot of energy and attention will be placed on examining this group in more detail and on examining additional strategies that can be put in place to help lead these folks to a cure.

Based on data from July 15, 2019 through August 31, 2021, over 8,100 individuals in Medicaid had started treatment. Of those, over 7,000 (87%) completed treatment and over 5,200 (65%) had sustained virologic response (SVR) testing performed. Of those, approximately 4,700 (90%) achieved SVR and 514 (9.8%) had a failed SVR. Examining the Medicaid population by birth sex, 88% of females who started treatment completed treatment and 87% of the population of who started treatment completed treatment. There was a larger rate of SVR failure within the male population (10.5%) compared to the female population (8.7%).

By race and ethnicity, 93% of American Indian/Alaskan Natives (AI/AN), 87% of Blacks, 83% of Hispanic/Latinx, and 8% of Whites who started treatment have completed treatment. Of those who failed treatment, 10.2% were White, 9.3% were Black, 9.3% were Hispanic/Latinx, and 7.7% were AI/AN. By age, 80% of persons 18-29 years of age, 84% of persons 30-39 years of age, 89% of persons 50-59 years of age, and 88% of persons ≥60 years of age completed treatment and achieved SVR. Among those who experienced failure, the highest failure was among persons 18-29 years of age at 19%, followed by persons 30-39 years of age at 11.6%, persons 40-49 years of age at 9%, persons 50-59 years of age at 8.9%, and persons ≥60 years of age at 6.6%.

Assessing completions and failures by regions helps LHD prioritize regions that may be experiencing more difficult challenges. Also of interest is that 653 providers have prescribed for the first time. Determining where those providers sit within the state and using provider details can help identify and work with the regions with slower increases in new providers prescribing DAAs for the first time. From a regional perspective, Region 9 (13.7%), Region 2 (11.9%), and Region 1 (10.8%) had the highest rates of failure. Regions 4 (6.6%), 5 (6.9%), and 6 (6.5%) are doing somewhat better. Region 7 (3.7%) has had the most success, which is the Shreveport/Monroe area. Among persons who have identified as having an opioid use disorder (OUD), 84.9% have completed treatment versus 93.2% with no OUD. The completion rates for males and females seem to be fairly consistent, while there is slightly variation in terms of race and ethnicity and by age group. There are some variations from a regional perspective as well.

To summarize, Louisiana has made significant progress in addressing that HCV epidemic. If not for COVID-19 and severe weather conditions, it is anticipated that more people would have been treated. Based on data received earlier in the day, the number of individuals accessing treatment from the Medicaid and corrections populations is close to 11,000 combined.

Transitions Clinic Network**Shira Shavit, MD**

Family Physician

Executive Director & Co-founder

Transitions Clinic Network

Dr. Shavit explained that the Transitions Clinic Network (TCN) is a national non-profit organization that supports health system transformation for primary care clinics that are serving communities disproportionately impacted by incarceration. In San Francisco in 2006, TCN developed an evidence-based model of primary care for people returning home from incarceration. All of the community health centers employ CHWs with histories of incarceration within primary care teams to address the health and well-being of people returning from incarceration. To date, they have worked with 48 primary care clinics in 14 states and Puerto Rico.

People who are incarcerated are disproportionately impacted by a variety of chronic medical conditions, HIV, and substance use. People who are incarcerated have 3 times the prevalence of HIV, a much higher prevalence of hepatitis C with rates approaching 30% to 40%, and increased risks of STIs of 30% to 40%. Incarcerated people also have higher rates of chronic medical conditions and high rates of SUD and mental health conditions. With 95% of people returned home, the primary care system is a natural place to think about providing care to these individuals since they have multiple, complex, comorbid conditions. It is important to remember that in terms of cross-sector collaboration and working across systems, the carceral system and the health system have very different cultures and that really dictates a lot of what can be done and how. The punitive aspect of the carceral system sometimes plays out significantly and can impact what is known to be best practice for caring for people in the health system.

While people may not receive great care while they are incarcerated, people's health actually worsens when they are released from incarceration. Their HIV or SUDs may become worse, their viral loads may increase, they are more likely to be hospitalized post-incarceration, and they are more likely to die. A seminal study showed that people were 12 times more likely to die in the first 2 weeks post-incarceration from drug overdose, cardiovascular disease (CVD), suicide, or cancer. While great strides have been made on a policy front via ACA and Medicaid Expansion, many people who previously did not get Medicaid now have Medicaid and are eligible for services upon release. Having that Medicaid card is not always enough to get people in the door to treatment and it does not always translate to increased engagement or use of services.

That is because people face tremendous barriers when they come out of incarceration that are not just about access to care or having insurance. There is little continuity of care between systems. People may not even get medications or if they do, they get a shortened supply of medications that is not enough to bridge them to the health system. They have competing priorities, with all of the SDOHs evident (e.g., housing, employment, food on the table, stigma and mistrust with the health system due to negative experiences prior to incarceration, et cetera). These are Black and Brown communities that have experienced discrimination at the hands of health systems and then have negative experiences in the carceral system, so it is no wonder that they have a healthy mistrust of systems when released. They also face a lot of challenges in navigating complex services and services in the community that may not meet their needs.

The TNC Model of Enhanced Care was created to try to build capacity in the community health side. While it is easy to point the finger at the carceral system as not being a robust health system, the outside health system also was not meeting the needs of people returning home. Services need to be enhanced in community health systems to provide patient-centered services and engage people into care. In collaboration with communities, the TNC Model of Enhanced Care was created. This model is based on existing primary care clinics where each clinic hires CHWs who have experienced incarceration in prison or jail, most of whom have felony convictions. TNC also works with the clinics to ensure that they are providing patient-centered services like treatment of hepatitis C, HIV, OUD, behavioral health conditions, et cetera. They also work with the clinics to build cross-sector collaboration with the criminal legal system, as well as many other systems to address SDOH (e.g., re-entry organizations, community networks, faith-based networks, family systems, behavioral health system, public health system, tertiary care system, housing system, et cetera). This forces clinics to open their walls and be more contiguous with these important systems in supporting the care for people who are coming home.

This model has been successful because it follows what the community dictated as being needed. They have iterated on the model and have studied it, which has shown that this is an evidence-based model of care. Hiring CHW with lived experience in incarceration and embedding them into clinics has reduced urgent care utilization. For instance, a randomized control trial (RCT)²³ was conducted in San Francisco that assessed 200 people with chronic medical conditions or >50 years of age just released from prison. All of them were engaged into care by CHWs with lived experience. They were then randomized to either staying in the TNC or receiving primary care in the remainder of the system. They found that patients in the program had 50% fewer ED visits in the first 12 months post-release, and that having CHWs engaged study participants at much higher rates into primary care than is seen in the community.

Some information has come from unpublished administrative data from one of TNC's programs in Santa Clara County in California that works very closely with their jail.²⁴ Their health system is part of the jail health system as well, so they were able to make appointments in the jail for people pre-release, but only 33% of people were going to their appointments. When CHWs with lived experience go inside and meet people in the jail, the appointment attendance rates increased to 70%. This demonstrates that the CHW component is critical in bridging systems and engaging people in care.

A propensity-matched study²⁵ in Connecticut of enhanced primary care on contact with the criminal justice system among individuals recently released from prison to New Haven compared to individuals who were released to Hartford where there was no transition clinic program. This study found that individuals in the TNC program had fewer preventable hospitalizations and fewer probation and parole violations. They were spending 25 less days re-incarcerated in the first year post-release. The takeaway from this is that when investments are made in the health system to support these populations, costs can be reduced and outcomes can be improved in other sectors.

²³ E.A. Wang, et. al. AJP 2012 Jul 19

²⁴ Data provided by Dr. Ari Kriegsman, Santa Clara Valley Health & Hospital System 2017

²⁵ E.A. Wang, et. al. BMJ Open 2019

The last 2 years have laid the groundwork for the opportunity to build more bridges between carceral systems and health systems. Because of COVID-19, correctional leadership for the first time really understood what it meant to the importance of bridging these systems. Like everything else in the pandemic, many of these disparities and the need to address them became evident. Many of the statewide systems within TCN built stronger bridges with their carceral systems to be able to connect with people pre-release and provide care coordination systematically from those systems back to community health systems, and back to networks of patient-centered services in the community.

The timing of that groundwork has been fortunate in that some major policy shifts are emerging in the country, such as policies to waive the Medicaid inmate exclusion policy. When people are incarcerated, they are excluded from using Medicaid for their routine services. The idea would be to turn on Medicaid 30, 60, 90 days, pre-release from incarceration to allow health systems or other entities in the community to help provide care coordination from one system to the other. Another policy opportunity relates to providing targeted services to people returning home from incarceration. In California, individuals returning from prison or jail are eligible for enhanced care management services, which is a team-based approach to support people in navigation of the health system and around SDOH. Recent legislation that was passed and pending supports the idea of Section 1115 Demonstrations that would allow for states to turn Medicaid on at some point pre-release to bridge the carceral system and the community health system.

On paper this sounds feasible, but it is important to recognize that it requires a lot of system transformation. The primary care system requires tremendous system transformation to successfully care for this population. In the carceral system, there are many barriers to cross-sector collaboration and a lot of transformation is needed there as well. It is important to recognize that some of the barriers are structural. For instance, having 35 prisons across a very large geography could be a major barrier for local entities that support individuals coming out in terms of meeting with patients and supporting them in the transition home. Other barriers that may play a role include the leadership in place, lack of discharge planning services, lack of meaningful health information exchange, absence of timely identification/access to patients, lack of telehealth services, limited access for all types of community service providers, the siloed nature of carceral systems, patient mistrust, and/or isolation from/lack of community partners. Much remains to be done to build better capacity within the carceral system to enable partnerships with health systems.

The TCN has demonstrated that the policy strategy of supporting the integration of CHWs into health systems who have lived experience of incarceration means that these individuals can give back to their communities to make a difference to improve health outcomes, and health systems can contribute to reversing the harms of mass incarceration by providing job opportunities for people who normally are excluded from health systems because of their criminal record. This really is a win-win.

CHAC Member Discussion Panel 2

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What policy changes are needed to improve access to care and prevention services and tools for HIV, other STIs, and viral hepatitis among populations disproportionately affected by these infections?
2. What policy-making partnerships should CDC/HRSA establish or expand to improve care and prevention among these populations?
3. What are the opportunities for CDC/HRSA to inform and collaborate with states on evidence-based policies that establish enabling environments to decrease HIV, other STIs, and VH?

The following questions, observations, and suggestions were raised:

- Regarding non-viral hepatitis and hepatitis C, Dr. Mehta said it is clear that barriers are disproportionately faced by PWID and other marginalized populations. Related to the barriers pertaining to testing, genotyping, and pharmacy pick-ups described, a recently published study demonstrated that in a global population, people with chronic hepatitis C can be treated with minimal initial monitoring and providing all 84 tablets with little in-person contact. The study demonstrated that it was safe and that SVR rates were comparable to other real-world studies of persons with hepatitis C. This is important to think about in terms of policies going forward and data collection on barriers and acceptability of providers on such an approach.
- Dr. Dowler emphasized that getting Medicaid Expansion in every state would be amazing and that establishing CPT and HCPCS codes for at-home testing is critically important in terms of billing and reimbursement. CHAC probably could have some influence on this effort and perhaps could make a recommendation about this.
- Dr. Mermin asked what advice Dr. Simmons and Ms. Harvey could give to CDC and CHAC about how the agencies could help states and local jurisdictions do X, Y, and Z to make a major difference in terms of helping them make the changes recommended.
- Ms. Harvey emphasized that there are many reasons why policies changed over the last 5 to 7 years. For instance, prices have changed, the Center for Health Law and Policy Innovation brought litigation in a lot of states based on the fact that the restrictions were illegal, and there has been a ton of very forceful patient advocacy around these issues. Thinking about the specific questions Dr. Anderson read is that federal guidance in this space would be very valuable. Thinking back to the 2016 Bulletin that was jointly put out in the HIV space around treatment and prevention by CDC, HRSA, and CMS has been an essential tool in some of her other work to help move the needle on Medicaid access. There is an opportunity for a similar initiative in the Hepatitis C space as well.
- Dr. Simmons added that another helpful tool states had over the last few years was the HHS Hepatitis C Medicaid Affinity Group (Affinity Group), which engaged in collaborative efforts between Medicaid, departments of health, corrections, et cetera to discuss innovative payment models. Many have cited this group as a catalyst for demonstrating that evidence-based policy change and evidence-based programming can make major impacts.

- Dr. So noted that it would be beneficial to know how many state Medicaid programs are covering hepatitis C treatment among incarcerated populations, particularly given that over 20% of incarcerated populations are estimated to have hepatitis C. It is clear that evidence-based policy change has made an impact, such as requiring pregnant women to be screened for syphilis, hepatitis B and C screening law, and linkage to care law. He emphasized the need to address health disparities/inequities and incentives/laws for providers to incorporate recommendations from various bodies (CDC, HRSA, USPSTF) into health records, waivers, and screening recommendations/requirements. CDC and HRSA should reach out to electronic medical record (EMR) providers to incorporate recommended screenings, linkage to care, and clinical support/decision tools to ensure that patients are identified and receive appropriate treatment.
- Dr. Anderson agreed that while there may be guidance or policies in place, in hectic daily 10- to 15-minute visits with patients, it is difficult for this to rise to a priority. Also, there may be issues related to lack of knowledge. Having decision aids in the EMR is invaluable.
- In terms of Dr. Shavit's comments about the policy suggestion Dr. Wester made during her presentation about ensuring the best price restrictions in Medicaid do not preclude access of strategies for incarcerated populations at the state or county level justice-involved populations, particularly for hepatitis C treatment and other expensive medications. Louisiana has used 340B pricing, but she asked whether there are any examples of jurisdictions that have successfully been able to put waivers in place for that.
- Dr. Shavit clarified that in the study in which they were assessing cost savings for patients who were receiving care in their program compared to other programs, they did a propensity match for another city in Connecticut and found that they had a reduction in preventable hospitalizations and parole probation violations. The cost savings was primarily on the criminal legal side with 25 days or less incarceration. While she was not specifically talking about pharmaceuticals, investments in Medicaid saves costs in other sectors. No states have successfully waived the Medicaid exclusion policy yet. CMS had a listening session and is developing some guidance based on that. Multiple states have applied, including California, but none have been approved yet to her knowledge. However, it is an emerging opportunity.
- Dr. Wester asked whether there has been any integration of a requirement for hepatitis C screening among pregnant persons. Through claims data, they are seeing about a 30% uptake of hepatitis C screening among pregnant persons and they would like to see that increase quickly.
- Dr. So indicated that the California law is based on recommendations from the USPSTF, which recommends screening for all adults for hepatitis C. Because universal screening has become the law in California, it makes it much easier to implement screening in EMRs. He has been trying to convince Kaiser and other large groups to introduce all of the USPSTF recommendations into EMRs. As of this month, Stanford has incorporated universal hepatitis B and C testing, even though the USPSTF recommendation is not quite universal for hepatitis B.
- Dr. Ramos indicated that they started a pilot project in Orange County, California to provide medication to individuals who are HIV-positive within that county incarceration system. It is paid through the CDPH AIDS Drug Assistance Program (ADAP), which is a mixture of general funds versus HRSA funds. They are currently going through an estimate package.

It looks like they will be able to expand to more counties if they are interested in participating in the program. Some of the more conservative counties were not testing everyone for HIV as they entered some of the jails. To ensure that screening is done, treatment for those found to be positive will be paid for by CDPH versus using the county's general funds. The hope is to expand to at least 6 more counties that have shown interest.

- Dr. Anderson said she was impressed with the recent state laws in California and their innovations have moved this topic along. She observed that one barrier seems to be that there are so many different county and state laws. While it is not clear if/how CDC/HRSA could impact that, perhaps a central compilation of innovative strategies as laws arise could be beneficial. Access to knowledge about innovations in some states might be very appropriate in terms of pushing the discussion forward in other states.
- Mr. Williams indicated that NCHHSTP funded the National Conference of State Legislatures (NCSL) to create a Legislative Data Tracking System.²⁶ That is exactly what the system is designed to do, and the system refreshes every 2 weeks. As states introduce pieces of legislation that fit certain key words across all of these areas, including laws that affect healthy youth and sex education curriculum, these will be displayed. It is easy to ask NCSL to make adjustments to the system to ensure that everything is captured.
- Dr. Dowler pointed out that even when there are laws, they are very hard to track and enforce. She noted that the Guttmacher Institute maintains a good listing.
- Dr. Mermin said he was intrigued by the differential aspects of the pharmacy program for PrEP that Dr. Ramos described. Based on the examples presented, it seems that the emergency aspects of receiving PrEP through pharmacies is harder than receiving PEP. The ongoing benefit of having a pharmacist as a provider is lost if they can give only a starting dose. While receiving a starting dose can be helpful, he wondered why the PrEP restriction of 30-60 days once every 2 years was included and whether it could be changed.
- Dr. Ramos indicated that there is a history. Originally, there was a push from some of the clinics that had a pharmacy within their organization since it would be easy for someone to present, be started on PrEP, and then go next door to see their PCP. While she did not have the data, PrEP has been under-utilized from what she has seen. However, the specialty pharmacies within those clinics would not like it to go away because they can administer and at least start PrEP. Implementation has been slow. The state is seeing more dispensing for PEP than for PrEP. Because of COVID-19, this was averted to do the training that is required.

Wrap Up Day 1

Travis Gayles, MD, PhD
CHAC Co-Chair, CDC Appointee

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Dr. Anderson observed that it had been a tremendous day with a lot of information that began with reports from CDC and HRSA. They heard some statistics on continued increases in syphilis and congenital syphilis, as well as increases in adolescent mental health concerns and

²⁶ <https://www.ncsl.org/research/health/state-public-health-legislation-database.aspx>

the need to find ways to address these. Some of these negative statistics were offset by the data CHAC heard about the dramatic improvement in viral load suppression overall and in key populations; demonstrable reductions in disparities; and very impressive successes reported in CDC-funded programs in schools to decrease risky sex behaviors, safety concerns, and sexual assault. She congratulated CDC and HRSA for their work and deep thinking in terms of integration and collaboration strategies and the use of the syndemic approach to deal with these interrelated problems, which is critical. In the afternoon, they heard about innovative models of care and continued challenges. Some of the innovations and the ability to address challenges are constrained by state- and county-level policies and legislation, funding, and lack of time or knowledge on the part of physicians. They also heard about a lot of flexibility and innovation during the COVID-19 pandemic and in many cases inspired by it. They heard about the role of integration of different relevant infections, as well as issues related to SDOH.

Dr. Gayles expressed his gratitude for the great presentations and for the work everyone does on a daily basis in order to be able to present the data that you provide. He further emphasized the continued notion of evolution in terms of the need to be modern and think outside the box moving forward with regard to funding to sustain programs and to continue to pivot to keep efforts moving. This includes the ability to speak fluently to young people to make sure that they are engaging and they are able to effectively communicate their needs in safe spaces. With regard to engaging in conversations about increasing services that folks need, it is important not to use mental health as a crutch to not do the necessary work to root out racism, systemic issues, bias, transphobia, and all of the other things that significantly influence the potential success of projects in the future in terms of being able to sustain funding and considering the significant variability in terms of the differences in geography and the level of services available. A lot of tremendous work has been done but there are still many headwinds in the way moving forward.

Adjourn

Dr. Mermin officially adjourned the meeting for April 26, 2022 and CHAC stood in recess until 11:00 AM ET on April 27, 2022.

Day 2: Welcome and Roll Call

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

The proceedings were called to order at 11:00 AM ET. Dr. Mermin welcomed participants to the second day of the CHAC meeting. He conducted a roll call and asked members to disclose any new COIs. COIs did not differ from the previous day and are reflected in the table on page 8 of this document. He confirmed that 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 27, 2022.

Special Presentation: Turning the Tide on Self-Testing and Sample Collection

Moderator: Elizabeth DiNenno PhD; Division of HIV Prevention, NCHHSTP, CDC

FDA Regulation of HIV Self-Testing Devices and Self-Collection Kits for HIV Diagnosis

Julia Lathrop, PhD

Associate Deputy Director
Division of Emerging and Transfusion-Transmitted Diseases
US Food and Drug Administration

To lay the groundwork Dr. Lathrop explained that in vitro diagnostic devices (IVDs) are medical devices per Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) [21 CFR 809.3] that defines medical devices as: “Reagents, instruments, and systems used in the diagnosis of disease or other conditions . . . in order to cure, mitigate, treat, or prevent disease intended for use in collection, preparation, and examination of specimens from the human body.” Clearly, self-testing and self-collection kits are considered to be medical devices. As such, they are subject to the provisions of the FD&C Act. It also means that regardless of whether a device is regulated either in the Center for Biologics Evaluation and Research (CBER) or the Center for Devices and Radiological Health (CDRH), it is subject to the provisions of the FD&C Act.

The review of all IVDs, regardless of where they are reviewed or what their use is, is based on the balance of the benefit and risk to the individual and that the data provide a reasonable assurance of safety and effectiveness of the device. A risk for an IVD is providing an incorrect result to the individual. For an HIV diagnostic, that would be a false positive or false negative. Risks from receiving a false negative could be that an individual is denied life-sustaining treatments and could transmit a life-threatening disease. The risk for having an incorrect result, especially a false negative for HIV, is very high. One element of assessing for reasonable assurance of safety and effectiveness and the balance of benefit/risk pertains to whether the device does what it is intended to do.

All IVD reviews begin with a review of the intended use because this is where the determination of the risk lies. Intended use pertains not only to the HIV diagnosis, but also the sample type, population, conditions (e.g., professional use only or self-collection). The risks all lie in the intended use and it is from the intended use that the review logically flows. It is important to keep in mind that one device may have more than one intended use and those uses can have different risks. For example, HIV diagnostics and viral load monitoring have very different risks

associated with incorrect results. The risk involved and what is necessary to mitigate the risk determine whether a device is categorized as a Class I, Class II, or Class III. Colloquially speaking, those mean low, moderate, and high risk, respectively. However, that is not entirely accurate because there can be a high-risk device like an HIV diagnostic that can be safely regulated as a Class II device. FDA is in the process of reclassifying HIV diagnostic supplemental and viral load tests from Class III to Class II. The risks associated with an incorrect result have not changed; these are still high-risk devices. Having approved many devices over many years allows FDA to establish special controls, which are provisions associated with the demonstration of the safe and effective use of the device. Establishment of special controls allows for successful mitigation of the risks in order for FDA to safely review these as Class II devices requiring a PMA. Special controls can be requirements such as performance criteria, post-market reporting, et cetera, that are necessary to provide reasonable assurance of safety and effectiveness of the device. Because reviews are based on intended use, there is no expectation that all Class II devices should have the same special controls since the risks associated with each intended use differ.

Turning specifically to FDA regulation of HIV self-testing devices (HIVST), HIV devices are Class III devices that require approval of a PMA before they can be marketed. There is one approved self-testing device on the market, the OraQuick® HIV self-test approved in 2012. HIVST devices were not included in the reclassification of HIV diagnostic, supplemental, or viral load tests due to a lack of sufficient experience with these devices to write special controls that will safely mitigate the risks so that they can be regulated as Class II devices. FDA does agree wholeheartedly that there is an urgent need to improve access to self-testing for HIV. To that end, FDA is working with manufacturers to consider alternative validation strategies and streamlining of the review and approval process to expedite entry into the market. When the OraQuick® HIV self-test was approved, the process was very laborious and very careful because there were a lot of concerns, even with the whole concept of self-testing, but HIVST has since been demonstrated quite clearly to be safe and effective. Thus, many of the concerns that caused the original process to be so laborious have been mitigated through experience with the devices. FDA has been working with manufacturers to determine ways they can use existing data, for example, especially if it is an already approved point-of-care device, and adding a self-testing claim to that. This differs from a manufacturer who is submitting a brand-new device never approved before.

HIV self-collection kits also require FDA approval. All self-collection kits are medical devices that require FDA authorization before they can be distributed regardless of their intended use, but the review pathway can vary based on the intended use of the device. For example, a device might be intended for home use or use in a clinic for self-collection that is supervised or unsupervised based on disease indications. The reason that FDA needs to review these devices is that adequate and appropriate sample collection is essential for device to meet performance expectations. Self-collection means that an untrained individual is collecting their own sample, so there is no automatic assurance that collection has been performed properly when the sample arrives at a laboratory. FDA reviews instructions for sample collection and the device's performance with the intended sample type to ensure a reasonable assurance of safety and effectiveness of the device.

In terms of the current landscape, FDA recognizes there is a need for self-collection kits for HIV diagnosis for individuals who are unable or unwilling to attend a clinic. However, HIV self-collection kits require approval of a PMA or clearance of a 510(k) following reclassification of HIV diagnostic device to comply with the FD&C Act. Distribution of unapproved HIV self-collection kits is a violation of the Act. There are no FDA-approved HIV self-collection kits that use blood samples currently on the market. FDA's goal is to bring unapproved/uncleared

devices into compliance with the law and regulations. In the interest of public health, FDA is committed to working with device developers to meet the requirements.

Turning the Tide on Self-Testing and Sample Collection Background and Need

Michele Owen, PhD

Associate Director of Laboratory Science
NCHHSTP, CDC

To ensure that everyone was on the same page, Dr. Owen first shared the following terminology and definitions:

- **Point-of-Care Test (POC):** Conducted near an individual also referred to as point of contact or rapid tests administered by trained staff or health care providers
- **Self-Test:** A complete test conducted by an individual for their own knowledge—also referred to as an over-the-counter test (OTC) or direct-to-consumer test (DTC).
- **Self-collection (self-collected test):** A scenario where an individual collects their own sample, and hands it off or ships the sample to a laboratory for testing

There are many considerations for self-testing and self-collection testing. It is very important for populations where clinic or laboratory testing is difficult or not feasible. However, it is very important to provide clear information regarding assay limitations. For example, the oral fluid assays will detect some early infections.²⁷ These are never the final diagnosis. They are used in conjunction with clinical testing for a definitive diagnosis. Ideally, these tests should be available at a price point that will allow wide access for many people to have the ability to use them. As noted, OraQuick® is the only FDA approved HIV self-test. This is an oral fluid test that costs about \$35 to \$40 retail. It is important to note that this test does not detect acute HIV infections (e.g., up to 90 days for positive result post infection) and there are limitations for its use in the context of PrEP. Based on delayed reactivity shown in PrEP trials, this test is not optimal for prescribing PrEP. There are currently no cleared self-tests for STIs or viral hepatitis.

In terms of HIV self-testing data in the US, CDC in conjunction with Emory University conducted a longitudinal randomized control trial (RCT) known as eSTAMP²⁸ that demonstrated the feasibility, acceptability, and benefit of distribution of self-test kits. The study used the FDA-approved OraQuick®, a fingerstick test under IDE (Sure Check®), and a dried blood spot (DBS) test. Infection was identified in first time testers and social contacts and no harmful adverse events (AEs) were reported. A partnership with CDC's Let's Stop HIV Together Campaign-to launch TakeMeHome distributed approximately 100,000 HIV self-test kits through a portal on the CDC website.²⁹ This event demonstrated that self-testing serves people who might be reluctant or unable to seek clinic- or community-based testing. This tool was identified by 80% of jurisdictions that are part of the EHE as being very important for their community EHE plans.

The World Health Organization's (WHO's) stance of self-testing is informative. WHO has made recommendations twice that self-testing should be part of eliminating HIV or identifying people and getting them into treatment. The first recommendations were in 2016. After reviewing the data in 2019, the WHO updated their recommendations to make a strong recommendation for HIV self-testing. They also pointed out that testing in this manner reaches high-risk people who

²⁷ Stekler et al, JCV 2013 and 2016; Luo et al JCV 2013

²⁸ MacGowan et al. JAMA Intern Med, 2019

²⁹ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7038a2.html>

might not test otherwise, so it should be an ongoing approach for testing services.³⁰ There are a number of HIVST products available outside of the US with WHO pre-qualification.³¹

As mentioned earlier, there are no FDA-cleared self-collection test for HIV and Home Access is no longer on the market. Commercial laboratories have set-up laboratory-developed test (LDT) services, primarily because of testing during COVID for HIV, STIs, and PrEP initiation because it was known that people were not getting tested. This also was done for hepatitis B and C antibody tests. Multiple studies have been conducted on STI self-collection inside and outside the US. WHO also funded a meta-analysis of STI self-collection tests³² after which they published recommendations for self-collection testing for STIs. Similar to HIV self-collection, WHO pointed out that self-collection of samples for *Neisseria*, gonorrhea, and chlamydia are very important and reach people who might not normally be tested.

In the US, various institutions have set up programs for self-collection for STIs.³³ One of the most well-known program is I Want the Kit³⁴ that came out of Johns Hopkins where they are doing chlamydia and gonorrhea testing. Originating in Baltimore, this testing has now been expanded to Maryland, Alaska, and Arizona residents. The District of Columbia (DC) conducted a similar type of project called GetCheckedDC.³⁵ This is a mail-in STI testing program. Both programs have reached priority populations and data indicate that the methodology is feasible.

CHAC Member Discussion on Special Presentation

To focus the discussion, Dr. Gayles reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. How important is self-testing and self-sample collection to overall public health efforts?
2. Are there specific analytes (e.g., antibody or antigen tests for HIV, HCV or treponemal/non-treponemal test for syphilis) that CHAC would consider a priority?

The following questions, observations, and suggestions were raised:

- Dr. So emphasized that there is a lot of value in having rapid tests for home use and use at outreach events for HIV, STIs, and hepatitis. He asked whether one reason for not having more approved rapid tests and self-tests was because industry is not submitting applications and if FDA should be sending out notices to welcome industry to submit applications.
- Dr. Lathrop indicated that FDA has engaged in increasing outreach to manufacturers to encourage them to submit all of these devices. There tends to be a lot of mythology around what FDA will and will not consider in terms of data. Some of that is because that is the way it used to be and some of it is because people talk amongst themselves and have decided this, or they may have gotten an unhappy answer and then decided that FDA would never consider using data from outside the US. In some cases in the past, that might have been true. However, FDA has been working hard to open up alternative validation strategies that might not have been considered in the past, and is trying to engage outreach to get people

³⁰ WHO recommends HIV self-testing. (2016) World Health Organization. <https://apps.who.int/iris/handle/10665/251549>; Consolidated guidelines on HIV testing services. <https://www.who.int/publications/i/item/978-92-4-155058-1>

³¹ Latest list of WHO prequalified products: https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

³² Ogale et al. BMJ Glob Health 2019

³³ Kersh et al: J Clin Microbiol, 2021

³⁴ <https://iwantthekit.org/>

³⁵ <https://www.getcheckeddc.org/>

to come in. Fundamentally, FDA can only review what people submit. People also can simply start conversations with FDA regarding what is/is not required. There is a pre-submission process that is simple and can be informational. They want people to talk to them about what they have and what the expectations are. There is no penalty or user fee to clarify what is needed. In a pre-submission, FDA's feedback is binding. If they say that a study design is acceptable, they cannot change their mind later unless the science changes. It also is confidential on the part of FDA.

- Dr. Anderson observed that there seemed to be no question about the need for self-testing and self-collection devices for various infections. Perhaps the barrier at this time is that more data are needed for validation. She wondered whether manufacturers and laboratories do not have the protocols, are not interested, et cetera. Obviously, the need for more data has cost implications. While FDA is reaching out to individual manufacturers for technologies that are already developed and being used abroad, she wondered what realistically could be done to move this along in the US such as some sort of incentive structure. It sounded to her like a lot of data already have been generated, at least in a global setting, some of which may be useable for US approval. She clarified that when she said "incentivize," she was not suggesting that they pay manufacturers. She just wondered what outreach mechanisms might be available.
- Dr. Lathrop said she could not speak to whether FDA has the ability to incentivize manufacturers and they do not sponsor trials. Manufacturers may assume that the barriers are so high that they could not possibly get approved, but validation is validation. FDA recognizes Clinical and Laboratory Standards Institute (CLSI) standards for measuring assay precision. These are voluntary standards, but they are best practices developed by the device manufacturers. CDC and FDA are on the panels for some of the standards and follow those principles. Good device validation follows the CLSI standards to be properly validated in many cases. FDA has a number of roundtables that are designed specifically to engage in open discussion with manufacturers. She agreed that finding ways to reach out to various manufacturers who are developing these tests is crucial.
- Dr. Owen added that CDC also has tried very hard to engage in outreach with manufacturers by interacting with the Advanced Medical Technology Association (AdvaMed) to discuss the needs for HIV, STI, and HCV tests. In addition, CDC recently convened a diagnostics conference that they have had for many years. Most manufacturers either attend and/or have booths. Manufacturers have said that they will not bring a test to the market if they do not see a market share for that. They are private companies and they want to make money. It is important to continue to emphasize the need for these devices and that there will be a market for them.
- Dr. Dionne-Odom inquired about the role of clinical investigators who design RCTs. In order to reach this vulnerable population who is at-risk and not accessing care, self-testing for HIV and STIs is critical. If researchers receive funding for trials from NIH to conduct this type of research with donated kits from companies that have told them the bar is high for validation through the FDA, she wondered whether that would be the type of data that would be compelling or if the real work needs to be done at the level of the company to put their specifications and QI in place.
- Dr. Lathrop indicated that the clinical data is part of the package, but someone has to actually sponsor and submit the application. There is nothing that says a clinical laboratory or a university cannot do that, but they have to have all of the information that supports the analytical validation for the device as well. That can be challenging. A kit can be made that

works on an already approved instrument, and that a laboratory or university could submit that as their test and take responsibility for it. It does not have to be the manufacturer. While there are some risks associated with that, it can be done. It is difficult when someone is just doing the trial component, because they may not have access to all of the information needed. That would have to be acquired from the manufacturer or the researcher working with the manufacturer to provide that for an FDA application. The data generated in those kinds of studies, if well-designed and potentially can be submitted to FDA in the end, speaking very generically, should be usable.

- Dr. Mermin observed that while the efforts to reach out to manufacturers are appreciated, it is extremely expensive to put forward an application for PMA for a Class III device. For a university to want to conduct the clinical trials is not an easy process, for HIV in particular.
- Dr. Lathrop indicated that the user fee for a PMA is substantial. One benefit for reclassification is that when diagnostics are 510(k), it is a much lower user fee. At the moment, a self-collection kit is a PMA because the assay is a PMA. Once the assays are reclassified as Class II, the self-collection kits can come in as a 510(k). FDA is awaiting the finalizing of the reclassification, but when that occurs, it should lower the financial cost. The clinical studies still need to be done with performance criteria that are in the special controls, but certainly the submission and maintenance of that application are much lower.
- Dr. Markham reported that the IWantTheKit program from Johns Hopkins has made an incredible impact in reaching Native American and Alaska Native communities working with colleagues at the Alaska Native Tribal Health Consortium (ANTHC) and the Inter Tribal Council of Arizona, Inc. (ITCA). They are expanding their work to the Southern Plains Tribal Health Board (SPTHB) in Oklahoma. This has been a phenomenal program and working with the Johns Hopkins team has been outstanding. Testing is only one part of it. There also is a need for funding the culturally sensitive outreach and marketing, because those testing kits are only as good as the folks that they reach. It also is important to have support to linkage to care in local communities. For remote tribal communities where youth do not want to go see their Auntie at the local clinic because that is not going to be confidential, the importance of having that self-testing and anonymous/confidential access and linkage to care is critical.
- In terms of the mention earlier that different centers within FDA have adopted different approaches, Dr. Mermin asked whether thought has been given to aligning the requirements of both centers so that there is more consistency.
- Dr. Lathrop clarified that they do not have different interpretations. They have different intended uses. The requirements for an HIV diagnostic will differ from the requirements for an HCV diagnostic because the risks associated with the intended uses are different. Both centers are assessing them in the same way in terms of the potential impacts of the incorrect results to the individual. For instance, the risk from an incorrect result for a viral load monitoring test versus a screening test are very different. The centers talk all of the time and try to align as much as possible.
- Dr. Mermin indicated that CHAC, CDC, and HRSA have discussed that they do not believe the distinction between hepatitis C and HIV diagnostics at the point of use are different. They talked with FDA about that as well. They are left with a situation in which they are an organization trying to get testing out to the people who need it, but see different routes being required by different centers in the FDA even when it is not clear why one is being treated differently than the other.

- Dr. Lathrop said she understood why it appears that way sometimes. FDA's feeling is that the risks from a wrong result for HIV are not the same as the risk of a wrong result from HCV, especially in terms of a false negative and a person believes they are not infected and go about their life. HIV is treatable when people know they are infected.
- Dr. Dowler expressed an interest in understanding from the payer perspective how they can pay for these tests so that companies will invest the resources to go through the process. No Medicaid program is going to pay for a self-collected test with no incentive to do that. There is an opportunity for CHAC to assess the rigor of going through the approval process, incentives for industry to want to do that, and making sure that tests are equitably distributed and accessible to various communities in terms of being offered and the payment structure.
- Dr. Daskalakis shared a resource for HIV self-testing:
Issue Brief: <https://www.cdc.gov/hiv/policies/data/self-testing-issue-brief.html>

Panel 3: Applied Syndromic Approach to HIV, VH, and STIs: Focusing on People

Moderator: Demetre Daskalakis, MD; Director, Division of HIV Prevention, NCHHSTP, CDC

Comprehensive Harm Reduction Supports Navigation to Curative Hepatitis C Virus (HCV) Treatment and Syphilis Services

Andrew Gans, MPH

HIV, STD and Hepatitis Section Manager
New Mexico Department of Health

Josh Swatek

Hepatitis and Harm Reduction Program Manager
New Mexico Department of Health

Mr. Gans and Mr. Swatek presented on comprehensive harm reduction supports navigation to curative HCV treatment and syphilis services provided by New Mexico Department of Health. Typically, when speaking about harm reduction and high-volume, high-quality, low-barrier harm reduction programs as a great access to services, it is normal to assume that there will be hepatitis C, maybe HIV testing, and syphilis services to build trust in the community. Unfortunately, with the release 10 days ago of the STD surveillance data for 2020, New Mexico is number one in congenital syphilis. Small number, high rate, and very alarming.

New Mexico is able to do navigation because they have such a high-volume harm reduction program. While previously they were performing rapid HIV and hepatitis C testing, they have moved away from rapid hepatitis C testing because they have clients who have been antibody tested repeatedly over a decade or more, but it does not actually get them into care. It is expected that all harm reduction includes navigation to substance use services. New Mexico's enhanced model is about navigation to services rather than just referrals. As part of the hepatitis C elimination plan, it is necessary to get people into curative treatment. This involves getting them insurance, getting them into primary care, getting them medication opioid use disorder (MOUD) treatment, syphilis services, and ensuring that the DIS who are involved in a lot of these services can be doing partner services, testing, and linkage to STD or hepatitis treatment as well.

New Mexico wants to be among the first, if not the first, to eliminate hepatitis C as a public health threat by 2030 meeting national and international goals. New Mexico has 5 wins and innovations in the state that really place them ready to do this:

1. Project ECHO, which was founded in New Mexico at the University of New Mexico specifically to increase access to HCV treatment.
2. New Mexico Corrections Department (NMCD) is actually providing STD treatment actively and was doing antibody testing upon entry for almost a decade, switched to do confirmatory testing as well, and now has funding in the legislature to do curative treatment for about 2,800 inmates.
3. New Mexico has one of the most progressive Medicaid policies, which opened up for hepatitis C treatment without pre-authorization, fibrosis restrictions, or sobriety restrictions in 2015. The consultant who pulled off this amazing feat is now their Cabinet Secretary for Health.
4. New Mexico has an innovation with a high-risk pool, which they have been using to ensure that everybody living with HIV has insurance coverage, even if they are categorically ineligible due to immigration. The New Mexico Medical Insurance Pool (NMMIP) was approved at the end of 2019.
5. Comprehensive harm reduction services are available statewide.

Project ECHO has a peer education program working with state corrections, which does a lot to promote referral to hepatitis C treatment. They have the funds now and the 340B discount, which has allowed them to increase from about 150 inmates being treated for hepatitis C prior to this innovation to an average of about 600 a year. They have to motivate people to ask for it. It is not just for people with advanced disease, fibrosis, et cetera. It is for everybody, but not everybody knows they need it. NMCD has a plan for HCV elimination and received a very large allocation of funds. Project ECHO is a key part of that in terms of consultation and includes the NM Peer Education Program that educates the population on HCV screening and treatment. Partnerships are highly essentially in New Mexico. New Mexico's innovative policies for hepatitis C treatment that began in 2015 increased access to treatment for Medicaid recipients. They have good coordination that is constantly improving with Medicaid MCOs, which helps somebody who leaves corrections who did not start or complete treatment get community treatment as well. A lot of people are cycling through jails where there is less excellent coverage, state prisons, and then back into the community for Medicaid.

New Mexico's innovative high-risk pool has done very well with wrap around insurance. Before ACA, New Mexico was a state that never had an HCV drug assistance program waiting list, because with this high-risk pool, they were ensuring everybody with HCV who could not get insurance 10 years ago. When ACA rolled out and there was Medicaid expansion, a lot of folks with HCV moved to Medicaid or to an ACA plan. Others still have employer insurance. The NMMIP is still the last option. There are only about 200 people with HCV in the state, but the hope is to be able to serve 50 to 100 people with hepatitis C who cannot get any other insurance. The exciting part is that they thought this would be a treatment model where the state health department and public health offices would be the wrap-around safety net. In some communities, one of the few providers in the county is the Department of Health Public Health office. Even in some of the larger communities, there may not be a lot of providers who are willing to provide hepatitis C treatment, so they hope to ramp this up. While they got set back about 2 years by the pandemic, they have a protocol for hepatitis C simplified treatment and can serve a lot of people who do not have advanced disease right in their health offices to be that safety that helps people get access to MOUD, which is essential for a lot of the population. New Mexico has comprehensive harm reduction program services available statewide. More than 18,000 unique people were provided with syringe services in 2021. An important piece of

that is that 87% of people have been tested for hepatitis C, but only 24% have had access to treatment. Harm reduction programs are a key place to provide services for viral hepatitis. Component 3 through the 2103 CDC DVH grant has allowed New Mexico to expand its services, which is essential for preventing reinfections.

Some of the strengths of the New Mexico model are negotiated exchange, which allows tailoring to client needs while still striving to maximize collection of used syringes. Services are comprehensive. Locations at NMDOH Public Health Offices offer HIV, HCV, and STD testing and services, WIC (Women, Infants, and Children), family planning, et cetera. Many sites are within FQHCs or other health care providers. Services are low threshold, meaning that new clients can enroll with just a brief interview. The program is confidential, but unique client identification codes can be used to ensure immunity from prosecution for possessing syringes. Program sites were an ideal venue to provide hepatitis A vaccines during an outbreak among persons experiencing homelessness.

This is a comprehensive model that provides new, sterile syringes. Safe disposal of syringes can be done through both program interactions and community drop boxes. Small sharps containers are provided to participants to return to the program. There also is provision of other “works” needed to prevent the spread of infectious disease, as well as overdose prevention services. Referrals and navigation are provided to substance use services, public health interventions, and social services. Some people might not be ready for treatment because of the circumstances of their lives (e.g., lack of childcare, food insecurity, lack of housing, et cetera). Active navigation helps to address those gaps first, with the eventual goal of getting people into treatment.

In terms of messaging, New Mexico’s older campaign had 6 messages for people in their services who may not have thought of PrEP, PEP, curative treatment, or rapid testing. The new campaign is being rolled out as harm reduction across the state around maternal testing for syphilis, which is very important for responding to congenital syphilis. The issue with New Mexico’s congenital cases is that a lot of people are not in prenatal care, very often due to substance abuse.

The New Mexico Harm Reduction Act passed in 1997. It authorized the Department of Health to compile data to assist in planning and evaluation, provided immunity for exchange or possession of hypodermic syringes from the Controlled Substances Act for both participants and providers, and approved community providers across the state. Program operations started in 1998. There were a lot of problems with the original policy. Original state rules were detailed in terms of data collection and reporting. This necessitated long intake interviews and some irrelevant questions (i.e., sexual behaviors). Eligibility is only for state residents aged 18 and over. Some educational messages that became outdated (i.e., use of bleach) were written into initial regulations. Exchange was one-for-one only with a limit of 200 syringes per interaction (hindering secondary exchange). However, policy changes have increased the scope of harm reduction services. House Bill 52 passed in the 2022 legislative session, with a lot of bipartisan support. It allows NMDOH to promulgate rules that reduce negative health outcomes associated with drug use such as overdoses and infectious disease and reduce harm by improving participant engagement in harm reduction.

Harm reduction is now being used to respond to maternal and congenital syphilis. New Mexico has a lot of moms who are not accessing prenatal care due to immigration status, using substances, experiencing homelessness, engaging in transactional sex work, et cetera. They fear that if they get connected to a system of care, they will lose custody of their baby. A lot of training is being done for providers to make sure those who do come in are tested. Harm reduction efforts include strategies to engage at-risk persons in harm reduction, including meth users and those who do not inject; rapid and conventional syphilis testing; incentives for testing, including for male partners of persons of child-bearing age; social network strategies (SNS) to recruit; and integration with DIS to ensure treatment, disease investigation, and better quality services.

Corrections Health is Public Health for the Justice-Involved Community!

John J. Hagan, MD

State Correctional Health Authority

North Dakota Department of Corrections and Rehabilitation

Dr. Hagan noted that he has the privilege of leading a small but mighty team of medical and psychiatric professionals who provide care to a unique and vulnerable population. Together, they change the lives of residents in the North Dakota Department of Corrections and Rehabilitation (DOCR). There is an epidemic of incarceration, with 1.43 million adults held in federal or state prison facilities currently. There are about 735,000 persons in jails. Across the country, about 0.7% of the adult population are held in jail or prison. The North Dakota State Prison system houses 0.3% of the adult state population. That does not include folks on parole or probation. North Dakota is a very rural state of 774,000 total humans. The adult count in the prison system is very small at 1,685. They are happy to be small and are trying to go out of business if they can. Their average turnover is 1,500 admits per year, the median length of stay about 16 months, and the recidivism rate has been about 40% over 5 years.

North Dakota residents are a vulnerable and underserved population. People of color are over-represented in prison in probation and on parole. Someone who is Black in North Dakota is 4.2 times as likely to be under DOCR control compared to their White counterparts. Latino North Dakotans are 1.8 times as likely and Native Americans are 5 times as likely to be incarcerated. Residents arrive uninsured with very fragmented medical care. They suffer significantly higher rates of hepatitis C, SUDs, serious mental illness, diabetes, and hypertension. The goal is simple. The mission of the North Dakota DORC is to transform lives, influence change, and strengthen the community. They work hard because they believe the work is worth doing. They practice dynamic security, the goal of which is to create a humane, normalized environment to the extent possible. They have security available if having issues, but they found that when their patients are treated normally, they respond normally. They are trying to get folks ready to head home by creating an environment in which residents attain and practice prosocial skills in a setting where they are safe.

DOCR's plan for success in treating STIs, hepatitis C, and HIV is straightforward. DOCR is tremendously well-supported by the North Dakota Department of Health (NDDOH). DOCR partners with NDDOH to bring screening and treatment service to the DOCR system, and they form a large platform for DOCR's more comprehensive treatment programs. DOCR would have no opportunity to do this without the superb NDDOH, which underpins everything DOCR does.

One of the things that drives DOCR's programming at every level of operations and security is that their residents are going to become their neighbors. Of the individuals in DOCR's care, 98% will be discharged to North Dakota, South Dakota, or Minnesota. They ask themselves with their programming what kind of neighbors they want. They are very much person-centered rather than diagnosis-centric. DOCR considers what these folks need to be successful in the community, and challenge their clients to work to remodel and revitalize themselves. The testing and treatment programs that they offer are concrete actions that convey to the residents that DOCR is heavily committed to investing in their future. This is a great place to find and treat folks. Upon arrival, 31% of DOCR residents identify themselves as PWID. It is suspected that the numbers are higher. About 15% of the residents suffer from chronic hepatitis C with elevated viral load. In the last 10 years, DOCR has had 2,388 unique patients arrive with hepatitis C antibodies and 80% of them are typically HIV-positive. Only 0.6% of DOCR residents test positive for HIV. The chlamydia rate is 20.7/1000.

The goal is to build trust from day one. In the first 30 days, there is an orientation program during which the DOCR Nurse teaches health-related issues and answers questions. The result of offering a stable and humane environment is that residents asked for treatment on arrival. There is an opt-out program for testing. Virtually nobody opts out. For the first time in 6 months, only one individual in the state of North Dakota asked not to test, so the environment definitely is right for this. The only reason DOCR succeeds with this program is because of the unwavering support of the NDDOH. This translates to 20% of adult men on arrival are antibody positive and 15% overall have active virus, while 37% of women are antibody positive and 25% have active virus. This is known due to the ability to perform universal testing on arrival. The reason they can do this is because their cost for HCV antibody is \$26 underwritten by the NDDOH. The HCV RNA/Genotype is \$55. The average screening cost for hepatitis C is \$37 dollars per arrival. DOCR cannot come close to that anywhere in the private world, so that helps them a great deal. That turns out to be important because NDDOH reports that 15% of individuals in North Dakota who have an HCV positive laboratory result reported to NDDOH each year have at least one HCV associated laboratory report in a correctional setting.

DOCR cures hepatitis C. They have the support of leadership and their legislature. DOCR treats and cures 43% of the people who come through the door who are infected and they test everybody. Because we partner with the NDDOH and have access to 340B pricing, their average cost is \$12,560. Their 2021-2023 budget is \$1.9 million. For an additional \$2.4 million for a joint program, they can get to micro-elimination and treat everybody they see. This is a great opportunity to impact the state. Since NDDOH steeply discounts their laboratory costs through Section 318 of the Public Health Service Act (PHSA), DOCR's GC and chlamydia tests are \$10 and HIV tests are \$10. They treat by protocol for GC and chlamydia. As soon as they are notified, their staff completes Level I contact tracing on behalf of NDDOH. They also are the first to notify patients on HIV results on a regular basis. People have wanted testing, they have feared testing, but they feel safe at DOCR. Fortunately, they have immediate counseling, psychiatry, psychology, primary care, and infectious disease services available.

Prisons face challenges in treating justice-involved individuals. Most states do not have a unified system. Jails and prisons look the same on television, but they are not at all the same in real life. They are separate organizations. They speak to each other and about each other, but they are not in the same organizations. Jails are funded by county budgets and prisons are funded out of state budgets. The scope and breadth of services differ by county and by state. Some counties have comprehensive services, while some counties have no services. DOCR does not have direct control over prisons. They have a relationship, but programs written for jails and prisons may not work in one setting or the other.

It is important to note that justice-involved individuals are ineligible for Medicaid, Medicare, VA, or private insurance as soon as they are incarcerated—even if they are still paying premiums. States pay cash for all DOCR services. They negotiate and pay out of the general fund. Public funding opportunities for these services is fragmented and separate programs exist for hepatitis C, GC and chlamydia, HIV, SUD, serious mental illness, and wraparound services. For all of the issues that this vulnerable group is expected to have, support disappears when the door is slammed shut by law. Another challenge is attracting and retaining providers. Medical staff are state employees who are underpaid compared to the community. State medical and mental health case management for transition is badly underfunded in most states, so they do not have the services that are known to have a high impact. Jail resources for education, screening, and treatment are very sparse and jails are unable to shoulder the burden as a result.

The next step is to expand the import model. The ultimate goal is to engage the community and patients. That is working well. DOCR partner with federal, state, and local agencies to bring services that already exists into the prison system. The advantages include a steady and predictable volume for agency partners, a solid source of reliable care for this vulnerable population, and continuity of care on release. A great example is DOCR's cooperation with the UND Family Medicine Residency Program, which runs the Center for Family Medicine and also takes care of Custer Family Planning, which is the public health STD treatment programs. For its residents, DOCR also uses the HerCare clinic to bring in onsite prenatal/obstetric care and reproductive health services (e.g., LARC, reversible contraceptives, education). There also is continuity of care, in that those leaving DOCR's care are plugged into that service and they continue to work. Another example like this would be the use of methadone and opioid treatment providers in the community to perform services. DOCR's goal is to expand this important model.

The takeaway messages are that prisons and jails are ideal settings intervening in the syndemic of HIV, STIs, and VH. Justice-involved individuals are a vulnerable population at high-risk for these conditions and are eager to accept treatment. Corrections health is community public health in its purest form. It is important to remember that these individuals are not always in prison or jail. There are actions that can improve the health of justice-involved community members dramatically. While DOCR has 1,685 folks in prison and 800 in jail currently, the total count is 7,500 to 8,000 who are in prison or jail and on parole or probation. It is important to envision justice-involved individuals as a community, and jails and prisons as an ideal location to deliver impactful programming. Further developing programming to discount the cost of syndemic testing in jails and prisons has been highly effective. It is entirely the low cost that allows them to be universal. It is no longer risk-based, there is no stigma, and people are very accepting of it. Allowing flexibility to unify and align existing programs to meet the unique needs of this vulnerable population is very beneficial. Restoration of the HRSA/HPSA special designation for determining workforce shortages for jails and prisons that is independent of the surrounding community represents a major need. This is an incredibly effective way to add staff.

Providing Comprehensive Sexual Health Services to SFUSD Youth

Rosalia Lopez, M.Ed

Student Family Services Division
San Francisco Unified School District

Dr. Lopez shared information on how comprehensive sexuality education and how sexual health services or appointments outside of the school system work in the San Francisco Unified School District (SFUSD) in the context of policies and mandates that support programs, community partnerships, and the tier systems of support. It is extremely important to have intentional policies and mandates that support programs at the state, local, city, and school district levels. Several policies and mandates are highlighted below:

- **Health Education Content Standards for the State of California**³⁶ for which 2 examples of interest are: 1) 1.9.G, which explains laws related to sexual behavior and the involvement of minors; and 2) 3.2.G, which identifies local resources concerning reproductive and sexual health, including all FDA-approved contraceptives, HIV/STD testing, and medical care.
- **The California Healthy Youth Act (AB 329)**,³⁷ which went into effect in January 2016, requires that schools provide comprehensive sexuality education for students in grades 7-12 at least once in middle schools and at least once in high school.
- SFUSD Board Policy **6142.1 Sexual Health and HIV/AIDS Prevention Instruction**³⁸ requires comprehensive sexual health education and HIV prevention education shall be offered to all students in grades 7-12, including at least once in junior high or middle school and at least once in high school.
- **Sensitive Services/Minor Rights: California Family Law Code Section 6920-6929**³⁹ Parental/guardian consent is not required for minors under the age of 18 to access sensitive services. These services may include treatment having to do with drugs/alcohol, reproductive health, sexually transmitted diseases, and mental health.
- **Condom Availability Program - SFUSD Board Policy 5141.25, California Education Code 19-24- Sp1** requires a Condom Availability Program at all SFUSD Middle and High Schools; delineates guidelines, parent/guardian notification, exclusions, education component, and abstinence message; and creates alliance with schools and community health care providers.
- **Meeting the Needs of LGBTQ Students - SFUSD Board Policy 610-8A6, California Bill AB537** prescribes a variety of activities, interventions, accountability, and support to ensure that schools are a safe place for LGBTQ youth; and ensures that sexual orientation and gender identity be included as protected categories in all non-discrimination policies and procedures applying to all SFUSD students, teachers, staff, administrators and other employees.

³⁶ <https://www.cde.ca.gov/be/st/ss/documents/healthstandmar08.pdf>

³⁷ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB329

³⁸ <https://go.boarddocs.com/ca/sfusd/Board.nsf/goto?open&id=BDVSWC74A618>

³⁹ <https://law.justia.com/codes/california/2005/fam/6920-6929.html>

In terms of partnerships, SFUSD has a cooperative agreement with CDC-DASH, San Francisco Department of Public Health (SFDPH), and other CBOs to implement programs that support sexual health, education, sexual health services, and safe and supportive environments. SFUSD uses a multi-tier system of support, including health education, wellness programs, and LGBTQ student services programs. Because of the partnerships with the SFDPH and other CBOs, SFUSD has been able to support comprehensive sexuality curriculum to ensure that there is a common language (Be Ready, Be Real for High School; Healthy Me, Healthy Us for Middle School; Healthy Me Resource Guide). Staff training is provided on policies and procedures to providing youth-friendly services; providing sensitive services and referring students to local clinics if needed; and logging services and follow-up one-on-one services to youth when needed.

The SFUSD team work closely with the Wellness Program and the LGBTQ Student Services Program for consistent assessment of the health education curriculum to determine where it needs to be updated to meet the needs of LGBTQ and all other students. One example would be if the topic of human trafficking is being discussed, a social worker is in the classroom in case students need services beyond just awareness. Because of policy, schools are not allowed to pass out condoms and the role of the teacher is just awareness. The nurse in the Wellness Center would provide students with condoms. Because a student would need to go to the Wellness Center to complete a quick needs assessment and receive condoms, there is relationship-building between the teacher, the nurse, and the students in terms of where students receive services. Those who need further services beyond what the Wellness Center can offer are referred to a local teen clinic.

SFUSD's Sexual Health Services & Multi-Tier Systems of Education has 3 tiers: Intensive, Targeted, and Universal. Health education is considered Tier 1, given that it is for everyone. Tier 2 is for those who need smaller social groups. Tier 3 is for those who need more support (e.g., testing, mental health services, medical issues, et cetera) for which students are referred out to partner organizations. This year more than ever, there is a lot going on in schools and the help of CBOs and health clinics has been key. Though it has been somewhat difficult to reconnect during the pandemic, this is a work in progress.

These innovative collaborations have yielded some excellent expected and unexpected results, including fantastic lessons, connecting classrooms to services, and increased collaboration of SFUSD partners with over 50 CBOs. The top 5 types of services based on number of students served include general counseling, case management, medical services, behavioral health counseling, and sensitive services.

Advancing Syndemic Approaches Through Cluster Detection and Response

Alexa Oster, MD, CAPT USPHS

Acting Chief, Detection and Response Branch
Division of HIV Prevention, NCHHSTP, CDC

Dr. Oster pointed out that cluster detection and response offers a framework to guide tailored implementation of proven HIV prevention strategies where transmission is occurring most rapidly. After an outbreak, detection helps to identify when HIV is spreading quickly and to work to stop that spread. The presence of a cluster or outbreak indicates a failure of care and prevention services that needs to be addressed to improve access to services, such as antiretroviral therapy, PrEP, and sub-transmission. This is an opportunity to identify the needs of affected communities and generate ideas for improving services, because cluster and outbreak response involves curating care and prevention services to be more accessible to the

people who need them most. Cluster response is an opportunity to identify gaps in services and curate tailored treatment and prevention interventions where standard population interventions have failed. Importantly, cluster detection and response involves adapting resources for those who use them rather than expecting people to adapt to access services in a system that has failed them.

Concurrent with the opioid crisis, there have been a number of HIV outbreaks among PWID in the US over the past several years, beginning with a large outbreak in Scott County, Indiana that was detected in 2015. PWID experience numerous syndemic conditions, including HIV, STDs, VH, SUD, and mental health challenges. In addition to these medical issues, they often face unstable housing, food insecurity, and other needs for social services.⁴⁰ Clusters and outbreaks affect a variety of populations, and these principles apply to sexual transmission as well as injection-related transmission.

In an example from Kanawha County, West Virginia, HIV diagnoses among PWID drugs increased rapidly beginning in 2019.⁴¹ As a result, the West Virginia Bureau for Public Health requested CDC assistance with an HIV outbreak investigation. CDC built its team with syndemics in mind. The CDC team, led by DHP, also collaborated with HRSA's HAB and the Department of Housing and Urban Development (HUD), both of whom have become very important partners for response support. This team collaborated to support the state and local health departments in conducting an investigation that included a medical record review and a rapid assessment with qualitative interviews. At the local level, a diverse set of partners from the state and local health departments and multiple other healthcare CBOs were involved.

To highlight some findings from qualitative interviews with 26 PWID and 45 key community members, many people described using substances to cope with feelings of hopelessness and despair associated with a confluence of health and social challenges, such as unstable housing, depression and anxiety, and unemployment. Among the numerous health and social conditions PWID faced at the time, HIV and SUD were just a couple of the many issues. This constellation of challenges underpins the complex needs of the populations served, as well as the challenges that can slow progress in implementing holistic approaches.

The medical record review, which included 496 healthcare encounters among 65 people with HIV, showed missed opportunities for prevention and care for a wide range of conditions, including low provision of naloxone and medication for OUD. Medical encounters for overdose and STIs were infrequent. Hepatitis C diagnosis was common and preceded HIV diagnosis by about 4 years. Most people were covered by Medicaid and housing instability and incarcerations were prevalent.⁴² Surge DIS staff from the Division of STD Prevention brought a syndemic approach to partner services, going above and beyond to ensure appropriate testing, treatment, and linkage to care for various syndemic conditions and working to meet a variety of other food and social service needs. The findings mentioned informed one of the team's recommendations, which was to improve access to HIV, hepatitis C, substance use, and mental health services through service integration by co-locating services and cross-training service providers to improve access to effective infectious disease prevention efforts. Co-location of services, along with multidisciplinary teams and intensive case management, can help to address important barriers to care for multiple conditions. Low barrier, one-stop-shop models can help. It also is important to involve people with lived experience in the development, implementation, and monitoring of programs.

⁴⁰ Lyss SB et al., JID 2020

⁴¹ Hershow R et al. MMWR 2022

⁴² Bonacci R et al. CROI 2022; Hudson A et al. CROI 2022; https://oeeps.wv.gov/hiv-aids/documents/data/EpiAid_Report.pdf

In terms of challenges to syndemic success, integrating data sources from multiple conditions can be difficult, but is essential to understand the various needs of the people served. Silos in data systems can reflect silos in programs, and bridging those programs silos can be critical to facilitating integration of data. Policy barriers also can be a major challenge. For example, expanding harm reduction services and SSPs was a primary recommendation of the investigation. Although SSP policies were changed where possible, state laws and city ordinances related to SSP limited the ability to expand these services to meet the need. Likewise, limitations to eligibility for hepatitis C treatment for people covered by Medicaid meant that testing and linkage ended up being deprioritized. Limited eligibility led to misconceptions that affected the care-seeking behaviors of even those who were eligible for treatment. Program and funding silos are an important consideration. This is relevant at a macro-level, including how federal funds are distributed, but also applies to how health departments are structured with separations between infectious diseases and behavioral health and also at a micro-level where providers and systems have incentives to only address immediate needs, including in EDs and correctional settings. Finally, health department capacity limitations also were a challenge. Even when funds are available, health departments sometimes have difficulty hiring and retaining staff, and this limits their ability to perform recommended activities, including partner services for every new diagnosis of HIV and syphilis. CDC can provide surge support to help address a backlog of cases or additional cases during an outbreak, and federal support provides an opportunity to build program and systems capacity, but this can be limited by other capacity issues at that health department.

It is important to note that although outbreaks among PWID have been highly visible due to concerns about rapid transmission in these populations, most clusters of rapid transmission are related to sexual transmission. Among 144 clusters first identified through molecular analysis in 2018-2019, 82% were primarily among gay and bisexual men. Among the largest clusters that had grown to more than 25 people as of September 2021, 72% were among gay and bisexual men. These clusters were typically small when they were first detected, but grew to be just as large as the concerning outbreaks seen among PWID. Many of the same syndemic issues and others apply to gay and bisexual men, who also face homophobia and other systemic injustice.

To share an example of a cluster related to sexual transmission that resulted in response to syndemic issues, Michigan identified a molecular cluster of rapid transmission in 2021 in Wayne County affecting a network that included Black or African American transgender women. About half of the network members indicated participating in sex work or having partners that engaged in sex work. The health department immediately began engaging with community partners that serve trans communities to talk through potential gaps in services and how to improve them. Over a few months, 13 meetings were held with these community partners. The health department also spoke with members of the network, who were supportive of the response efforts and willing to share information about the community's needs and also helped to indicate additional people in need of services. They indicated that there were not enough providers who provide gender-affirming care. As a result, Michigan has created a mobile services initiative to offer gender-affirming care that includes general health and wellness checks, immunizations, a food pantry, and HIV and STI testing. Michigan is also developing community-oriented social media and messaging campaigns developed with input from the trans community.

Although value and opportunity have been demonstrated in advancing syndemic approaches through cluster detection and response, there are a number of needs and considerations, most of which are not unique to cluster and outbreak response. Those at the federal level can support syndemic approaches by communicating the priority of a syndemic approach from federal funders to state and local recipients consistently across all federal funding programs

and partners. This work cannot be successful if driven by a single program. This includes working to minimize silos between federal funding that serves as a disincentive to collaboration. Teams need to be designed with syndemics in mind, modeling at the federal level what is thought to be needed at state and local health levels. This collaboration cannot occur only when there is an escalated response, but must involve long-term work to integrate and align programmatic guidance and technical assistance.

Additionally, policy issues are often at the heart of the most stubborn barriers and where possible, state and local partners must be supported to address these policy issues. It also is important to build systems to meet the needs of the people served rather than expecting people to adapt to systems. To do so, it is necessary to listen to people with lived experience. Qualitative interviews have been a powerful tool to identify what is broken in systems and get ideas for how to fix them. Often the barriers to delivering seamlessly integrated services are issues like funding, training, separate service organizations, time, or physical space. Funding and program requirements can help to dismantle these barriers. That core set of integrated services should be a primary goal and not a bonus or afterthought. Solutions need to address syndemic health conditions that people are facing, but that is not enough. Intervening only on health concerns may not be effective if social conditions are not considered and addressed.

Identifying partners well-equipped for syndemics is key to success. Local health departments, health centers, or community organizations that receive broader funding that is not siloed or who receive funds from various sources already are well-positioned to support this work. Likewise, providers that recognize their clients' holistic needs and meet clients where they are have the most success in linking and engaging them in services. Community outreach workers and partner services staff can embody this approach and this trust is so critical for populations stigmatized on many levels. Moving from the current systems to a gold standard syndemic approach, while an important goal, will take time, so it is important to be prepared to accept incremental progress. Setting expectations too high can sometimes have the unintended effect of disincentivizing staff from initiating response efforts and other work that can unmask the many changes that are needed. Syndemic approaches rely on building cross-cutting teams that can best support this work and the people served.

CHAC Member Discussion on Panel 3

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What priority policies and actions should be considered in operationalizing a syndemic approach to service provision?
2. What settings should be considered for the highest public health impact?
3. How can CDC and HRSA make syndemic strategies and programs more common and effective?
4. What are the best practices for integrating non-HIV-specific services into HIV systems?
5. What strategies would better link youth to clinical services through school health programs with collaboration with public health departments?

The following questions, observations, and suggestions were raised:

- Dr. Anderson noted that one of the fun aspects of these meetings is hearing about all of these impressive programs that a lot of them would not hear about otherwise.
- Mr. Driffin said one of his finals for ethical consideration for one of his DrPH classes is on HIV sequencing and non-positive response. He wondered whether the presenters could share additional insight on racial and ethnic demographics that have been observed in response to the cluster response teams.
- Dr. Oster indicated that they looked at people who were in clusters of rapid transmission nationwide and found that about a third were White, about a third were Black or African American, and about a third were Hispanic or Latino. Rapid transmission is occurring in a variety of populations, and it is important to ensure that they are assessing the gaps that are driving this and supporting changes in programs and services along with those populations. In the analyses that assessed large clusters among gay and bisexual men, they found that most were in the South and West.
- Mr. Lindsey noted that a key barrier to syndemic approaches has been segregated funding streams in the past, which also was a barrier to personnel or workforces who are unable to work together because of segregated funding streams. He wondered whether it is all state funds or if there is anything else that can be done to address ideological or financial barriers to allow more of these population focuses and syndemic approaches to flourish.
- Mr. Gans responded that New Mexico integrated HIV, STD, hepatitis, and harm reduction into one section in 2015. Because they are a centralized health department, having all programs under one roof and operating on the statewide and local levels gives them a lot more flexibility. New Mexico is unique in a couple of ways. First, they have a lot of state support for a variety of programs and second, they have a lot of flexibility as long as they meet performance measures globally. For instance, they have had a long-term shortfall in their harm reduction budget, but they have about \$1 million in state funds in harm reduction. When he started it was \$4 million or \$5 million a year and now it is closer to \$12 million. It has dipped somewhat as people moved to fentanyl and smoking rather than injecting. While they could not afford that out of that budget, they could use state general funds in HIV prevention, HIV care, STD, et cetera. The other thing is that they have other revenue sources. They generate pharmacy revenue, which sustains a lot of HIV PrEP programs around the country, including community health centers. They do something similar with their direct services. Generally, they do not have a huge amount of flexibility in federal grants but when there is flexibility, they use it. They always have had fully integrated DIS who are largely funded in HIV and STD, and they are all cross-trained in HIV, hepatitis, harm reduction, and other navigation along with STD as the focus. New Mexico is always looking for ways to be creative. It is easier to have a syndemic approach at the local level, when they are all located in the same building and talk about their budgets all of the time across the agency.
- Dr. Hagan responded that they have syndemic issues with treating different illnesses. More importantly, most of their program availability begins and ends at their doorstep. There is a sharp cutoff when folks are detained or when they are incarcerated. When incarceration ends, the transition of services is a particularly weak section for them. That is where the natural silos have occurred as people try to create programs for incarcerated folks and folks in the community. That crossover is missing for them because there is not longitudinal thinking. They have the same problems in prisons and jails. When the door slams or opens,

programs begin or end and they are not well-connected. A lot of efficiency is lost that could be capitalized on. We track data out into the community and have tremendous longitudinal data for parole, probation, and recidivism, and recognize the continuum of care. We are taking actions based on the data. Prisons have the infrastructure, and it is shocking how much data they have, but do not crunch it. He can say which of his residents bought FUNYUNS® last week and other incredible data. They have to be careful with it, but they do have incredible data. They just do not use it as well as they might.

- Dr. Lopez stressed the importance of working together in order to provide universal services for everyone and to avoid duplication of efforts.
- Dr. Greene said she was hearing themes throughout about meeting people where they are, low barrier and low thresholds to care, flexibility, and how self-testing could help facilitate people where they are. As someone who works in geriatrics, she pointed out that this is very relevant to older adults, people with mobility limitations, and people with other issues that affect their access to care across all of these systems.
- Dr. Hagan replied that their approach in jails has been largely to try to get services. For instance, for some of the large local jails, they have worked hard to bring the university residents on site. These folks need customers, need to meet people, and need to understand their population. They do have folks with serious mental illness (e.g., schizophrenia, bipolar psychosis, major depression) who come off of their medication and cannot operate well within the social system. Once someone has had a single felony, they become felonized. He thinks there should a DSM-5 diagnosis called “felonized” because they never again will go to public health or mental health care. They will go to prison or jail. The first thing is linking work and bringing folks on site, irrespective of the ability to pay. In jails the focus is largely on getting patients what they need most and establishing trust. Some folks will be up to a year in jail depending on the jail, but most are not. The focus in jails is to get them basic services.
- Dr. So congratulated Dr. Hagen for running such a great program in the prison system. It is a model program. He asked whether they test their prisoners for hepatitis B and whether they are offered hepatitis B vaccination. Some prior CDC studies showed that about 2% of the incarcerated population have chronic hepatitis B and as many as 6% will develop acute hepatitis B infection in this country who have a history of prior incarceration.
- Dr. Hagan said that while they do not do universal testing, they do offer universal immunization. On arrival, they check everybody in the immunization registry, which is very complete in North Dakota. They are proud to be the state’s number one provider of adult hepatitis B immunizations. They have lost their funding for hepatitis A immunizations. The American Correctional Association’s goal is to fully immunize everybody for hepatitis A and B and fully test everyone for C. They do not do the testing unless there is a question clinically, but immunization is offered to everybody on arrival as a public health function.
- Dr. So suggested considering testing before vaccination, because the Medicare cost of a 3-panel hepatitis B test is only \$30. If they had prior infection or already have a chronic infection, it would save on vaccine cost since the vaccines are still very expensive. They also would pick up those who have chronic hepatitis B and may need antiviral therapy.
- Dr. Mermin said he was struck by the fact that in some ways, they were doing too good a job. Each of the presenters showed so much of what could be done with screening, comprehensive SSPs, comprehensive student health services, et cetera. He wondered

whether there were policies that would need to be put into place that would prevent people from getting hepatitis C, HIV, STDs, TB, et cetera—something that would have an effect even more upstream to make the work easier.

- Mr. Gans indicated that New Mexico wanted to get ahead on hepatitis C curative treatment to move towards elimination because they had some of the highest prevalence in the country. They are working to improve their surveillance system because the quality of active risk factor and race/ethnicity surveillance in hepatitis C is not the quality of HIV because it has not been funded as well. It is probably too late for the upstream changes, but they are probably a good model for all of the best policies He wished Medicaid expansion was universal, but it is not.
- Dr. Lopez said that while California has some of the strongest policies, the problem is that they are unfunded policies. That is well-intentioned, but it becomes challenging to address the policies.
- Dr. Hagan said he would like to see much better availability for needle exchange, which is still a taboo subject in his state. The state is really good at taking care of incarcerated folks. The rationale is simple. Everybody is someone's brother, cousin, uncle, daughter. Everyone knows somebody. He also would like to see better access to SUD treatment in the community. One place to focus is on jails since many people enter and cycle out of jails a number of times. Before they ever get to prison, they have been to jail 10 or 15 times.
- In terms of specific policies, Dr. Guilamo-Ramos said that from his point of view, the "low-hanging fruit" is to look at the workforce. The example shared about limitations on pharmacists and PrEP could be applied to other disciplines. The largest segment of the healthcare workforce is nurses, yet they have many regulatory limitations around the country that do not make any sense and limit the ability to improve access to prevention and treatment. Another thing that was striking to him in terms of settings was that he had not heard a lot about the important role of families, biological or non-biological. Families are an important setting, particularly for young people. Thinking about SDOH is impressive in terms of trying to integrate services, co-locating, and cross-training. Consideration must be given to how particular groups or communities thrive and overcome adversity despite significant challenges. He is a little concerned about the narrative, given that it has been focused on vulnerability but does not provide a path forward in terms of how to use the science of how people overcome and what has worked as being important to understand.
- Mr. Driffin suggested that more consideration be given to additional community engagement strategies that can continue to be lifted between CDC, HRSA, and other federal partners to ensure that communities move along with them to beef up strategies.
- Dr. Oster indicated that they are collaborating on some sessions with HRSA HAB for the Ryan White conference that relate to cluster detection and response. Some of the topics include community engagement, partnering with community organizations and providers, how everyone can come together to ensure that they are responding to clusters in a way that helps to make services better for these populations, et cetera. Community engagement around this topic is a major focus. She and Dr. Daskalakis have been spending a lot of time together working to have discussions with lots of different partners, community organizations, policy partners, healthcare organizations, and public health partners over the past few months.

- Ms. Hayes indicated that PACHA is hosting an HIV molecular surveillance small group think-tank that will include their community and federal partners.
- Dr. Anderson indicated that there is a current ECHO program related to the intersection of HIV, substance abuse, mental health, and intimate partner violence (IPV) for which she could share information.

Telehealth/Telemedicine WG Report

Dr. Shannon Dowler, Lead CHAC Telehealth WG

Dr. Dowler reported that the Telehealth WG had engaged in several meetings since its launch during the last CHAC meeting. The first thing the WG did was dig into the benefits and risks of telehealth and summarized their findings into potential areas of interest for CHAC. In terms of benefits, telehealth broadly has the potential to improve various types of access (e.g., geography, transportation, provider limitations, et cetera). Particularly in the sexual health space, telemedicine offers a unique opportunity to reduce stigma. It results in decreased costs, such as non-emergency transportation, lost work time, and practice infrastructure. It has the potential to close care gaps and improve health equity. Telemedicine also has the potential to improve retention in care, empower folks who are receiving services to take control of their healthcare, be more patient-centered, and increase provider productivity. There are many reports showing that patient no-show rates using telehealth are improved and that the barriers that keep people from getting to a scheduled office visit are mitigated with virtual care. As an example, North Carolina Medicaid wanted to know what was happening with its beneficiaries, so they added an adult experience and child experience with telehealth into their Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. They found that people were generally as happy with their care whether they had telehealth or in-person care. There was not a statistically significant difference for adults or children. Beneficiaries/patients seem to be happy with this modality of care.

There also are risks and challenges to telehealth. The WG found that there is disparity in terms of access to technology and broadband access depending upon where someone lives and the ability to pay for technology and services. Maintaining confidentiality and privacy in the home setting can be a risk and challenge. Not everyone has a large home in which they have the benefit of spreading out or going somewhere private for telehealth visits. There is a loss of ability to identify IPV. There is a risk of influence or manipulation by people who are not seen in the visit, which has significant implications. It takes time and energy to train people to use telehealth technology. There is a potential to break up services and have multiple visits, which may not be ideal. From the standpoint of fragmentation of care, there is always the risk of breaking up the medical home experience, not having good communication, and creating challenges in continuity of care—particularly when there is not shared documentation. There is a risk of losing some of the components of in-person care. This raises questions about the percentage of visits using technology versus in-person visits so that critical pieces of care are not lost. The issue of language barriers comes up repeatedly. In terms of the payment and integrity standpoint, there is a risk of fraud and abuse, particularly in the telephonic arena where it is not possible to confirm someone's identity.

Another challenge in the field pertains to the fact that everyone is using different terms and has different rules. Until everyone can come together nationally and agree on certain terms and on what is/is not covered, there will continue to be of mixed-metaphor of what people are saying. When the terms telehealth, telemedicine, or virtual health are used, everyone is saying and

allowing for different services or benefits. North Carolina Medicaid has 2.8 million beneficiaries. They began an evaluation to determine what was happening. There was a huge plummet in visits when the stay-at-home order was issued by the Governor. Simultaneously, there was an exponential and steep rise in telehealth. There were essentially no services prior to the pandemic, so the baseline was zero. The dramatic improvement in access would have been lost if people had relied on in-person visits, because it completely dropped off the radar.

After studying these data for over 2 years and looking at the relative probability of adults using telehealth services as a function of race, ethnicity, and geography, Black and Hispanic persons and those living in rural areas were less likely to engage and there was not a tremendous amount of improvement over time. While there is a lot of discussion about all of the great opportunities Telehealth offers to improve health equity and access, the lived experience in North Carolina is that the odds are still against closing those gaps. On the other hand, people with chronic conditions leaned in hard and fast to use telehealth early in the pandemic. Over time, that number decreased. In the rural/urban space, there has been an increase in the last 6 months with people beginning to use the technology more consistently in rural areas.

Looking at some specific codes, North Carolina assessed child developmental services to decide what would be kept as permanent policy versus what would not. Consideration was given to a service as a function of whether it changed geographic, racial, or ethnic equity. Consistently, the findings did not identify changes. They found that urban individuals were more likely to engage in telehealth even though they have more child development centers than in rural areas. The same patterns were observed by ethnicity in that someone who was not Hispanic was more likely to engage in child development virtually. The same difference was seen in terms of whether someone was Black or White. Gaps were not being narrowed in this area, and this pattern was reproduced across multiple codes. The data show that the same people who are using telehealth are the same people who are using in-person care, and that new patients are not being entered into care.

The WG talked specifically about opportunities to improve sexual healthcare in the context of modernization of technology and proposed a few areas they think are the most important. One opportunity is with home or alternate testing for STIs. The conversations over the last 2 days of the CHAC meeting aligned nicely with these recommendations. Consideration should be given to ways to normalize home testing and increase home delivery of medications, which could reduce the stigma of going into a pharmacy to ask for something. PrEP access could be enhanced to have a more patient-centered approach. Inequities around access to PrEP are significant and broad across the country, and PrEP is just not getting to people in an equitable way.

With this background information in mind, the WG developed the following recommendations and invited input regarding any priority areas for which CHAC thought proposals might be made to CDC, HRSA, or both.

- **Build on the PrEP letter that went out early in the COVID-19 Pandemic (CDC):**
 - Recommend that CDC launch a formal campaign to teach providers how and where virtual services can assist in the EHE goals specific to PrEP
 - Recommend the potential for the same initiative related to retention in care for HIV

- **Explore how virtual services can enhance routine STI screening for all populations (CDC):**
 - Recommend that CDC fund pilot home testing service delivery models broadly to seek to understand the impact of this model
 - Award sites based on factors such as poverty indicators, payer mix, population and geographic disparities
- **Study health equity as it relates to telehealth service provision (CDC/HRSA):**
 - Early data suggest that telehealth has not overcome barriers to access to care
 - A formal study could spawn interventions that might impact equitable service delivery more effectively
- **Deploy a Tele-PrEP initiative for FQHCs (HRSA):**
 - Recommend that HRSA fund a Tele-PrEP initiative for FQHCs to pilot focused on areas with high need to PrEP ratio

CHAC Member Discussion and Vote on Telehealth/Telemedicine WG

Dr. Gayles noted that while he and Dr. Anderson would moderate this discussion, they both recused themselves from participating in the discussion and any related votes due to COIs related to telehealth.

The following questions, observations, and suggestions were raised:

- Dr. Driffin said the only thing he would add, especially for others as they begin, was that the processes address the nuts-and-bolts questions around what success looks like for communities. This means ensuring that Black and Brown people have access to the internet, tablets, and/or whatever other vehicles are necessary to get them to the option of telehealth/telemedicine.
- Dr. Mermin noted that the data presented were very impressive and showed that a smaller proportion of certain populations participated in telehealth during the pandemic. He wondered whether they still participated in health visits and if those using telehealth were the same as those presenting in-person. He thought it would be beneficial to understand whether people who did not participate in telemedicine dropped out of care entirely or continued care through in-person visits.
- Dr. Dowler indicated North Carolina found that the same people who are using telemedicine are the same people who are presenting in person. The Duke-Margolis Center for Health Policy also performed a data analysis and came to the same conclusion that the same people who are using telehealth are the same people that are presenting in-person and new patients are not getting into care. People who are engaged in health care are engaging in health care maybe in more convenient ways or in different ways, but access to care is not actually being broadened. The exception to that seen in North Carolina was in primary care homes. Rapid adopters picked up telehealth really quickly and made it a large part of their practice, increased the number of patients they saw overall and improved access to care. Generally, the beneficiaries who are accessing care are just accessing care differently. In terms of whether people who did not participate in telemedicine dropped out of care entirely would have to be analyzed specifically. While they saw overall engagement, the beneficiaries did not change. North Carolina Medicaid

maintained a lot of telehealth services, but their commercial partners have not been as clear. The things that they are keeping would allow people to use their smartphone. In the sexual health arena, there are many positive opportunities because of stigma in that people will feel more comfortable in using self-collected tests and it would feel more patient-centered.

- Dr. Mermin emphasized that technologies are increasingly being seen as tools for helping people stay healthy. Perhaps providing someone with a smartphone and software might make a difference in people participating. Consideration would have to be given to whether there could be reimbursement by Medicaid or private insurance. The upfront investment could be prohibitive for both providers and individuals unless it was covered by insurance, but this could eliminate some of the obstacles for people—particularly those with limited resources.
- In terms of the idea of a more formal campaign to teach providers how/where virtual services can assist in the EHE goals specific to PrEP, Dr. Daskalakis indicated that NCHHSTP's Capacity Building and Technical Assistance Branch has materials⁴³ for providers that focus on telemedicine around PrEP, which probably could be nuanced more to specifically identify places where telemedicine may be more or less appropriate.
- Dr. Greene suggested that perhaps the proposed recommendation to study health equity as it relates to telehealth service provision should be elevated to the first bullet.

CHAC Action

Mr. Riester made a motion to approve the proposed Telehealth/Telemedicine letter, with the suggestion of moving health equity to the top bullet in terms of prioritization. Dr. Markham seconded the motion. CHAC approved the letter with 8 affirmative votes and 2 abstentions.

Public Comment Period

Mark Misrok

Executive Director

National Working Positive Coalition

I am Mark Misrok. I'm Executive Director of the National Working Positive Coalition (NWPC), which works to strengthen responses to the long-ignored employment needs of people living with or at greater vulnerability to HIV. I'm a person living and aging with HIV and a member of the Steering Committee for the US People Living with HIV Caucus (US PLHIV Caucus). Last Summer, the CDC released their most recent data report from their ongoing collection of surveillance data of people living with HIV in the US from their MMP, or Medical Monitoring Project, surveillance data. This latest data report is for 2019, the last full year before the impacts of the COVID-19 pandemic in this country. This most recent data report presented 41% of people living with HIV as unemployed prior to the impact on employment and the job market of the pandemic. This extraordinary high unemployment rate among people living with HIV in this era of care and treatment reflects the profound lack of access to employment-related

⁴³ <https://www.cdc.gov/hiv/effective-interventions/library/telehealth/implementation-materials/cdc-hiv-ei-telehealth-practitioners-guide.pdf>

information, services, and resources within HIV supportive services that has continued unchanged across all areas of the epidemic. We know that communities most vulnerable to HIV and most impacted by COVID and a host of health crises are always also communities with long histories of unequal access to quality education and to employment and economic opportunities. Meanwhile, the HIV/AIDS Bureau has kept directives in place since the 90s that ban use of supportive services dollars by Ryan White HIV/AIDS program grantees to provide employment or job readiness services, suppressing growth of responses to the employment needs of people living with HIV, that could grow organically and community-based programs most trusted and often most committed to communities not prioritized in mainstream workforce development or vocational rehabilitation initiatives. It is time that our leaders, and advisory bodies, and government agencies shaping the US HIV response end the cruel abdication from understanding and addressing the employment-related needs of people living with or at greater vulnerability to HIV that has been our long-sustained pattern. Thank you.

Amy Killelea

Killelea Consulting (PrEP for all)

Hi everyone. My name is Amy Killelea. I am a consultant and for the purposes of what I'm going to talk about today, I've been working with Johns Hopkins University over the past about 12 months working on a proposal for a national PrEP program. Thank you for the opportunity to speak to you all today. I want to highlight that we have got an opportunity presented to us in the President's Budget for FY23, which was released a few weeks ago. It includes an incredible opportunity to expand access to PrEP in this country and includes a call for Congress to enact a new \$9.8 billion 10-year national PrEP program for the uninsured and underinsured, coupled with significant reforms to ensure that people on Medicaid who need PrEP can easily access it. I want to focus my remarks on both the opportunity before us with the new momentum from the Administration as well as what I think is a growing and should be a growing sense of urgency around PrEP. PrEP uptake, as I am sure this body has discussed in meetings prior, continues to be very low in the US, with only about a quarter of folks who could benefit from PrEP actually taking it and growing disparities among Black, Hispanic, and Latino communities in particular. I think it is becoming more and more apparent that we will not end the HIV epidemic without a drastically different approach to PrEP. A few things to really highlight in terms of the systems failures when it comes to PrEP. One is that we have a system for PrEP access, particularly for those who are uninsured and even those on Medicaid that is fragmented, that is confusing, and that is incomplete. For those who are uninsured, the medication is often available through a different program and mechanism than the lab services, which may also be separate from the ancillary services for PrEP. We also have put our thumb on the scale of a largely clinical approach to PrEP heavily dependent on primary care, on community health centers, and 340b entities who are big and savvy enough to navigate the complexities of PrEP financing. And let me be clear, because we heard from the previous presentation about community health centers and telehealth clinical entities are necessary for PrEP access, but they are nowhere near sufficient. And so the opportunity before us, I think, is to re-envision what a national PrEP program and functioning system for PrEP access could look like. What was submitted in the public comment was a sign-on letter from over 20 national, state, and regional organizations that really outlined a set of principles that provide a foundation for a national PrEP program, so I want to highlight just a few of those. First is that the program has to prioritize equity, has to invest in mechanisms that increase access to Black and Brown communities, trans folks, cisgender women, folks in the South, and others who are currently failed by our current PrEP delivery systems. The program has got to be simple and it has got to be accessible and include medication, labs, and the ancillary services needed to support PrEP access. I think the accessibility part means that it has to be available through a greater range of community-based access points outside of just clinical delivery sites and community health centers. By expanding

those touch points, the goal is also to increase PrEP demand in communities who are not well-served by, and not touching frankly, traditional healthcare delivery sites. Finally, a PrEP program has to be sustainable and it has to be based on evidence. We have got a generic form of Truvada, TDF/FTC, that is safe. It is highly effective. It is incredibly cheap. It is clinically appropriate for the vast majority of folks. But we aren't maximizing that potential to open the floodgates for PrEP, largely because we have a current system that incentivizes brand name drugs at every turn. We are also going to fail to maximize some of the newer forms of PrEP like long-acting cabotegravir if we don't insure that that drug and the drugs that are coming down the pipeline are available at fair public health prices and through a much broader network of public health providers. I will close with just saying that this is an opportunity and it's a challenge. We have a tough political environment to get this ambitious proposal through Congress, but I hope that through the CHAC and the folks on this call today that we can harness the momentum that we have with the President's Budget and build a better system for PrEP access. Thank you.

Chris Jowett

Chief Commercial Officer
Visby Medical

Good afternoon. Thank you for the opportunity to summarize our recommendations committee. I'm Christopher Jowett and I represent Visby Medical. I am the Chief Commercial Officer with Visby Medical based out of San Jose, California. Accurate STI point-of-care tests can revolutionize patient care. The "CDC's 2021 STD Treatment Guidelines" recommend nucleic acid amplification testing (NAAT) for the detection of chlamydia and gonorrhea and specifically call out chlamydia and gonorrhea in symptomatic women. In the "STI National Strategic Plan," there is a recurring theme requesting innovative solutions and approaches to address the ongoing and emerging challenges in STI prevention and control. Specifically, it calls out the need to develop point-of-care diagnostic tools. Visby Medical has developed such a tool which delivers PCR results in less than 30 minutes in the palm of your hand and received FDA clearance and CLIA waiver in August 2021. Visby Medical developed this rapid point-of-care platform with substantial support from the NIH and yet there remains significant hurdles to deliver these tests equitably nationwide. The CDC and other government agencies can help in the following ways. Support implementation science studies to assess clinical adoption in various settings. Implement policies and funding to provide equitable access to technologies that can improve patient health. Understand the true prevalence of trichomonas, a silent epidemic and not yet reportable. Support reimbursement incentives to promote breakthrough innovations. Breakthrough technologies come at a cost. Extraordinary pressure to reduce testing costs comes at the expense of patient care. Rather than reimbursement based on reagent and operational costs, CMS should consider the value that rapid and accurate point-of-care diagnostics provide to the patient and to public health. Visby has engineered out the need for highly trained lab personnel to interpret and operate the results. This and enabling specific targeted treatment based on PCR diagnostic results at the point-of-care is better for the patient, reduces the risk of antibiotic resistance, lowers operational costs, and reduces spending over the long-term by preventing more expensive sequelae, like pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. As the CDC is focused on advancing health equity and insuring access to diagnostic innovations, the Visby medical sexual health test is designed to support that goal and can fundamentally transform patient care and the public health. This point-of-care test platform is patient-centered and convenient, which in-turn can address access and equity concerns across the country. We asked the committee to focus on the value of point-of-care diagnostic testing and consider how to incentivize its use to address the STI epidemic. We are eager to serve as a resource for you at the CDC, HRSA, and HHS to reduce and prevent STIs moving forward. We look forward to continued opportunities for collaboration

with the Visby medical sexual health preventive care product and our future direct-to-consumer STI product offering. Thank you.

Jules Levin

Executive Director/Founder
National AIDS Treatment Advocacy Project

Hi, everybody. This is Jules Levin. I'm the Executive Director and Founder of the National AIDS Treatment Advocacy Project (NATO). I come to you as a person today living with HIV for 40 years. I'm now 72. I've been an advocate for 25 years. I am HIV aging and am now what I call "elderly." I think the CDC, Jonathan, calls people over 65—that's the category "elderly." Over 50 is "aging." I also come to you as a person cured of hepatitis C 21 years ago with pegylated interferon and ribavirin. I'm going to discuss 2 things today, hepatitis C and aging and HIV in 3.5 minutes. Number one, hepatitis C. I think it's disgraceful that here in the United States where we have had a cure for a number of years for hepatitis C, where you can cure hepatitis C in an inexpensive, safe manner with 8 or 12 weeks of therapy that we don't have a national hepatitis C elimination program. It's beyond talk. It's beyond speech. The discussion over the past 2 days around hepatitis C at this CHAC meeting has not been fully comprehensive. The needs for people living with hepatitis C have not been adequately discussed or addressed. Curing hepatitis C requires, in my opinion, a program, a Ryan White Care Act type program, that can be done in 5 or 6 years of limited time or \$5 or \$6 billion dollars, which is in the full scheme of things nothing. A drop in the bucket for the federal government. We need full funding for screening. We need to use electronic health records. We already have new models of care that provide support services for IDUs that could be utilized. The CDC is not working. They are not doing their duty. They are not providing and meeting the needs of this community and what is needed. The CDC is not working with local departments of health, many of whom already have elimination plans. We need funding and the CDC does not seem to be working with the local and state DOHs to develop and push these programs forward and help support them further. They're not providing resources and collaborations. Yesterday, somebody said DAAs are expensive. Are you kidding? They're \$15,000 for a course of treatment. To treat someone like me with HIV for 20 years is \$400,000. Syringe exchange programs and needle exchange programs is only one issue in the full framework that needs to be addressed to eliminate hepatitis C. Aging and HIV. The response has been completely inadequate. It's also a disgrace that this CHAC meeting at CHAC meetings have not had a panel on aging and HIV. We are experiencing more comorbidities than people without HIV. We have reduced life expectancy. We're getting bad care. The 20-minute visit does not work. African Americans get the worst care. Suffice it to say and in summary, it's just really unfortunate and a disgrace that aging and HIV is not adequately addressed and is not part of the discussion in almost every circle that participates in that is a discussion amongst the leaders at the NIH, CDC, many circles around leadership and HIV, our federal government, and state governments as well. Thank you.

Lorren Sandt

Executive Director
Caring Ambassadors Program, Inc.

My name is Lorren Sandt. I am the Executive Director of the Caring Ambassadors Program in Portland, Oregon. We do education and advocacy for people living with hepatitis C and lung cancer since 1997. Dr. Mermin opened the meeting discussing the Center's equity initiative strategy to achieve equity and eliminate health disparities, and the need to address some syndemics. You said you wanted to become as holistic as possible and asked what you could do better. Well, with all due respect, funding holistically, break it down, break down the silos, include reimbursement silos across all agencies. If these funding silos are not broken down,

hepatitis and STIs, health disparities, and health equity will never come to fruition in our country. The \$40 million in funding is frankly something everyone at CDC should be ashamed of. One program highlighted yesterday gave 36 community-based organizations \$400,000 dollars in funding to address one part of HIV. The average funding each state receives in hepatitis funding is \$315,000 dollars. The last professional judgment from the CDC and 2016 called for closer to \$400 million in funding each year for 10 years. This is a finite number so we can reach our elimination goals. We have an elimination plan like HIV, but we have no implementation plan and we have no funding. In Oregon, we have 7600 people living with HIV. We have dozens of case managers and a room full of epidemiologists. We have 90,000 people living with hepatitis C, 1 case manager at 1 HIV organization, and 1 state epidemiologist that we just got after 15 years of no epi. Funding must be commensurate with the impact of the disease. Almost every presentation we've seen, and they've been great, has been a call to break down silos so programs can meet people where they are. We are missing too many opportunities to help people when they reach out for care to help them. There is a cost-savings when people are tested and treated for the disease they present with rather than sending them down the road to test for something else or go somewhere else for care. Every time someone is denied, we are telling them they are not worthy. Hepatitis care and treatment is cost-saving to our health system. I respectfully ask every member of CHAC to be bold. Consider asking the Administration and Congress for an expansion of Ryan White programs to fully integrate hepatitis care and treatment and STI care and treatment, and the CDC to fully integrate the Center with your programs and your funding. We're done PCSIs. We're done with demonstration projects. We know what works. We need the political will to change the policies that keep these funding and silos and place. Thank you very much. And one final comment. I never heard what the outcome was on the discussion of whether the CHAC should weigh in on the mental health of our children. I firmly believe that it is your duty to weigh in on that. I hope that you guys voted to do that and will be weighing in and helping our children to live fully as they grow. Thank you very much.

Daniel Raymond

Director of Policy

National Viral Hepatitis Roundtable

I'm Daniel Raymond. I'm the Director of Policy for the National Viral Hepatitis Roundtable (NVHR). You heard from my colleague yesterday, Adrienne Simmons, with our colleague from Harvard Law School, Julia Harvey, on the current state of Medicaid access to hepatitis C direct-acting antiviral. I just want to go back to their remarks and note that, John, when you asked for guidance that there was a recommendation that more guidance to state Medicaid programs would be enormously helpful. My colleague Adrienne specifically called out the value in recent years of the HHS Medicaid Affinity Working Group, which the Office of Infectious Disease Policies led, but wrapped up its work last year. That Affinity Working Group was really instrumental in aiding states, not only in removing barriers to coverage, but also serving as a catalyst and incubator for discussing innovative payment and financing models for comprehensive care, including elements like case management and peer patient navigation that can be especially vital for achieving health equity goals, but also for analyzing administrative data to construct care cascades for states' Medicaid beneficiaries. This kind of work has become even more important. As some of you may be familiar, the manufacturers of hepatitis C therapeutics have recently imposed greater restrictions on 340B-covered entities. The need for strategizing about ensuring access and scale-up of care is vital. I would encourage CHAC to consider opportunities for making recommendations to further that work through concerted efforts. And then secondarily, I wanted to note the release last week of the White House Office of National Drug Control Policy's "Drug Control Strategy," which included very strong discussion of harm reduction, including support for syringe services programs and

specifically in their performance measures, committed to increasing the number of counties with elevated overdose rates that had an operational SSP by 85% between a 2020 baseline and 2025. I would suggest that there's an opportunity here for CHAC to make recommendations that CDC and HRSA, as part of broader efforts, provide guidance, technical assistance, and policy development on accelerating SSP implementation. I would call attention particularly to opportunities through federally-funded facilities, including Ryan White-funded providers and clinics, STD clinics, and Federally Qualified Health Centers. As we heard earlier today in terms of, for example, the West Virginia experience with clusters and outbreaks, this work has taken on an increased urgency. With the leadership of the Biden/Harris Administration and the new drug control strategy, there is ample opportunity to dive in and make meaningful progress. Thank you.

Recap Day 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson emphasized that CHAC heard some incredible presentations and some very important topics covered. Reflecting on those and high-level messages, they started the morning with a special presentation from FDA and CDC about self-testing and self-collection of specimens in the diagnosis of HIV, HCV, and STIs. There was broad agreement on the needs and advantages of these tools now more than ever. The technology is available. Many of these are available globally. However, there are some barriers that they learned more about during the day in terms of meeting regulatory requirements. Some of the barriers identified include a possible need for additional validation for some tests, the high cost to seek regulatory approval, perhaps the lack of incentives for manufacturers regarding return-on-investment (ROI) in putting in the time, effort, and funding. The take-home message is that there needs to be concerted outreach, which to some degree already is being done, to key players and key stakeholders. It seems like the first step is to discuss with FDA avenues to reduce cost and consideration of where and when manufacturers can be incentivized to provide these critical tools. In the afternoon, CHAC heard about exemplary programs from New Mexico, North Dakota, and San Francisco. All of them exemplify a syndemic approach. They also heard a presentation on CDC cluster response and interventions. The take-home messages include the fact that in New Mexico, North Dakota, and San Francisco, the local or state policies enabled some of these programs and were able to breakdown silos and address things in a cross-cutting way. The issue of silos has been a recurring theme of this meeting and every CHAC meeting in which Dr. Anderson has been involved. The issue of the importance of meeting people where they are intersects with the discussion on self-testing and self-collection. There is a need to link to care and to pay attention to certain high-risk key populations, including incarcerated individuals and pregnant and post-partum women in terms of congenital syphilis, mental health disorders, and SDOH. There also was mention of some of the workflow issues that brought to mind some of the work that has been done in low- and middle-income countries on task-sharing and task-shifting and how the US could do a much better job of that.

Dr. Gayles indicated that in addition to Dr. Anderson's very thorough and comprehensive summary of the day, he had only a couple of points to add. Everything that Dr. Anderson mentioned was a reminder of the importance that all of this work takes into consideration the whole person and not just one aspect as they continue to think through access to testing, access to healthcare, and the full picture of what people face in terms of being able to access

and fully utilize all of the available resources needed to be successful. Regarding a comment raised during the public commentary about looking into the issue of children's mental health, particularly in the face of different legislative efforts occurring across the country specifically tied to sexual and gender identities, he assured everyone that CHAC is looking into that and would be addressing that as a group during the next day's Business Session. CHAC does believe this is an important issue, does take their role as a committee seriously, and hopefully will be able to utilize this role to raise further awareness to the relevant parties who may have an opportunity to fill some of the gaps or address some of the issues that are secondary to the various efforts underway.

Adjourn

Dr. Mermin thanked everyone for another day of outstanding presentations and discussions. He then officially adjourned the meeting for April 27, 2022 and CHAC stood in recess until 10:00 AM ET on April 28, 2022.

Day 3: Welcome and Roll Call

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

Dr. Mermin called the proceedings to order at 10:05 AM ET and welcomed participants to the third day of the CHAC meeting. He conducted roll call and asked members to disclose any new COIs. COIs did not differ from the previous day and are reflected in the table on page 8 of this document. He confirmed that 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 28, 2022.

Recap of Days 1 and 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles provided some high-level highlights from the previous 2 days. The first day began with updates from colleagues at CDC at HRSA describing the fantastic work that they continue to do, including efforts to better understand the increased presence of mental health concerns among children, the increased work at CDC regarding health equity and infusing equity into all aspects of their work, and the great work underway at HRSA and introductions to new key staff members there. There is a lot of great innovation and it is important that CDC and HRSA continue to lead the way at the federal, state, and local levels. One of the key issues that arose during the morning session regarded the role CHAC might play in terms of commenting on or putting forward recommendations to offset some of the political efforts that are putting the great work at CDC and HRSA have invested in at risk, as well as creating obstacles and challenges for communities in being able to take advantage of the programs and opportunities that result from the work of these agencies. Programs from Mississippi, New York, and Minnesota highlighted innovative strategies they are implementing to increase utilization and access to testing, such as using the school space to increase access to young people and leveraging some of the technologies and strategies that were put in place during the COVID-19 response to modernize the public health infrastructure. These programs underscored the importance of using COVID-19 pandemic innovations as models for securing and sustaining funding to continue to support these efforts and codify that work moving forward in a post-COVID world.

During the second day, CHAC heard presentations highlighting how impactful self-collection kits could be in communities that have historically not utilized traditional brick-and-mortar structures. As a result, the availability of self-collection kits increased testing practices in a number of communities. It is known that when people are tested more frequently, the incidence of new cases is reduced. Self-testing also can be used as an opportunity to connect people to clinical care, social-emotional support, and other services such as those that address SDOH. There were discussions with colleagues from FDA regarding the pipeline and approval process for self-collection kits, given concerns that arose with regard to how FDA views HIV versus HCV self-collection kits. CHAC wondered if/how manufacturers producing self-testing kits could be incentivized to increase production in the variety and availability of self-test kits. There are authentication methods domestically and internationally that could serve as models to increase the self-test kit approval process. CHAC also engaged in discussion related to key topics in syndemic analysis, which continues to underscore the need for all work to take a whole person

approach with respect to the various issues that influence an individual's ability to access resources that are being put forward, utilize them effectively, and have successful health outcomes. Exciting and impressive syndemic approaches were presented, along with limitations many jurisdictions will have in moving those creative ideas forward due to financing challenges, particularly in under-resourced districts that do not have significant financing outside of the federal government. While this may not lend itself to a letter at this point, this topic deserves further discussion and consideration in future CHAC deliberations. The Telehealth WG put forth an excellent letter, which was approved and will be sent out following the meeting. Suggestions were made for potential development of 2 letters, one to the Secretary of Health regarding LGBTQ youth and one to FDA regarding the pipeline and approval process for self-collection kits.

Business Meeting

Adoption of November 2021 CHAC Minutes

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson indicated that members had been provided with a copy of the November 2021 CHAC minutes for review. No errors or omissions were identified, no questions or concerns were raised, and no edits were suggested.

CHAC Action

Dr. Mehta made a motion to approve the November 2021 CHAC minutes, which Dr. Greene seconded. CHAC members unanimously approved the minutes with no changes or further discussion.

Update from the Presidential Advisory Council on HIV/AIDS (PACHA)

Ada Stewart, RPH, MD, FAAFP, AAHIVS, HMDC

PACHA Liaison Representative for CHAC

Dr. Stewart reported that PACHA last met virtually on March 14-15, 2022 for its 73rd full council meeting where they had an opportunity to bring back "PACHA-to-the-People." When PACHA was re-established in 2019, the goals of the Co-Chairs recognized the importance of reaching out to the people on the ground—the individuals working in, living with, or at risk for HIV and AIDS—to help guide the work of the PACHA. She expressed gratitude to PACHA's current Co-Chairs for allowing "PACHA-to-the-People" and thanked them for a very successful virtual meeting. The first day consisted of a welcome from Dr. Rachel Levine, Assistant Secretary for Health at HHS, and Harold Phillips, Director of the White House Office of National AIDS Policy regarding NHAS and their commitment to EHE. Reports were presented from PACHA's Stigma and Disparities, EHE, and Global Subcommittees and the Stigma and Disparity Subcommittee's WG that prioritizes molecular surveillance and cluster detection issues. PACHA took this on as a priority due to the growing number of responses they have heard from individuals living with HIV and others regarding the application of this response tool, especially in terms of criminalization of HIV and other social justices.

During the PACHA-to-the-People interactive community engagement session, community members provided feedback in breakout sessions focusing on 2 main topics. The first breakout session focused on HIV prevention in the context of EHE. This group focused on prevention of HIV in women and adolescent girls, those 55 years of age and over, persons living with substance use and mental health disorders, the LGBTQ+ community, and PrEP assistance programs. In the NHAS and EHE Initiative breakout, community folks provided input about how the strategy is working in their states, cities, and territories and how PACHA can help. During these community engagement sessions, there were passionate and robust discussions from communities highlighting the need for whole person care; addressing QOL issues; the need to address aging with HIV; the need to address persons with physical and/or mental health issues, and/or SUDs; the importance of elevating U=U and recognizing the needs of all women, cisgender and transgender; ensuring that there is a national comprehensive program to address barriers to prevention and making sure that rural communities are engaged; and the importance of advocacy in terms of funding.

There was an update on the President's Emergency Plan for AIDS Relief (PEPFAR). PACHA's Global Subcommittee has worked diligently to ensure that HIV/AIDS is elevated from a global perspective, making sure that future guidance is sought from global and domestic lessons learned. There was an important panel discussion related to HIV amongst women and adolescent girls and why representation matters in response to HIV in this population. There was an emphasis on the importance of women, especially women of color, being part of clinical trials and addressing the bias that exists in prescribing of PrEP to women. There was a call to action to shift the narrative to ensure that all women living with HIV need to have a seat at the table and that IPV and QOL must be addressed for both cisgender and transgender women.

There was a panel discussion regarding PrEP for the nation and how to get PrEP to everyone who wants and needs it. There was discussion and approval of a draft letter to the HHS Secretary with PACHA's recommendation on scaling up PrEP to the nation. There also was a panel discussion on strengthening the HIV workforce. Dr. Wendy Armstrong and Vincent Guillermo-Ramos presented as part of the panel about how this important goal can be accomplished. They discussed the importance of removing regulatory barriers that place restrictions on practice at the highest level of training and licensure to ensure that the talents of Advanced Practice Nurses (APN), Nurse Practitioners (NPs), and Social Workers can be leveraged to the fullest of their ability to increase the HIV workforce; ensuring that CMS offers reimbursement for decentralized, team-based, whole person, HIV prevention and care services; supporting a shift toward education and training for the future health workforce that emphasizes key competency of team-based, whole person, HIV care; providing training for those not only pursuing full-time HIV work, but also those who are intimately involved in that; having the knowledge to be able to address co-morbidities using training tracks, residency programs, access to experts, et cetera; investing in infrastructure; developing decentralized and differentiated HIV prevention and care such as telehealth and community-based services; and allocating funding toward HIV using specific demonstration projects.

CHAC Member Observations/Suggestions: PACHA Update

The following questions, observations, and suggestions were raised:

- Dr. Guilamo-Ramos noted that this speaks to the issue of meaningful engagement of people living with HIV in the workforce and expanding definitions of the workforce beyond the clinical to think about a range of important actors who could help to end the epidemic in the country.
- Mr. Lindsey pointed out that there is a community health worker apprenticeship program that came out of the broader HRSA environment.
- Dr. Armstrong indicated that HRSA established and put many resources behind a Community Health Worker Training Program (CHWTP). More programs such as this are needed, but do require additional resources for childcare, transportation, and other supports peers will need to take advantage of such opportunities.
- Dr. Driffin emphasized that it is important to be mindful of diversity, equity, and inclusion in the workforce so that there is racial and gender diversity in key health departments along HIV jurisdictions and such that the community sees more people who look like them in key leadership and executive decision-making roles.
- Dr. Gayles said that he was hearing that perhaps it would be beneficial to stand up a CHAC Workforce Development WG. There previously was a CHAC HIV and Aging WG. Perhaps it would be beneficial to hear an update on this WG and the status of its efforts.

Action Item #1: Potential Letter Regarding LGBTQ Children/Youth**Jean Anderson, MD**

CHAC Co-Chair, HRSA Appointee

Dr. Anderson reminded everyone that the work that CHAC does and the advice they can give to CDC and HRSA is somewhat limited between meetings. The reason they chose the 2 action items for this business meeting was because they felt that there was some sense of urgency for these topics and that some bullet points could be created that CHAC could vote on during this meeting, which could then be developed into a letter over the next few weeks. She then reviewed the proposed components for the letter:

- Background:
 - In December 2021, the Surgeon General warned of a “devastating mental health crisis among adolescents.”
 - There was a 60% increase in major depressive disorders from 2007 to 2019 (National Survey of Children’s Health. HRSA October 2020).
 - Suicide rates increased nearly 60% in youth 10-14 years of age from 2007-2018 (National Vital Statistics Reports September 2020).
 - These problems are magnified among LGBTQ youth (CDC Adolescent Behaviors and Experiences Survey (ABES) 2021).
 - More than 60% of LGBTQ students experiencing poor mental health during the pandemic, which is over twice that seen in heterosexual students.

- LGBQ students were more than 3 times as likely to have attempted suicide in the past year.
 - Three-quarters of LGBTQ students experienced emotional abuse at home during the pandemic.
- For youth to thrive in schools and communities, they need to feel socially, emotionally, and physically safe and supported.
- There are ample data showing that LGBTQ students experience more bullying, harassment, and physical assault as compared to heterosexual students (2015 National Youth Risk Behavior Survey).
 - Young gay/bisexual men are at increased risk for HIV infection (**need update**). In 2014, they accounted for 8 of 10 new HIV diagnoses among youth (HIV Surveillance Report 2014).
- LGBTQ-supportive school policies and practices support all youth with decreases in depressive symptoms, decreases in suicidal thoughts and behaviors, and decreases in suicide attempts—especially among LGBTQ students (National YRBS 2015 & 2017; CDC School Health Profiles 2014 & 2016).
- From 2015-2019, over 200 pieces of anti-LGBTQ legislation were proposed in 35 states. In 2022 alone, over 300 bills have been introduced in state legislatures, often focusing on restricting school curricula, access to books or other educational materials relating to gender identification/gender-affirming care, or sexual orientation (<https://childtrends.org/publications/anti-lgbtq-policy-proposals-can-harm-youth-mental-health>; NYT 4/27/22)
- Implications/Concerns:
 - These legislative efforts send a clear message to LGBTQ youth that they are not okay.
 - Legislative efforts at the state level likely will create significant gaps in access to health care and social support services critical to these youth, including mental health services.
 - These legislative actions also can cause significant anxiety and depression that can further impact adherence to and engagement in medical care.
 - These legislative efforts will put HRSA and CDC efforts (demonstration projects, funding mechanisms) at risk and will impair successful delivery of services.
 - These gaps in care introduce spaces for the federal government to step in and provide a connection to support services that fill that void.
 - Recommendations:
 - Develop and disseminate resources at the federal level for youth and their families, as well as teachers and school counselors, to try to mitigate the potential harmful effects of any LGBTQ legislation.
 - Develop and disseminate resources at the federal level targeted to healthcare providers to better educate them about LGBTQ health and mental health and risk reducing strategies, and to provide information about assistance when problems are identified.
 - Develop public service messages (PSAs) and social and other media to educate the public about these harms and the need to reduce/prevent stigma and discrimination for these vulnerable youth.
 - PSAs also should be developed to target social media and other electronic platforms most utilized by youth, including LGBTQ youth, to provide information and resources.

CHAC Member Observations/Suggestions: LGBTQ Letter

The following questions, observations, and suggestions were raised:

- Consider forming a CHAC WG around these issues.
- Be explicit about promoting ways to encourage healthy sexual behaviors.
- Be specific about risk reduction strategies for at-risk adolescents, such as availability and provision of PrEP.
- Recognize the importance of school counselors at the state and county levels, and support school connectedness in general.
- Thinking particularly about youth who are in the foster care system, target information to social service providers outside of the schools.
- Discuss the potential need for housing assistance, which often goes unnoticed as part of their lived experience.
- Discuss the lack of gender-affirming care and the lack of provision of services/information that involves gender identity, and be more explicit about the mental health challenges that entails. There are efforts to prohibit conversations about sexual or gender identity, some of which is legislative and is actively seeking to bring child abuse charges against anyone who provides gender-affirming services and/or information.
- Perhaps there should be something about starting earlier than the education system. For instance, Oklahoma wants to ban any markers of non-binary gender identities on birth certificates. This seems to be going even further in an effort to erase identities that have been long and hard fought for.
- Highlight the importance of safe spaces, including safe spaces in which families can receive high quality and accurate information. For youth who already feel isolated or for whom the online space or social media is exacerbating their mental health issues, perhaps there could be some opportunities for in-person convening or collective healing through safe spaces or similar avenues. Parental consent was raised during the presentations. Sometimes, parents may be the bullies. Youth need to have safe places where they can speak freely about bullying from one or both parents, as well as school and/or social bullying that is occurring.
- Willful disinformation campaigns should be mentioned in the background section.
- Discuss funding.
- Perhaps there could be a leading bullet point before getting specifically into LGBTQ youth to recommend enhanced effort across the board to increase access to mental health services for all children, particularly around connectedness, coping mechanisms, access to therapy in a timely manner that addresses their mental health needs. That could be the big take home since all youth are currently behind the metaphorical 8 ball. Then it could go on to say, because of everything Dr. Anderson laid out, there needs to be special attention to

LGBTQ youth given particular legislative efforts and include the data showing the implications and connections within all of that.

- Dr. Cheever noted that the topic pertains to LGBTQ issues. If the letter and recommendations are made more general, this topic could be swept into a more general set of discussions around mental health for children. While this is critical as well, it would not focus specifically on the needs of trans and LGBTQ youth who are in places where there have been specific political movements to make it more complicated for them.
- Dr. Mermin added that there are data that support the idea that not only is there a disproportionate effect on mental health among LGBTQ youth, but also there is a fairly large proportion of youth who identify as LGBTQ and, therefore, this has public health importance in this political and social environment that CHAC has been discussing. It is possible to make a difference and it seems like a very important issue, particularly because for STDs (though maybe less) and HIV, there is a highly disproportionate rate among gay and bisexual youth, males particularly. This is a strong rationale for the focus. Based on the discussions, it is very hard for parents, youth, and teachers to obtain information about how to deal with this. The idea for the first bullet to focus on dissemination and access to credible resources is the next generation. CDC/HRSA and other partner organizations have a responsibility to get information out that can be useful and there is also the legal/policy level.

CHAC Action

Dr. Anderson made a motion to approve the letter for LGBTQ youth, which will be developed and circulated for review by CHAC before sending it out, including the 4 original recommendations presented and the addition of the following 4 recommendations:

- Increase efforts across the board to develop and disseminate information and resources for youth and their families, as well as teachers/school counselors addressing the mental health crisis in adolescents.
- Develop and disseminate messages about healthy sexual behaviors and resources to improve access to PrEP and other preventive services to at-risk youth.
- Encourage development of safe spaces for youth in general and LGBTQ youth specifically to access accurate information and support.
- Ensure that resources for LGBTQ youth are available to address disparities in care related to social determinants of care (including homelessness, domestic violence, and racial/ethnic discrimination).

Dr. Dowler seconded the motion. CHAC unanimously approved the LGBTQ letter.

Action Item #2: Letter on Self-Collection and Self-Testing

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles noted that while this proposed letter to the FDA was not fully fleshed out, the CHAC discussions prompted them to put this forward, recognizing that data will need to be identified in order to further shape the letter before it is ready to move forward. Some of the highlighted

points discussed as key areas of concern pertaining to self-collection testing included the following:

- There is a differentiation in how HCV and HIV are viewed, particularly around the impact of results.
- Criteria required for the authentication process domestically versus internationally. One of the major issues was that there are similar tests that are utilized internationally that are not accessible in the US.
- There is a need for incentives and an increased sense of urgency to foster and facilitate a production pipeline. This may involve proactive outreach to manufacturers to encourage them to seek approval for tests, beginning with a discussion with FDA to explore how to decrease the costs associated with premarket approval (PMA). As raised the day before, the cost is just shy of \$400,000 for that process. Consideration needs to be given to how to remove barriers, as well as the existing data related to the impact of self-collection in terms of increased testing in certain groups. It is important to figure out ways to increase the pipeline and help foster a smoother process to move things forward in order to increase access to these testing modalities for certain groups.

CHAC Member Observations/Suggestions: FDA Letter on Self-Collection Testing

The following questions, observations, and suggestions were raised:

- This seems like a critical place for CHAC to focus its efforts to intervene.
- It is important to remember that payers cannot pay for self-collection tests without CPT HCPCS codes for home tests. This was done for COVID-19, which opened the door for other tests. Perhaps someone could reach out to the AMA to discuss this.
- There are some incentives already. Companies would like to market their products and have them widely used, which is why they develop them. Some companies have said the barrier is too high at the FDA level to get approval. FDA spoke about the risk-benefit comparison, but that does not align with the true risks and the true benefits of home testing. A high-level conversation is needed with FDA to come to an agreement that everyone needs to work together to make self-collection kits available to the people who need them. Regulatory barriers were put in place 10 or 20 years ago and need to be revisited.
- There are larger issues to consider when tests are brought to market pertaining to affordability, awareness of availability among communities who need the tests, linking people to services, payer issues, et cetera. With that in mind, perhaps CHAC should consider standing up a Self-Collecting Testing WG to further explore the issues.
- Dr. Mermin asked CHAC to consider whether a very specific, short-targeted, single-pointed letter could be more effective than one that tries to redress all of the comprehensive issues related to testing, which may be better suited for ongoing discussions. The first and part of the third bullets contain the major points. Based on the CHAC discussions throughout the meeting, FDA is aware that the marketing in Europe is different than in the US. While articles have been written about Europe's more efficient process, it is not going to change the US approach to approval processes. While it has been explicitly stated that HIV is exceptional in that it is much more dangerous for someone to have a false negative HIV test than it is to have a false negative hepatitis C test, there are theoretical arguments

against that view. Many years of HIV self-testing are already in place, so the rationale is unclear about the danger. High-quality thoughtful letters are more effective than ones that have not been thought out as well.

- Dr. Akolkar, FDA, clarified that the user fee is not determined by FDA. It is legislatively determined by the Congress. There are also regulations FDA has to abide by, even though they may want to do something for both HIV and HCV. HCV approval was basically done on the basis of persons with signs and symptoms, which is different than for HIV. It is not just a simple equation that HIV and HCV are the same—there are historical nuances. FDA has learned a lot from the self-test experience for HIV and is working with the sponsor, but it is important to remember that the sponsor must approach FDA before a process can begin. They are open to have preliminary discussions with sponsors who believe they have something of value and some data to support that.
- There was CHAC support for the idea of crafting a pointed letter that addresses and engages on the first bullet point specifically, plus/minus some language around asking for the deeper conversation to revisit the processes and how they can be updated to match current thinking versus the thinking of 20 some years ago when self-collection reviews were beginning.
- Some CHAC members wondered if perhaps they were rushing this and that it might be better to establish a WG rather than trying to litigate everything during this meeting. It was noted that an alternative to a WG would be to convene an interim business meeting, which would allow time to assemble the facts and develop a draft letter. Establishing a WG could prolong the process.
- Dr. Gayles recapped that they were hearing that there is still much to be clarified in terms of what would best fit into such a letter, which would take more time to flesh out into more detail. There are 2 mechanisms for moving forward that could work, which are to: 1) convene an interim business meeting that probably could not be scheduled until September; or 2) create a WG to study the key points, with specific tasks of differentiating the bullet points, determining whether the letter to FDA should focus on one point or be more general, and then reporting back to the full CHAC during its November meeting. Given the timeframe, the reality seemed that creating a WG would offer more time to further explore the issues and develop action items.

CHAC Action

Dr. Gayles made a motion to create a Self-Testing and Self-Collection WG to study this issue with the specific task of obtaining more information on: 1) differences in risk classification of HCV and HIV; 2) criteria required and data available for the FDA approval process; and 3) downregulation to Class II diagnostics. The WG will then propose messaging that should go into the letter related to self-collection, including the development of a set of recommendations to be presented during the November 2022 CHAC meeting. Dr. Dowler seconded the motion. CHAC unanimously approved the motion to create a Self-Testing and Self-Collection WG.

Action Item #3: Stand Up a Workforce Development WG

Dr. Anderson reminded everyone that a suggestion was made during the meeting to consider standing up a Workforce Development WG with several specific tasks.

CHAC Action

Dr. Gayles made a motion to create a Workforce Development WG to study this issue with the specific tasks of: 1) formulating a potential panel for the November CHAC meeting in order to have a larger discussion on this topic; 2) liaising with PACHA to ensure that CHAC is not duplicating and is supportive of their efforts that are already ongoing in this space; and 3) exploring the role of other health-related professionals and CHWs to enlarge the workforce and to task-share when appropriate. Dr. Guilamo-Ramos seconded the motion. CHAC unanimously approved the motion to create a Workforce Development WG.

Next Meeting / Proposed Agenda Items

The next CHAC meeting is scheduled for November 1-3, 2022. The following future agenda items were proposed:

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

Recap and Closing

Dr. Gayles expressed his personal gratitude to everyone for their thoughtful input, continued and consistent engagement across 3 days of Zoom meetings, and great input and work. He recognized that the work they all do on regular basis contributes to their expertise and membership on CHAC. He thanked Dr. Anderson for keeping the meeting moving along and for being the epitome of comprehensiveness and thoroughness.

Dr. Anderson echoed that this had been a tremendous meeting in terms of the topics covered, the work done, and the exciting future topics identified. She complimented Dr. Gayles on his amazing abilities not only to summarize, but also to draw out all of the implications. She also expressed gratitude to their CDC and HRSA support.

Adjournment

Dr. Cheever thanked everyone, recognizing that very good panels had been assembled with excellent presenters who brought forward important information. Secondly, she recognized the CHAC members for their ability to listen carefully and reflect on the information presented and engage amazing discussions. She expressed her gratitude for Drs. Gayle and Anderson for their leadership as Co-Chairs and their wonderful abilities to synthesize the information and discussions.

Dr. Mermin expressed his gratitude, emphasizing that he had learned a great deal. At its best, an advisory committee provides useful advice that can help influence the thought process on various topics. CHAC's did exactly that over the past 2.5 days with their thoughtful input, which raised important issues for CDC and HRSA to think about as they consider many issues of importance. He recognized that it is time-consuming and that everyone is very busy. Especially in the time of COVID-19 when site visits have been reduced, it is very difficult to understand what is occurring. It is great to have input from people who are thinking about the issues and want to make a positive difference in these areas of diseases that are of great public health importance and that experience a lot of inequity. He thanked everyone for their time and effort and emphasized that he was looking forward to the November 2022 CHAC meeting.

Certification

I hereby certify that, to the best of my knowledge, the foregoing minutes of the proceedings are accurate and complete.

Travis Gayles, MD, PhD
CHAC Co-Chair, CDC Appointee

Date

Jean R. Anderson, MD, Co-Chair
CHAC Co-Chair, HRSA Appointee,

Date

Attachment A: Participant List

CHAC Members Present

Dr. Jean Anderson (Chair)
Dr. Travis Gayles (Chair)
Dr. Wendy Armstrong
Dr. Jodie Dionne-Odem
Dr. Shannon Dowler
Mr. Daniel Driffin
Dr. Meredith Greene
Dr. Vincent Guilamo-Ramos
Mr. Kali Lindsey
Dr. Christine Markham
Dr. Shruti Mehta
Dr. Johanne Morne
Ms. Kneeshe Parkinson
Mr. Robert Riester
Mr. Leandro Rodriguez
Dr. Samuel So

CHAC Members Absent

Mr. Venton Hill-Jones
Ms. Gloria Searson

CHAC Ex-Officio Members Present

Dr. Pradip N. Akolkar
US Food and Drug Administration

Dr. Maureen Goodenow
National Institutes of Health

Dr. Neerja Gandotra
Substance Abuse and Mental Health
Services Administration

Mr. Richard Haverkate
Indian Health Service

Ms. Kaye Hayes
Office of Infectious Disease and
HIV/AIDS Policy
US Department of Health and Human
Services

Dr. Richard Wild
Centers for Medicare and Medicaid
Services

CHAC Ex-Officio Members Absent

Dr. Iris Mabry-Hernandez
Agency for Healthcare Research and Quality

CHAC Liaison Representatives Present

Dr. Ada Steward
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
Health Resources & Services Administration
HIV/AIDS Bureau Associate Administrator

Dr. Jonathan Mermin
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD
and TB Prevention Director

Attachment B: List of Acronyms

AAA	Area Agency on Aging
ABES	Adolescent Behaviors and Experiences Survey
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living
ADAP	AIDS Drug Assistance Program
AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ANTHC	Alaska Native Tribal Health Consortium
APN	Advanced Practice Nurses
ART	Antiretroviral Therapy
ARV	Antiretroviral
BPHC	Bureau of Public Health Clinics
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBER	Center for Biologics Evaluation and Research
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CDRH	Center for Devices and Radiological Health
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHOW	Community Health Outreach Worker
CHW	Community Health Workers
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CMO	Committee Management Office
CMS	Centers for Medicare & Medicaid Services
COI	Conflicts of Interest
CPT	Common Procedural Terminology
CRUSH	Community, Restoring, Urban Youth, Sexual, Health
CVD	Cardiovascular Disease
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DBS	Dried Blood Spot
DC	District of Columbia
DDID	Deputy Director for Infectious Diseases
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DHP	Division of HIV Prevention
DIS	Disease Intervention Specialists

DOCR	Department of Corrections and Rehabilitation
DSTDP	Division of STD Prevention
DTC	Direct-to-Consumer Test
DVH	Division of Viral Hepatitis
EHE	Ending the HIV Epidemic
EIS	Epidemic Intelligence Service
ELEVATE	Engage Leadership through Employment, Validation, and Advancing Transformation & Equity
EMR	Electronic Medical Record
EMR	Electronic Medical Record
EOB	Explanation of Benefits
EPT	Expedited Partner Therapy
ET	Eastern Time
FACA	Federal Advisory Committee Act
FD&C Act	Food, Drug & Cosmetic Act
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
GS	General Schedule
HAB	HIV/AIDS Bureau
HCP	Health Care Provider/Practitioner
HCPCS	Healthcare Common Procedure Coding System
HCV	Hepatitis C Virus
HHS	(United States Department of) Health and Human Services
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Tests
HOPWA	Housing Opportunities for People with AIDS
HPV	Human Papillomavirus
HR	Human Resources
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
IHS	Indian Health Service
IPV	Intimate Partner Violence
ITCA	Inter Tribal Council of Arizona, Inc.
IVD	In Vitro Diagnostic Devices
LARC	Long-Acting Reversible Contraception
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Questioning
MCH	Maternal and Child Health
MCO	Managed Care Organization
MFPP	Minnesota Family Planning Program
MIEP	Medicaid Inmate Exclusion Policy
MMP	Medical Monitoring Project
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MOUD	Medicated Opioid Use Disorder
MSM	Men Who Have Sex With Men

MSW	Men Who Have Sex With Women
NAAT	Nucleic Acid Amplification Testing
NAAT	Nucleic Acid Amplification Test
NACCHO	National Association of County and City Health Officials
NACCHO	National Association of County and City Health Officials
NASTAD	National Alliance of State and Territorial AIDS Directors
NATO	National AIDS Treatment Advocacy Project
NCHHSTP	National Center for HIV, Viral Hepatitis, STD and TB Prevention
NCIPC	National Center for Injury Prevention and Control
NDDOH	North Dakota Department of Health
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance
NHRC	National Harm Reduction Coalition
NHRTAC	National Harm Reduction Technical Assistance Center
NIH	National Institutes of Health
NMCD	New Mexico Corrections Department
NMMIP	Mexico Medical Insurance Pool
NOFO	Notice of Funding Opportunity
NP	Nurse Practitioner
NRWC	National Ryan White Conference
NVHR	National Viral Hepatitis Roundtable
NWPC	National Working Positive Coalition
NYC	New York City
NYC Health	NYC Department of Health and Mental Hygiene
OAA	Older Americans Act
OIDP	HHS Office of HIV/AIDS and Infections Disease Policy
OMB	Office of Management and Budget
OMB	Office of Management and Budget
ONAP	Office of National AIDS Policy
ONAP	Office of National AIDS Policy
OTC	Over-The-Counter
ODU	Opioid Use Disorder
PACHA	Presidential Advisory Council on HIV/AIDS
PACHA	Presidential Advisory Council on HIV/AIDS
PCSI	Program Coordination and Service Integration
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMA	Premarket Approval
PN	Peer Navigators
POC	Point-of-Care
PrEP	Pre-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
PWID	People Who Inject Drugs

QOL	Quality of Life
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SB	Senate Bill
SDOH	Social Determinants of Health
SFUSD	San Francisco Unified School District
SHCs	Sexual Health Clinics
SNS	Social Network Strategies
SPPS	St. Paul Public Schools
SPTHB	Southern Plains Tribal Health Board
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
SUD	Substance Use Disorder
SVR	Sustained Virologic Response
TA	Technical Assistance
TAP	Technical Assistance
TB	Tuberculosis
US	United States
US PLHIV Caucus	US People Living with HIV Caucus
USPSTF	United States Preventive Services Task Force
VH	Viral Hepatitis
WG	Working Group
WGS	Whole Genome Sequencing
WHO	World Health Organization
WIC	Women, Infants, and Children
YAB	Youth Advisory Board
YRBS	Youth Risk Behavior Survey

Attachment C: Public Comment Letters

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April 18, 2022

CDC/HRSA Advisory Committee on HIV, Viral
Hepatitis and STD Prevention and Treatment
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop US8-6
Atlanta, GA 30329-4027

Submitted by email to nchhstppolicy@cdc.gov

Subject: Spring CHAC Public Comment Registration

Dear Advisory Committee Members:

Thank you for the opportunity to submit written comments to the upcoming meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). Founded in 2015, Everly Health is an Austin, TX based company offering modern, diagnostics-driven care. Our goal is to meet the consumer where they are by leveraging our national clinical network composed of hundreds of physicians, nurses, genetic counselors, pharmacists, and member care specialists along with our digital platform and fully-owned CLIA certified, CAP accredited laboratories. We provide services both directly to the consumer through Everlywell as well as complete solutions for diagnostics-driven virtual care at scale to health plans and enterprises through Everly Health Solutions.

Everly Health is an industry leader in facilitating telehealth and at-home services for laboratory testing. In total, we offer over 2500 tests with our partner laboratories in addition to the thirty tests across six key categories within our own diagnostic laboratories. Our demonstrated success in at-home collection and testing enabled us to mobilize quickly and early in the pandemic to provide nationwide access to testing for COVID-19. We were the second company to receive emergency use authorization (EUA) from the Food and Drug Administration for our at-home collection kit and since March 2020, we have provided clinical oversight, care coordination, and physician services for tens of millions of tests for COVID-19. Everly Health Solutions' 50 state provider network can facilitate test ordering, follow up with patients who test positive, and offer assistance with accessing treatment.

Just released this month, the Centers for Disease Control (CDC) preliminary report on 2021 surveillance of sexually transmitted diseases (STDs) shows that rates of syphilis continue to increase, with a 34% increase among women.¹ The agency also reported that the pandemic led to underreporting of infections and increased transmission in 2020 due to reduced screening as healthcare clinics either closed or restricted in-person visits to limit spread of COVID-19.² Additionally, public health departments are already facing limited resources needed to move

¹ <https://www.cdc.gov/std/statistics/2020/preliminary2021.htm>

² <https://www.cdc.gov/std/statistics/2020/impact.htm>

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personnel from STD prevention and control efforts to the pandemic.³ Recognizing this shift in access to STD prevention, in its 2021 update to its Sexually Transmitted Infections Treatment Guidelines, the CDC identified an opportunity to build upon the lessons learned from the response to COVID-19 including the use of at-home collection for STDs.⁴ The pandemic clearly illustrated the critical role at-home testing plays in responding to and controlling infectious disease outbreaks and for these reasons, we were very pleased to see that the agenda for the upcoming CHACHSPT meeting included a focus on self-testing and self-sample collection for STDs.

We currently offer a direct-to-consumer testing channel for men and women to self-sample within the comfort of their own home to test for chlamydia, gonorrhea, hepatitis C, HIV, syphilis, trichomoniasis and herpes simplex virus type 2. For those who test positive, we provide access to providers who can initiate access to appropriate treatment. We have found that patients prefer privacy when testing for sensitive conditions and the seamless access to treatment to quickly resolve their infection and symptoms. In 2021, we had 77,800 sexual health kits ordered and registered to 47,400 unique users. Of those, 6202 tested positive for one or more STD, and 8,604 consults were scheduled. We have surveyed our customers about their at-home testing experience and they consistently report high levels of satisfaction.

We hope that our experience in providing access to laboratory testing directly to consumers will help inform future policy recommendations that support self-testing and self-sample collection for testing for STDs. Our own experience has proven that the sampling technology and digital platforms exist to successfully enable at-home collection and testing for STDs. Not only will it remove major barriers to access, including during public health emergencies, but our data show that people prefer and desire this testing option. Now we just need proactive policy to support the delivery of these critical and innovative prevention and treatment tools directly to those at greatest risk.

Thank you for your consideration of our comments and we hope that you will look to Everly Health as a resource and partner as you consider the role of self-testing and self-sample collection in preventing STDs. Please do not hesitate to contact me at marisa@everlyhealth.com if I may be of further assistance.

Sincerely,

Marisa L. Cruz, MD

Marisa L. Cruz, MD
EVP Regulatory and Clinical Affairs
Everly Health

³ Ibid.

⁴ https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm?s_cid=rr7004a1_w

April 4, 2022

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W. Washington, DC 20201

Dear Secretary Becerra:

We, the undersigned national, local, and state-based health, education, and civil rights organizations, outline our support for a national program to finance and distribute medications that prevent HIV infection, known as pre-exposure prophylaxis, or PrEP. A key goal of a national program is to scale up access to PrEP substantially in order to help end the HIV epidemic. A national PrEP program should be guided by these principles: accessibility, equity, simplicity, affordability, sustainability, and adaptability. We were pleased to see the historic investment in a national PrEP program included in the President's 2023 budget. We believe systems-wide reforms and innovative policies are needed to end the HIV epidemic in the U.S., and we look forward to working with the Administration to help make this ambitious proposal a reality.

HIV in the United States (U.S.)

In 2019, nearly 37,000 people in the U.S. were diagnosed with HIV. Black and Latinx/Hispanic individuals comprised 42 percent and 29 percent of new diagnoses, respectively. Every person living with HIV requires a lifetime of treatment at an estimated individual cost of about \$501,000, with potential adverse effects that include liver toxicity and insulin resistance. HIV was the underlying cause of death for more than 5,000 people in 2019 in the U.S.

A major gap in U.S. efforts to address HIV is the under-utilization of medications that can virtually eliminate the acquisition of HIV. Fewer than 25 percent of people who could benefit from PrEP actually receive it, with large and growing disparities by race, ethnicity, gender, and geography. In 2019, the CDC found that 63 percent of White Americans recommended for PrEP received a prescription, compared to 14 percent of Latinx/Hispanic Americans and just 8 percent of Black Americans.

The current role of the federal government in HIV prevention

In 2019, the federal government launched a major new initiative called *Ending the HIV Epidemic*, investing more than \$500 million in HIV prevention, treatment, and research programs. The goal is to reduce new HIV infections in the United States by 90 percent by the year 2030. Though achievable, success will require substantial improvement over the modest 9 percent decline in new infections from 2015 to 2019.

The recently updated National HIV/AIDS Strategy for 2022-2025 recognizes the need for much greater use of PrEP. The major reasons for poor access include high prices, expensive and inaccessible laboratory tests, complex and confusing eligibility requirements to access PrEP services, limited provider availability in many parts of the country, and stigma. The Department of Health and Human Services (HHS)'s *Ready, Set, PrEP* Program, launched in 2019, aimed to reduce this gap by providing free PrEP medication for those without prescription drug coverage; however, the program does not cover the required associated clinic and lab costs for PrEP. The program also relies on high-cost, brand-name oral medications from a single manufacturer, despite the fact there are currently 12 manufacturers marketing generic PrEP in the U.S as well as a new long-acting injectable form of PrEP approved in December 2021.

Benefits of a national PrEP program

To scale up PrEP as part of an effective, sustainable strategy to end the HIV epidemic, a national PrEP infrastructure must move away from the current reliance on high-cost, brand-name drugs that have resulted in overly complex, difficult-to-navigate programs for the un- and under-insured and a relatively small number of access points in the Medicaid program. The [proposal from Killelea and colleagues](#) provides one potential path for a national PrEP program focused on these populations. A call for a national PrEP program builds off of recent efforts to secure congressional and Administration support for expanded access to PrEP. Any new funding must be strategically invested to ensure that scarce dollars are stretched to help the most amount of people and focused on reversing growing inequities in PrEP access. A multi-pronged approach will be needed to create a system in which individuals and providers can equitably and sustainably access PrEP.

To reduce the growing inequities enabled by our fragmented PrEP financing system, we seek your support for a national PrEP program which:

- Expands access to PrEP medications and lab services for people who are uninsured and on Medicaid
- Allows the federal government to negotiate with manufacturers and labs for fair public health prices
- Scales-up access to generic PrEP medication as a safe, effective, and cost-effective option for the majority of those indicated for PrEP and provides access to other PrEP options when indicated
- Creates an expansive provider network of non-clinical community-based PrEP providers and local health departments serving the uninsured and Medicaid that are paired with clinical providers via telehealth partnerships
- Works in tandem with existing PrEP funding and programs to supplement, not supplant programs and activities that are working
- Creates a platform for the effective and rapid deployment of novel PrEP medications

- Provides new opportunities to effectively raise awareness and combat stigma by enrolling and educating a new, broad network of providers and building community-led campaigns that connect key populations to this new PrEP infrastructure

A national PrEP program would help put the U.S. on track to end the HIV epidemic.

If you have any questions, do not hesitate to reach out to Jeremiah@prep4all.org

Sincerely,

Advocates for Youth
AIDS Alabama
AIDS Foundation of Chicago (AFC)
AIDS United
Amida Care
AVAC
Black AIDS Institute
Callen-Lorde Community Health Center
Center for Health Law and Policy Innovation, Harvard Law School
Community Education Group
COVID Clinic, Inc.
Equality California
Fenway Health
Friends For Life Corp - Memphis, TN
Georgia AIDS Coalition.
Georgia Equality
HealthHIV
HIV Medicine Association (HIVMA)
Housing Works
International Association of Providers of AIDS Care (IAPAC)
John Snow, Inc. (JSI)
Latino Commission on AIDS
NASTAD
National AIDS Housing Coalition (NAHC)
National Association of City and County Health Officials (NACCHO)
National Coalition for LGBTQ Health
NMAC
PrEP4All
San Francisco AIDS Foundation
Silver State Equality-Nevada
Southern AIDS Coalition
The AIDS Institute
The Aliveness Project, Inc.
The Reunion Project
Treatment Action Group
Vivent Health



3010 North First Street
San Jose, CA 95134

(650) 257-7587
www.visbymedical.com

National Center for HIV, Viral Hepatitis, STD, and TB Prevention
U.S. Centers for Disease Prevention and Health Promotion
[1600 Clifton Road NE](#), Mailstop US8-6
Atlanta, Georgia 30329-4027
Attention: Marah Condit, MS, Committee Management Lead

Re: Written Comments for the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)

Dear Members of the CHACHSPT:

On behalf of Visby Medical, Inc. (Visby), a medical diagnostics technology company headquartered in San Jose California, and the patients and providers we seek to support with our point-of-care (POC) testing, we appreciate this opportunity to submit comments for consideration during the spring meeting. Our mission is to "empower anyone to test for any infection anywhere with near-100% accuracy." As such, we very much support the CHACHSPT's focus on activities related to the prevention and control of sexually transmitted infections (STI) and stand ready to be a resource and partner with you in your important work.

About Visby

Visby Medical is transforming the order of diagnosis and treatment for infectious diseases so clinicians can test, talk with, and treat the patient in a single visit. The Company's proprietary technology development program culminated in the world's first instrument-free, single-use PCR platform that fits in the palm of your hand and rapidly tests for serious infections. Originally developed for sexually transmitted infections, the Company's FDA-cleared, CLIA-waived Sexual Health Click Test for women returns accurate results within 28 minutes. The Visby Medical technology is also helping to fight the global pandemic via the Visby Medical COVID-19 Test, and its robust pipeline includes tests for other infectious diseases. Visby Medical is accelerating the delivery of fast and accurate, palm-sized PCR diagnostics to the point of care, and eventually for use at home. Visby Medical has received Federal funding from NIH and BARDA to support the development and validation of the PCR platform. For more information, visit www.visbymedical.com.

Accurate POC Tests Can Promote and Protect Public Health

The nation is in the sixth year-over-year increase in chlamydia and gonorrhea cases and this silent – and neglected – epidemic will not wane unless we become more intentional as a nation in how we deploy accurate, rapid test modalities. The Centers for Disease Control and Prevention's (CDC) 2021 Sexually Transmitted Disease (STD) Treatment Guidelines recommends Nucleic Acid Amplification Tests (NAATs) for detecting chlamydia and gonorrhea. The 2021 STI National Strategic plan includes a recurring theme of the need for "innovative solutions and approaches to address the ongoing and emerging challenges to STI prevention and control" and specifically calls out the need to develop "point of care diagnostic tools."

Visby has developed and introduced such a test to the market. We have the first FDA-cleared and CLIA-waived instrument-free PCR platform that can detect and distinguish

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between three of the most common and curable STIs – chlamydia, gonorrhea, and trichomonas. This test provides lab-accurate results in less than 30 minutes without the need for trained laboratory technicians to operate or interpret test results. These tests can be used in any POC setting that has a CLIA-waiver, including STI clinics, OBGYN offices, emergency departments (EDs), urgent care settings (UC), and mobile vans. Because this platform does not require an extra instrument, it lends itself well for use in resource-constrained and remote settings. Many tests can be run in parallel to meet surge capacity.

The standard of care (SOC) practice is to send-out STI test samples for PCR testing, which typically does not return results for at least 24 hours, oftentimes longer. In the absence of real-time test results, patients are presumptively treated based on symptoms and sexual history. While this generally no longer happens in any other disease-state, it is common practice for STIs. Often the initial diagnosis is incorrect, meaning that the patient will need to be contacted with the right diagnosis and a new prescription for treatment or the patient may have to return for a second appointment to get the appropriate treatment. Women bear the greatest burden of this delay in accurate treatment, where untreated STIs can result in pelvic inflammatory disease (PID), ectopic pregnancies, and infertility. Moreover, STI infection increases the risk of HIV transmission. In sum, the current SOC practice delays accurate treatment, inconveniences the patient, can burden providers, and increases costs – and decreases efficiency – within the health care system.

The reality is that we are treating patients before test results are available. The rates of overtreatment (e.g., patient is treated for chlamydia, but laboratory results show she is not infected with chlamydia) can be as high as 80%, especially in settings such as EDs and UCs where staff fear patients will be lost to care. The Visby STI test can prevent overtreatment thus reducing the unnecessary use of antibiotics and promoting antibiotic stewardship. Conversely, undertreatment (e.g., patients are not given treatment, but laboratory results show they are infected with chlamydia) are also high. The consequences of undertreatment are detrimental to both individual and public health as untreated STIs can lead to PID and other severe sequelae, and patients can continue to spread disease. Importantly, clinic staff spend time calling the patient back with their test results and, in many settings, can never get in contact with the patient. The patients lost to care can be as high as 40%, posing a risk to public health by continuing to spread untreated disease.

Because Visby test results are available during the span of a patient's clinic visit, this enables:

- Accurate treatment informed by real-time PCR results
- Patient education (treatment and how to avoid future infections)
- Expedited Partner Therapy (EPT) (this is permitted in most states)

POC STI testing is better for the patient because:

- Patients are accurately treated based on what they have. This in turn improves their outcomes directly and helps reduce the spread of STIs.
- Treatment in a timely fashion means chlamydia infection does not progress to pelvic inflammatory disease (PID), which if left untreated can result in infertility and

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ectopic pregnancies, which can be devastating for patients and expensive for the health care system.

- Accurate treatment means the patient does not receive an unnecessary antibiotic (and not subject to unnecessary side effects from the antibiotic).
- Unnecessary additional clinic visits are avoided and clinician effort spent trying to reach patients for follow-up is eliminated.

Taken together, these advantages reduce costs and decrease the burden on the health care system.

Visby's STI Test Helps Advance the 2021 STI National Strategic Plan

Deploying a test like the Visby sexual health test supports all of the goals in the STI National Strategic Plan that was released in 2021.

Goal 1: Prevent new STIs

- By treating patients with the right drug in the initial clinic visit patients are not at risk of transmitting disease to other sexual partners; this provides timely, appropriate care to the patient directly and results in a better outcome for public health
- The provider has an opportunity to educate the patient face-to-face in real time. This will help increase awareness of STI prevention and sexual health.

Goal 2: Improve health of people by reducing adverse outcomes of STIs

- By providing test results within a patient's clinic visit, morbidity is reduced:
 - Patients are accurately treated based on what they have, not the best guess of the physician.
 - Timely treatment will reduce morbidity and in turn, improve outcomes and reduce costs. As noted above, timely treatment means chlamydia, gonorrhea, or trichomonas infections do not progress to PID, which, if left untreated, can result in infertility and ectopic pregnancies. Because infection with these STIs can increase the risk of HIV transmission, it is important to test, educate, and treat patients quickly.
 - Accurate treatment means the patient does not receive an unnecessary antibiotic and is not subject to unnecessary side effects from the antibiotic: Antibiotic Stewardship.

Goal 3: Accelerate progress in STI research, technology, and innovation

- By using an innovative diagnostic like the Visby Sexual Health STI test, the government can support shifting the paradigm from syndromic treatment to 'test, talk, treat'. Evidence-based treatment and decision-making is strengthened by POC accurate testing.

Goal 4: Reduce STI-related health disparities and health inequities

- Making a POC test like this available as standard of care can help advance equity, reduce health disparities, and decrease implicit bias that may be a component in syndromic treatment and diagnosis.

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- Innovations in diagnostic testing, like that of the Visby STI test, can fundamentally transform the patient experience, making it more patient-centered and convenient, which in turn can address access and equity concerns.
- STIs disproportionately affect women, and particularly minorities. For example, even though the population/clinic-based prevalence for trichomonas is 0.2%, black women bear the highest burden of disease (9%).
- The newly released 2020 STD Surveillance Report showed that while STDs are increasing across many groups, some racial and ethnic minority groups, gay and bisexual men, and our nation's youth continue to experience higher rates of STDs.

Goal 5: Achieve integrated, coordinated efforts that address the STI epidemic

- A key attribute of the Visby test is that it does not rely on a separate instrument, meaning that it is deployable almost anywhere, and lends itself well for surge capacity; as many people as possible can be treated contemporaneously.
- These tests can easily be deployed in the community and utilized in mobile clinic vans. For example, Visby is supporting a study to assess how this test can be used when deployed into a harm reduction mobile van that reaches rural individuals with substance use disorders.
- As a POC test the Visby test facilitates the delivery of integrated, coordinated care; all within one visit, the patient will be tested, diagnosed, educated about their infection, and prescribed a treatment pathway.

Call to Action

The potential for innovative, game changing POC STI tests to have a significant, positive impact on the STI epidemic is enormous. However, a number of barriers preclude the test becoming available to all who need it. As such, we respectfully call upon the CHACHSPT to support and recommend to Department of Health and Human Services (HHS), CDC, and the Health Resource and Services Administration (HRSA) the following:

1. *Implementation science studies* to assess clinical adoption in various settings, especially those settings where health inequities can be improved, such as with underrepresented groups, rural populations, novel health care delivery settings (e.g, mobile vans), and others.
2. *Policies, programs, and funding for equitable access to innovative technologies.* Access to innovative technologies should not be limited to those with means; innovation, especially that funded with taxpayer dollars, should be available to everyone. HHS should advance policies, programs, and funding that facilitate equitable access to technologies that can improve individual and public health.
3. *Efforts to uncover the true prevalence of Trichomonas* in all geographies and demographics. Trichomonas, as with other STIs, is a silent epidemic. Currently, Trichomonas is not required to be reported, so the true prevalence is unknown. Some clinics in the South report 30% prevalence in women and 10% in men, but in other geographies it appears to be less prevalent; however, this could be

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because people are not being routinely tested for *Trichomonas*. Knowing the true prevalence will help guide CDC treatment and reporting guidelines.

4. *Adequate coverage and payment policies for breakthrough innovative technologies that can make a difference to patient outcomes.* Patients and providers want, need, and deserve access to accurate, POC testing. However, reimbursement for such tests can be so low that it thwarts utilization of the technology when and where it is needed most. Moreover, the current federal coverage and payment system – as operationalized by the Centers for Medicare and Medicaid Services (CMS) – is built around laboratory-based testing and not POC. As many commercial payors and Medicaid often follow CMS, the adverse impact on the adoption rate for new diagnostic technology can be significant. The Visby test was built intentionally to engineer out the need for highly trained laboratory personnel to operate and interpret the test results so that it could be used nimbly in a variety of care settings to have the maximum positive impact on public health. Unfortunately, without improved coverage and payment policies, the test will not be adopted, and its promise will not come to fruition.

Conclusion

Again, on behalf of Visby and the patients and providers we seek to support with our POC testing, we thank you for your consideration of our views and recommendations. With sufficient reimbursement and intentional deployment, we feel strongly that our POC STI test has the potential to make a significant difference in addressing the STI epidemic. We are eager to serve as a resource to you, CDC, HRSA, and HHS to reduce and prevent STIs.

Sincerely,



Christopher J. Jowett
Chief Commercial Officer

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EXHIBIT H

STATE OF FLORIDA Integrated HIV Prevention and Care Plan



2022-2026

Prepared for

Division of HIV/AIDS Prevention

National Center for HIV/AIDS, Viral Hepatitis, STD, and
TB Prevention

Centers for Disease Control and Prevention

HIV/AIDS Bureau

Health Resources and Services Administration

Submitted by

Florida Department of Health
Division of Disease Control and Health Protection
Bureau of Communicable Diseases
HIV/AIDS Section

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- AIDS Service Organizations and Community-based Organization Staff and Volunteers throughout the state
- The AIDS Institute
- State Agency and Association Partners
- Private Sector Partners
- Florida Department of Health Bureau of Communicable Diseases staff
- The thousands of Floridians who have provided input to the integrated HIV Planning Process

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Revision History

Version	Date	Author(s)	Revision Notes
1.0	9/30/2022	ISF	Draft to walkthrough with Department
2.0	10/10/2022	Department/ISF	Additional content added, edits made
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4.0	10/31/2022	Department/ISF	FCPN feedback incorporated
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6.0	11/28/2022	Department/ISF	Department feedback merged with final design
7.0	1/19/2023	Department	Final revisions incorporated

Acronyms

Acronym	Definition
ADAP	AIDS Drug Assistance Program
AETC	AIDS Education and Training Center
AHCA	Agency for Health Care Administration
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy/Treatment
ARTAS	Antiretroviral Treatment and Access to Services
ARV	Antiretrovirals (medication)
AZT	Azidothymidine
BRTA	Business Responds to AIDS
CBI-HIV	Capacity Building Initiative
CBO	Community-based Organization
CDC	Centers for Disease Control and Prevention
CHARTS	Florida Community Health Assessment and Resource Tool Set
CHD	County Health Department
CHW	Community Health Worker
CLAS	National Culturally and Linguistically Appropriate Services Standards
Department	Florida Department of Health
D2C	Data to Care
DIS	Disease Intervention Specialist
DUA	Data Use Agreement
EBI	Evidence-based Interventions
ED	Emergency Department
EHE	Ending the HIV Epidemic
EMA	Eligible Metropolitan Areas
FCHAR	Florida Consortium for HIV/AIDS Research
FCPN	Florida Comprehensive Planning Network
FDA	U.S. Food and Drug Administration
FDC	Florida Department of Corrections
FDCF	Florida Department of Children and Families

Acronym	Definition
FDOE	Florida Department of Education
FLHRC	Florida Harm Reduction Collective
FOCUS	Frontlines of Communities in the United States Initiative
FQHC	Federally Qualified Health Centers
FRTA	Faith Responds to AIDS
F.S.	Florida Statute
HAPC	HIV/AIDS Program Coordinator
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIE	Health Information Exchange
HIP	High-Impact Prevention
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HOPWA	Housing Opportunities for People with AIDS
HRSA	Health Resources and Services Administration
IDU	Injection Drug Use
HUD	U.S. Department of Housing and Urban Development
IBM	Insurance Benefits Management
IDEA	Infectious Disease Elimination Act
IPC	Integrated Prevention and Care
JLP	Jail Linkage Program
MAI	Minority AIDS Initiative
Marketplace®	Affordable Care Act Health Insurance Marketplace®
MAT	Medication Assisted Treatment
MHS	Molecular HIV Surveillance
MMP	Medical Monitoring Project
MMSC	Male-to-Male Sexual Contact
MSM	Men who have Sex with Men
NHAS	National HIV/AIDS Strategy

Acronym	Definition
NCHHSTP	National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
NHBS	CDC National HIV Behavioral Surveillance
OD2A	Overdose Data to Action
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PRPP	Pre-Release Planning Program
PWH	People (or Person) with HIV
PWID	Persons Who Inject Drugs
RFA	Request for Application
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SCSN	Statewide Coordinated Statement of Need
SDOH	Social Determinants of Health
SPNS	Special Projects of National Significance
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
T&T	Test and Treat
TCE	Targeted Capacity Expansion
TH	Telehealth
TIC	Trauma Informed Care
TOPWA	Targeted Outreach for Pregnant Women Act
U=U	Undetectable=Untransmittable
UM-AETC	University of Miami AIDS Education and Training Center
USPSTF	U.S. Preventive Services Task Force
US	United States
VA	Veteran's Administration
VL	Viral Load
WCBA	Women of Childbearing Age
WICY&F	Women, Infants, Children, Youth, and Families

1 Executive Summary and Statewide Coordinated Statement of Need (SCSN)

The United States (U.S.) has taken on a bold plan to end the HIV epidemic by the year 2030. In order to reach national goals of reducing new HIV infections by 75% by 2025 and by 90% by 2030, the country must take aggressive actions by scaling up key HIV prevention and treatment strategies. The presentation of **Florida’s HIV Integrated Prevention and Care (IPC) Plan, 2022–2026** is the culmination of several local (rapid HIV antiretroviral start programs), state (Data to Care programs), and federal initiatives including:

- *National HIV/AIDS Strategy, 2022–2025 (NHAS)*
- *Ending the HIV Epidemic (EHE) in the United States (2019)*
- *National Strategic Plan: A Roadmap to End the Epidemic for the United States, 2021–2025*

These plans work in unison to achieve national goals. This plan builds upon the previous work in Florida’s Statewide Integrated HIV Prevention and Care Plan, 2017–2021 and Florida’s Unified Ending the HIV Epidemic (EHE) Plan, 2020.

The impact of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) in Florida is far reaching with 120,502 persons with HIV (PWH) living in the state as of 2021, which represents only 86% of PWH—the remainder of whom are unaware of their status (approximately 14%). We believe people in Florida have the right to:

- Know their HIV status.
- Access Pre-Exposure Prophylaxis (PrEP) if they are negative but at risk for developing the disease.
- Receive services needed to achieve or maintain a high quality of life if they have tested positive.
- Obtain health care, free of stigma.
- Be a voice in their local communities to effect positive change.

According to the Centers for Disease Control and Prevention (CDC), in 2020 (the most recent data available), Florida was ranked third highest (15.7 per 100,000 population) for new HIV diagnosis rates in the United States (including the District of Columbia). In 2021, 4,708 persons received an HIV diagnosis in Florida, a 37% increase from the 3,441 HIV diagnoses in 2020. In 2021, 83% of those newly diagnosed were linked to HIV-related care within 30 days of diagnosis. The number of AIDS cases diagnosed in 2012 in Florida was 2,846, and in 2021 case numbers dropped to 1,860. The current estimate of 14% of PWH in Florida not knowing their status, along with the substantial decrease in AIDS cases over a 10-year period, together underscore the importance of HIV prevention and care service delivery in Florida.

The seven Florida EHE counties make up approximately 11% of the total national HIV burden as outlined in the EHE plan and represent 72% of the total persons with an HIV diagnosis in Florida. Five of the EHE

counties, Pinellas (77%), Hillsborough (71%), Orange (72%), Broward (70%), and Duval (69%) had a viral suppression rate equivalent to or greater than the state rate of 69%, while Palm Beach (65%) and Miami-Dade (63%) had lower viral suppression rates than the state at the end of 2021.

Florida is a large and diverse state. It has both rural and metropolitan areas, an extensive mix of cultures, and an oscillating population due to seasonal residents, tourists, and itinerant workers. These factors can challenge the planning processes of disease control. The IPC Plan is designed to demonstrate coordinated HIV prevention and care activities by assessing resources and service delivery needs across HIV prevention and care systems to ensure the allocation of resources based on data.

Florida receives funding for and implements a wide range of programs and services for persons with and those at increased risk for HIV, including: the AIDS Drug Assistance Program (ADAP), Ryan White HIV/AIDS Program (RWHAP) patient care programs, prevention (HIV testing, PrEP, linkage), housing, substance use disorder and mental health, and other programs.

Core medical and support services are provided by the federal RWHAP to low-income Floridians living with HIV or AIDS who have inadequate or no health insurance and are ineligible for Medicaid, Medicare, or any other public insurance programs through different entities. Services such as medical care, pharmaceuticals, dental services, payment of health insurance premiums, laboratory services, counseling and treatment for substance use disorder, and medical case management are provided through the various parts of the RWHAP. Each part has separate eligibility criteria that clients must meet.

Ending HIV requires partnership and collaboration. This IPC Plan was developed through collaborative efforts that span the continuum of HIV prevention and care, and with representatives from the Florida Comprehensive Planning Network (FCPN) and associated advisory groups, local HIV planning bodies, Department of Health staff, and communities living with and affected by HIV/AIDS. The IPC Plan also aligns with the previously submitted Florida EHE Plan (2020), Florida's 4 Key Component Plan (2016), and the NHAS goals and strategies.

Florida's IPC Plan encompasses the state's entire system of HIV prevention and care. The IPC Plan was reviewed with members of Florida's integrated HIV prevention and care planning body, FCPN, during the Fall 2022 meeting held in Lutz, Florida, October 18–19, 2022. During the two-day meeting, FCPN members and other stakeholders in attendance had an opportunity to provide feedback and suggestions on the draft plan. Concurrence for the plan was gained on October 19, 2022, through a vote of FCPN members. The Department of Health (Department) is pleased to present Florida's IPC Plan, which is intended to re-energize and strengthen a whole-of-society response to the epidemic while supporting PWH in Florida and reducing HIV-associated morbidity and mortality.

1.1 Approach and Partnerships

Critical information about the IPC Plan has been organized in the following sections:

- Community Engagement and Jurisdictional Planning Process (Section 2)
- Contributing Data Sets and Assessments (Section 3)
- Situational Analysis (Section 4)
- Calendar Year (CY) 2022–2026 Goals and Objectives (Section 5), organized by the goals of the National HIV/AIDS Strategy and inclusive of the four pillars of the EHE initiative: Diagnose, Treat, Prevent, and Respond.
- 2022–2026 Integrated Planning Implementation, Monitoring and Jurisdictional Follow Up (Section 6)

Plan development was facilitated by The AIDS Institute through multiple meetings with the FCPN. The FCPN became an integrated HIV prevention and care planning body in 2017 and is made up of representatives from HIV prevention, care, all parts of the RWHAP, federally qualified health centers (FQHC), state and local government, academia, service providers, consumers, and advocates as seen in the figure below. The FCPN is made up of three representatives per each of Florida's 14 HIV partnership areas—a prevention representative, patient care representative, and a Department representative (42 seats). In addition, there are five at-large representative seats—proposed and voted upon by FCPN—which represent specific populations and/or areas of practice (e.g., behavioral science). Each of Florida's six RWHAP Part A jurisdictions also have a representative at the FCPN table (six seats).

FIGURE 1: FCPN MEMBERSHIP DIAGRAM



The FCPN typically meets twice per year, in-person (with virtual meeting options for those unable to attend in person) and the FCPN committees (i.e., Membership, Nominations, and Bylaws Committee;

Medication Access Committee; Coordination of Efforts Committee; Needs Assessment Committee; and Executive Co-Chairs Committee) and associated advisory groups (Florida Gay Men’s HIV Workgroup, Community HIV Advisory Group) meet monthly via videoconference.

In 2021, in preparation for developing the IPC Plan, the Department, in collaboration with the FCPN and RWHAP Part A partners, hosted a series of virtual webinars delivered statewide to share information from the Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022–2026, released by CDC and Health Resources and Services Administration (HRSA) in June 2021. The figure below summarizes the key meetings held. Detailed descriptions of each meeting are bulleted after the figure.

FIGURE 2: PLAN DEVELOPMENT MEETINGS



- In January 2022, an integrated HIV planning kick-off meeting was held with Florida’s State Surgeon General, the FCPN Executive Co-Chairs’ Committee, representatives from Florida’s six RWHAP Part A areas (Fort Lauderdale, Miami, Tampa/St. Petersburg, Orlando, West Palm Beach, Jacksonville), The AIDS Institute, and the Department’s Division of Disease Control and Health Protection leadership, and HIV, sexually transmitted disease (STD), and viral hepatitis staff to discuss Florida’s approach to developing the statewide HIV IPC Plan for 2022–2026. There were 31 participants (29 in-person and 2 virtual).
- The first full-body FCPN meeting was held in April 2022 and was an in-person meeting with virtual attendance options. This meeting was used to develop goals, objectives, and strategies that were taken back to local planning bodies for discussion and feedback. There were 150 meeting participants (68 in-person and 82 virtual), representing all 14 HIV partnership areas.
- In August 2022, the FCPN met again as a full body to develop activities for the strategies that aligned with NHAS. This meeting included small-group exercises to ensure everyone around the table and attending virtually could provide input and actively participate in the activity development process. All proposed activities were collected, and a survey was distributed after the meeting to allow all attendees to vote on prioritized activities for inclusion in the IPC Plan.

Additionally, acquired consulting services from ISF, Inc. to assist in stakeholder coordination, research, reporting and writing for the 2022–2026 IPC Plan. ISF performed key stakeholder group interviews in each of Florida’s 14 HIV partnership areas and each group included lead representatives for the Department, RWHAP Part A, Part B, and local community planning group members. There were 165 meeting participants (52 in-person and 113 virtual), representing all 14 HIV partnership areas.

- The FCPN fall 2022 meeting was held in October and used to review the first draft of the IPC Plan, solicit public comment, and input, and conduct a concurrence vote with the full membership of FCPN. There were 149 meeting participants (53 in-person and 96 virtual), representing all 14 HIV partnership areas.

Letters of concurrence were drafted in November 2022 and subsequently signed by the community co-chairs of the FCPN for inclusion into the IPC Plan. The Department also worked to finalize and ultimately submit the IPC Plan in January 2023.

The Department prioritizes a collaborative approach and works directly with the six RWHAP Part A areas. Ongoing coordination efforts include monthly calls with RWHAP Part A and B programs which split responsibilities of running calls (each call hosted by one of Florida’s Ryan White Part A areas); the monthly calls are used to discuss major issues including the IPC Plan.

A data-informed approach was used to develop the IPC Plan, taking into account data and activities from Florida’s approach to HIV prevention and care, including routine HIV screening, rapid access to treatment and care (Test & Treat), epidemiologic data, HIV Care Continuum outcomes, and other data which help identify priority populations and HIV health disparities. The Department’s High-Impact Prevention (HIP) funding opportunity was developed with the HIV status-neutral approach at the forefront, and funds 44 community and faith-based organizations statewide to provide HIV testing and linkage to care, prevention, and essential support services. Florida also maintains more than 1,600 registered HIV test sites statewide. The HIV status-neutral approach to reducing new HIV diagnoses involves initial HIV testing services as the entry point to HIV prevention and/or care services irrespective of a positive or negative test result. The Department has also engaged in HIV stigma reduction efforts, participating in the University of Florida (UF) stigma workgroup, and contracting with UF for the provision of evaluation and planning activities that will be used to develop program interventions addressing the stigmas related to HIV. Information from Florida’s EHE plan was also used to develop content for the updated IPC Plan.

Florida’s RWHAP Part A areas have developed their own local integrated HIV prevention and care plans which, like the state’s plan, align with the NHAS goals and objectives, but contain locally developed activities tailored to each geographic region. Florida’s statewide IPC Plan and the RWHAP Part A IPC Plans will work in concert to advance the goals and objectives of the NHAS and build a pathway to end the HIV epidemic. Links to each of the RWHAP Part A IPC Plans are provided in Table 1.

TABLE 1: RWHAP PART A IPC PLAN LINKS

Grantee	Link
Fort Lauderdale (Broward County)	https://www.broward.org/RyanWhite/Pages/Default.aspx
Jacksonville (Duval County)	https://www.coj.net/rwpc
Miami (Miami-Dade County)	https://www.miamidade.gov/global/service.page?Mduid_service=ser1482944607068715
Orlando (Orange County)	https://www.ocfl.net/familieshealthsocialsvcs/hiv.aspx#.YFyrkj_-h9A
Tampa/Saint Petersburg (Hillsborough and Pinellas counties)	https://www.hillsboroughcounty.org/en/residents/social-services/health-care-plan/ryan-White-program
West Palm Beach (Palm Beach County)	https://discover.pbcgov.org/communityservices/Pages/Ryan-White-CARE.aspx

HIV service regions are broken down into 14 partnership areas, each with an HIV/AIDS Program Coordinator (HAPC) to oversee prevention and care program operations in the area and assure that program activities are planned in an inclusive and collaborative manner to ensure the other local resources and specific client needs are considered and addressed. They work closely with RWHAP recipients, health district resources, other county programs, and academic and university resources as available.

The HIV/AIDS Section also works closely with many organizations to ensure coordination of effort because of the co-morbidities often associated with HIV/AIDS and their impacts on public health. These organizations include STD, TB, and Viral Hepatitis and Outbreak Response Sections; Children’s Medical Services; local community-based organizations (CBOs) and county health departments (CHD); universities; the Florida Department of Corrections; the Department’s state laboratories in Jacksonville and Miami; and the Department’s central pharmacy.

The six RWHAP Part A Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs), and the RWHAP Part C, D, and F programs collectively bring more than \$94.6 million annually to Florida and are key resources in meeting the service needs of PWH in their service area. The RWHAP Part C program directly funds local projects to support service capacity building as well as early intervention services; there are 20 RWHAP Part C programs in Florida. The RWHAP Part D program directly funds a local Tampa project that provides clinical services to women, infants, children and youth (WICY); there are six RWHAP Part D programs in Florida.

The Department HIV Surveillance Program works closely with each local area to provide customized data reports that reflect key information about the epidemic in each area. These data reports are provided to the local CHDs, planning bodies, and each of the RWHAP Part A areas to assist them in preparing grant applications and other reports. Local planning bodies use epidemiologic data, demographic, and service

data, focus groups, resource inventories, and client and provider satisfaction surveys to gauge areas of program strengths and weaknesses.

The Department's HIV Prevention Program collaborates with the Patient Care, ADAP, Medical, and Surveillance programs to deliver comprehensive HIP strategies and services with overarching goals of reducing the number of new HIV transmissions, increasing the proportion of persons living with HIV who know their status, linking PWH to care and support services, and reducing risk behaviors that may lead to HIV and STD diagnoses. Florida's HIP program is multi-faceted and includes HIV testing, linkage to care, peer navigation programs, comprehensive prevention interventions for PWH, partner services, PrEP and post-exposure prophylaxis (PEP), perinatal HIV prevention, corrections initiatives, condom distribution, community outreach (traditional and Internet-based) and engagement, and other services. The Prevention Program also collaborates with the RWHAP Part A programs, FQHCs, CBOs, academia, PWH, and other stakeholders to implement many HIP interventions and strategies. These essential partnerships help to ensure individuals are receiving comprehensive HIV prevention services along the HIV care continuum, leading to improved health outcomes for those living with HIV/AIDS.

Stakeholder engagement occurs on a regular basis through the FCPN and assists the Department in planning patient care and prevention activities. The FCPN is composed of representatives from the Department, all parts of the RWHAP, FQHCs, academia, service providers, CBOs, PWHs, and advocates. The FCPN reviews and gives feedback on projects the HIV/AIDS Section develops, such as the Needs Assessment, the SCSN and statewide IPC Plan, other programs funded with state general revenue, as well as various program standards, and guidelines.

The HIV/AIDS Section routinely communicates with the RWHAP Part A administrators to ensure that they are informed of program activities and have an opportunity to comment and contribute to various projects. Areas of collaboration have been on the transition of RWHAP clients to the Affordable Care Act (ACA) Marketplace® (Marketplace®), work on the Statewide IPC Plan, and development of the ADAP HCV treatment pilot project.

Over the past two years, there have been multiple meetings to plan for a uniform methodology to select insurance plans and move clients to the Marketplace®. Determining eligibility criteria for insurance coverage, planning for the provision of wrap around services, and the potential local coverage of additional clients were main topics of discussion. This project has been very successful; clients, regardless of whether they receive services from RWHAP Part A or Part B ADAP, or are mutual clients, have the same options for insurance selection criteria and process to enroll in the Marketplace® for insurance coverage.

Collaborations, partnerships, and stakeholder engagement exist in many forms throughout Florida; however, opportunities exist to expand partnerships further and engage new and non-traditional partners in more regular communication (for example, Department of Veterans' Affairs and Indian Health Service) to further the objectives and support the strategies of Florida's statewide IPC Plan.

1.2 Documents Submitted to Meet Requirements

In order to meet the submission requirements of the IPC Plan, as outlined in the CDC and HRSA Integrated HIV Prevention and Care Planning Guidance (2021), Table 2 provides descriptions for each document referenced in the IPC Plan. Documents have also been flagged where new material was created specifically for the IPC Plan or where existing material was used. These documents have also been linked in the Appendix, Section 9.5.

TABLE 2: SUPPORTING DOCUMENTATION

Document	Description	Developed for this plan?
CDC and HRSA Integrated HIV Prevention and Care Planning Guidance, 2022–2026	Developed to support the submission of the IPC Plan for each state for the 2022–2026 cycle.	No (Existing)
Florida’s Unified EHE Plan, 2020	Unified plan representing the state and the seven counties identified as Phase 1 EHE jurisdictions: Broward, Duval, Hillsborough, Miami-Dade, Orange, Palm Beach, and Pinellas.	No (Existing)
State of Florida IPC Plan, 2017–2021	Developed collaboratively across Florida stakeholders to eliminate HIV transmission and reduce HIV related deaths for the 2017–2022 cycle.	No (Existing)
Meeting Notes from the August and October FCPN Meetings	The August FCPN meeting was used to identify Florida specific activities to address the Goals, Objectives and Strategies identified by the CDC. The October FCPN meeting was used to review the IPC Plan DRAFT with stakeholders, receive their feedback, and incorporate that feedback into the FINAL version of the IPC Plan.	Yes (New)
Local Area Resource Inventories	Includes recipients’ and community resources for prevention and patient care across 14 partnership areas in the state of Florida.	No (Existing)
Local Area Interview Questionnaires	Interviews were held with all 14 partnership areas and questions were raised to gather feedback in supporting multiple areas of the IPC Plan.	Yes (New)
Local Area Engagement Activities	Provided meeting summaries and feedback from a variety of engagement activities such as local area town halls.	No (Existing)
Documentation of Community Engagement	Describes Florida’s partners and the voices engaged along with engagement efforts at the statewide level and seven major metropolitan areas. Interviews were held with all HIV partnership areas to identify community groups active on local planning councils.	No (Existing)
Florida HIV Continuum of Care Dashboards	Consolidates “Resource Inventories” across the state.	No (Existing)

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Document	Description	Developed for this plan?
Florida’s Ryan White (RW) HIV Care Needs Assessment: Key Findings 2019	Survey to determine met and unmet service needs for PWH in Florida.	No (Existing)
RWHAP Part A Plans	Represents the latest collaborative effort for each Part A partnership area in developing their unique IPC Plan	No (Existing)
PS19-1906 EHE Plan Executive Summary Florida	Key points, including strategic partnerships and planning support, from Florida’s EHE Plan	No (Existing)

2 Community Engagement and Jurisdictional Planning Process

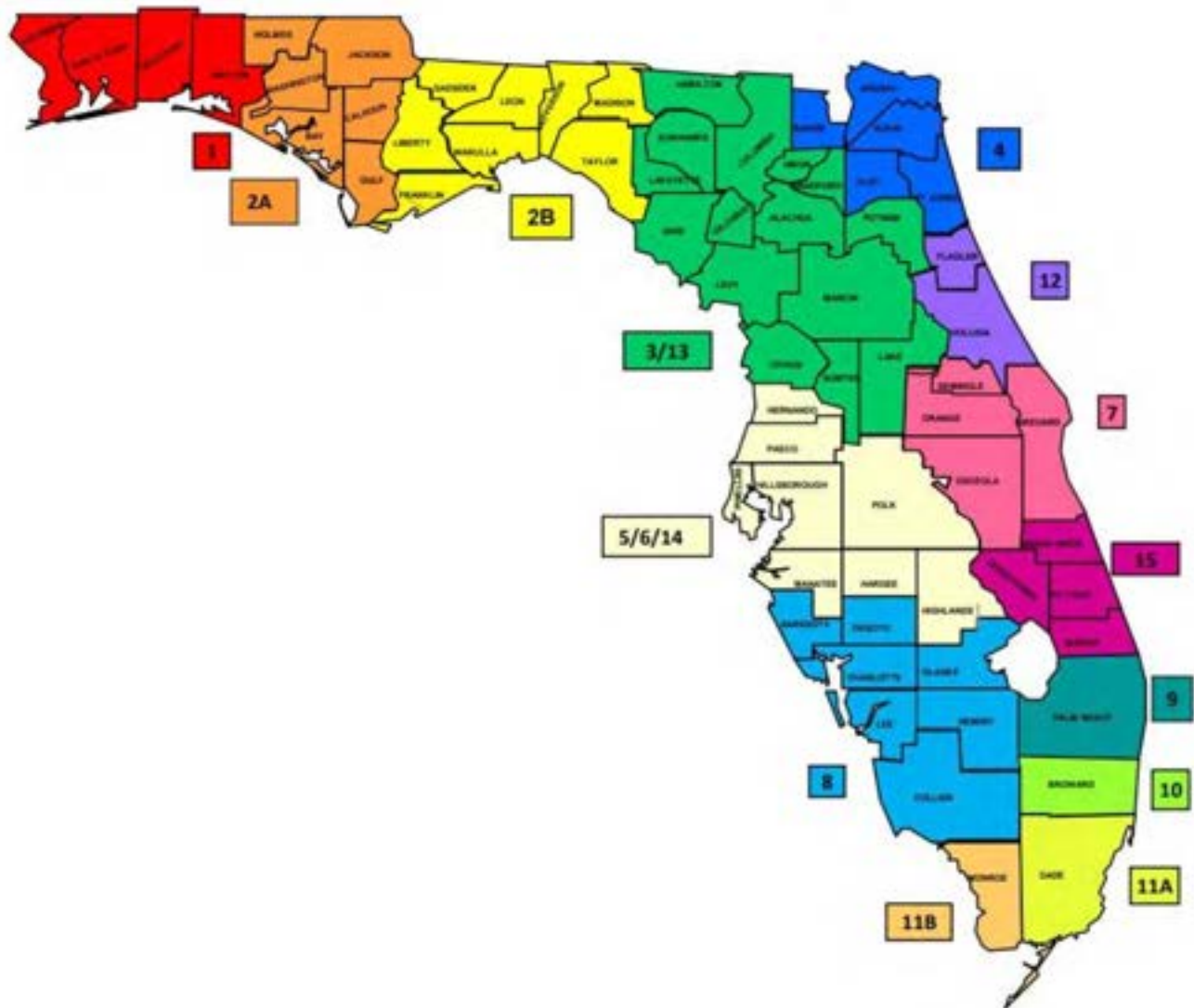
Community engagement is an overarching element of Florida’s 4 Key Component Plan which intersects with the four pillars of the EHE initiative and the NHAS. Community members were engaged in all phases of the planning process and will continue with the implementation of strategies and activities to build a pathway to eliminate HIV transmission in Florida.

During 2021 and 2022, varying degrees of community engagement took place at state and local levels in preparation for developing the IPC Plan. In addition to community engagement activities performed October 2019 through October 2020 for EHE planning and implementation, additional community engagement activities were conducted in each HIV partnership area to ensure stakeholders were included in the integrated HIV planning process.

The HIV Planning Process

Florida’s HIV planning process operates with the principle that determining the best way to support HIV prevention and care needs is through coordinated decision making with local entities, which collectively informs the overall statewide IPC Plan. As such, the Department engaged stakeholders and community members to create an IPC Plan for HIV efforts across the state. The remainder of this section outlines the planning process, inputs into the IPC Plan, analysis performed, priority goals and objectives, and a detailed plan to support successful implementation.

The Department arranges the state into 14 HIV partnership areas (shown in Figure 3), each with an HAPC to oversee prevention and care program operations in each HIV partnership area. HAPCs ensure that program activities are planned in an inclusive and collaborative manner to ensure other local resources and specific client needs are considered and addressed.

FIGURE 3: FLORIDA HIV PARTNERSHIP AREAS

Consortia are community-based regional planning entities established by RWHAP Part B recipients. The consortia plan and prioritize RWHAP Part B funds allocated to their area, promote coordination of services, and serve as a community forum. Representatives of local public and non-profit health and support service providers serve as consortium members. Lead agencies are member agencies in the consortium designated to perform contract administration as a fiscal agent.

Local jurisdictions around the state drive community engagement with the goal to educate and raise awareness about HIV and ensure programs and services are culturally and linguistically appropriate and developed with input from the populations intended to be reached. The local jurisdictions host focus groups, town halls, events for HIV/AIDS observance days, multiple outreach events, media interviews; teach public health classes at local universities; and use their social media presence.

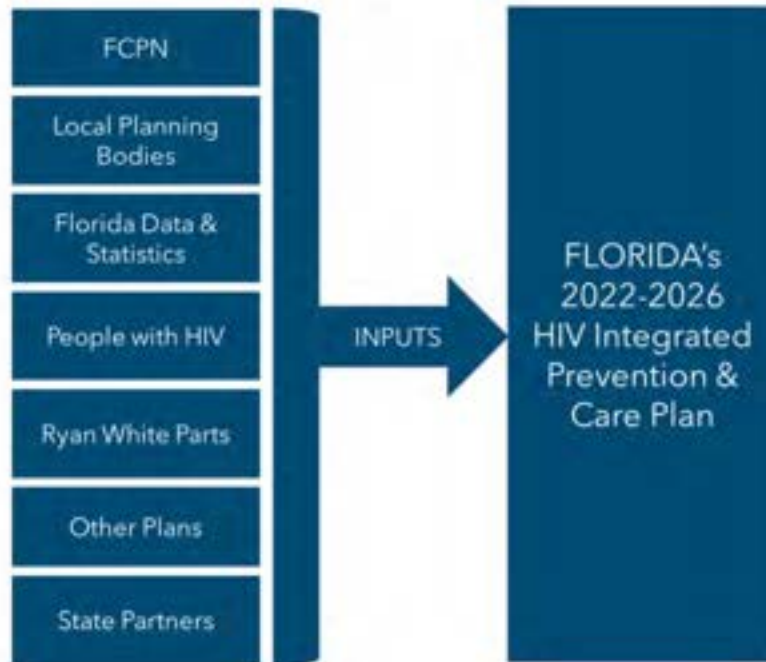
Table 3 provides an example of different groups that participate in the community engagement and planning processes.

TABLE 3: HIV PREVENTION AND CARE PLANNING PARTICIPANTS

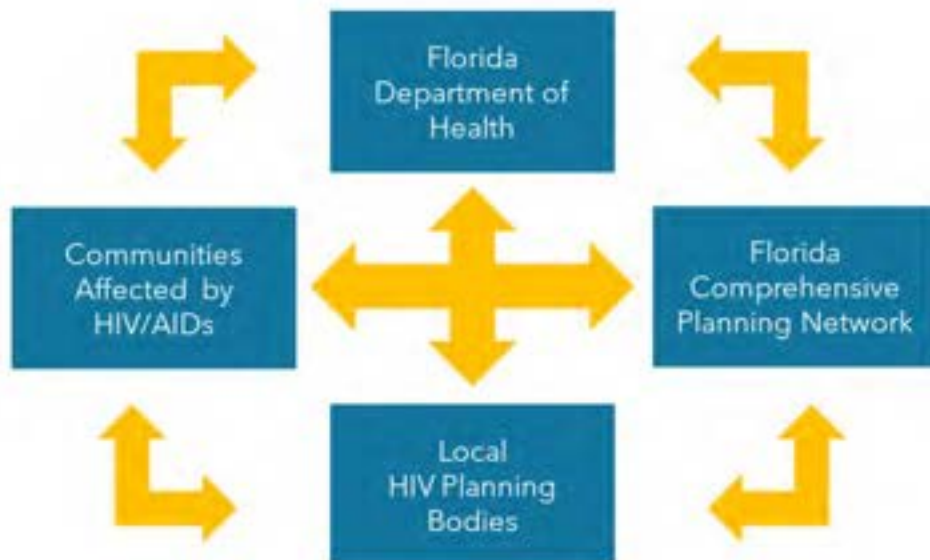
Local Jurisdiction Partnership Groups
• Existing community advisory boards • Community members resulting from new outreach efforts • Community members that represent the demographics of the local epidemic (e.g., race, ethnicity, gender, age, and others.) • Community members unaligned or unaffiliated with agencies currently funded through HRSA and CDC • STD clinics and programs • City, county, tribal, and other state public health department partners • Local, regional clinics, and school-based health care facilities; clinicians; and other medical providers • Behavioral health care agencies • Federally qualified health centers and community health centers • Medicaid/Medicare partners and private payors • Strategic planning and quality management collaboratives • Correctional facilities, juvenile services, local law enforcement and related service providers • Community- and faith-based organizations, including civic and social groups • Professional associations • Local businesses • Local opioid advisory groups • Local academic institutions • Commercial and retail pharmacies • Pharmaceutical and biomedical industry partners • Diagnostic industry partners • Digital media service providers • Adult entertainment industry partners

For a full list of specific community resources by partnership area, please refer to Appendix Section 9.3: Partnership Area Resource Inventories.

Florida's new IPC Plan for 2022–2026 was built upon the foundational goals, strategies and activities from the Florida Statewide Integrated HIV Prevention and Care Plan, 2017–2021; Florida's Unified Ending the HIV Epidemic Plan, 2020; the National HIV/AIDS Strategy; and input from local planning bodies and community members. Figure 4 shows the different inputs used to develop the 2022–2026 IPC Plan.

FIGURE 4: INPUTS TO THE 2022–2026 INTEGRATED HIV PREVENTION AND CARE PLAN

The Department's HIV/AIDS Section works in partnership with Florida's statewide integrated HIV planning body, FCPN. Members of FCPN include PWH and representatives across the state representing patient care and prevention groups, local planning bodies, state and local advisory groups, CBOs, academic institutions, local and regional clinics, city, and county governments, RWHAP programs and recipients, advocacy groups, substance use, mental health and social service providers and behavioral science groups. Figure 5 shows a representation of the community engagement and planning groups involved across the state.

FIGURE 5: COMMUNITY ENGAGEMENT AND PLANNING

In describing how the jurisdiction approached the planning process, the subsequent sections address steps used in the planning process, the groups involved, and representation from the priority populations:

- Entities Involved in the Process (Section 2.1)
- Role of Planning Bodies and Other Advisory Groups (Section 2.2)
- Engagement of People with HIV (Section 2.3)
- Social Determinants of Health (Section 2.4)
- Priorities (Section 2.5)
- Updates to Other Strategic Plans Used to Meet Requirements (Section 2.6)

2.1 Entities Involved in the Process

Florida has a long history of both engaging PWH and the broader community in developing plans for prevention and care services. This has been accomplished primarily through what is now known as the FCPN, which has been in existence since 1993. The available seats for FCPN are made up of three representatives from each of Florida's 14 HIV partnership areas—one representative each for prevention, patient care, and the Department of Health (total of 42 seats). Additionally, there are five at-large representative seats—proposed and voted upon by FCPN—which represent specific populations and/or areas of practice (e.g., behavioral science, substance use). Each of Florida's six RWHAP Part A jurisdictions also has a representative at the FCPN table (6 seats). There is a combined total of 53 representative, at-large, and RWHAP Part A seats available on the FCPN. Currently, 41 of the 53 FCPN representative seats are filled. Members of FCPN include PWH and other individuals across the state representing local partnerships. FCPN members are recruited statewide to represent local or at-large positions from patient care and prevention groups, local planning bodies, community and faith-based organizations, academic institutions, recipients of HIV prevention and care services, local and regional clinics, city, and county governments, RWHAP recipients, advocacy groups, substance use disorder and social service providers and behavioral science groups. The Department, in collaboration with the FCPN Membership, Nominations and Bylaws Committee will develop a plan of action to recruit for the remaining vacant seats.

Of the current FCPN member base—10 members disclosed living with HIV, 28 members disclosed they were not living with HIV, and 3 chose not to disclose their HIV status altogether. Nearly 60% of the current FCPN members are from the ages of 50 to 60+ years of age; followed by 30 to 39 years of age (20%); 40 to 49 years of age (15%); and 20 to 29 years of age (7%). Of the 41 current members, 49% are male, 46% female, and 5% are transgender. Approximately 54% of members reported their sexual orientation as heterosexual; 41% reported as gay, bisexual, and/or lesbian; and 5% chose not to disclose their sexual orientation. Race/ethnicity for members is as follows: White (52%), Black (18%), Hispanic/Latino (20%), Asian/Pacific Islander (6%), multi-racial/other (2%), and American Indian/Alaskan Native (2%).

Prior to 2017, the FCPN was made up of two planning bodies: the Patient Care Planning Group and the Prevention Planning Group. In 2017, the FCPN became fully integrated—merging prevention and care

planning bodies. Membership of the integrated planning body is made up of persons with and those affected by HIV; Department staff; representatives from mental health and substance use organizations; psychologists; social workers; case managers; AIDS service organizations; CBOs; RWHAP Part A, B, C, and D providers; RWHAP Part B lead agencies; advisory groups; and FQHCs. The FCPN maintains a biannual, integrated meeting structure and members are responsible for disseminating information from the meetings back to their respective areas of representation, as well as bringing concerns from those same areas to such meetings, ensuring that the voice of PWH in Florida are part of the integrated planning process. The HIV/AIDS Section oversees the composition of these groups, ensuring that they are representative of Florida's HIV epidemic in the various geographic regions, using the principle of Parity, Inclusion and Representation.

The Department routinely communicates and coordinates with other state partners such as The AIDS Institute; health planning councils; Medicaid/Medicare; Agency for Health Care Administration; Department of Corrections (FDC); Department of Children and Families (DCF); Department programs such as the STD, Viral Hepatitis, and TB programs and other state partners; and the Florida HIV/AIDS Advocacy Network (FHAAN). The AIDS Institute is a national nonprofit organization that promotes a full spectrum of HIV activities including prevention, care, and treatment, through public policy, research, advocacy, and education. Medicaid, FDC, DCF, and the STD, Viral Hepatitis, and TB programs are all state programs that impact and serve PWH. Medicaid is the single largest funder of HIV care in Florida. The HIV/AIDS Section contracts with FDC for pre-release planning services that link discharged inmates with HIV services upon release. DCF oversees mental health services and several housing and homeless programs. The STD Section is a key partner to the HIV Prevention Program, with Disease Intervention Specialists (DIS) providing partner services and following up with newly diagnosed individuals. FHAAN is a statewide effort comprising of PWHs, community advocates, HIV/AIDS and industry professionals, and anyone wanting to be involved to coordinate HIV advocacy efforts.

Collaborations, partnerships, and stakeholder engagement exist in many forms throughout Florida; however, opportunities exist to expand partnerships further and engage new and non-traditional partners in more regular communication (for example, federal Department of Veterans' Affairs and Indian Health Service) to further the objectives and support the strategies of Florida's statewide IPC Plan.

2.2 Role of Planning Bodies and Other Advisory Groups

The Department's HIV/AIDS Section receives advisement on HIV programs and services from various community partners and workgroups, some of which report out directly to the FCPN. These various groups consist of both members of the community, as well as PWH. These groups consist of the Florida Gay Men's HIV Workgroup, the HIV Section Medication Formulary Workgroup, and the Community HIV Advisory Group. Other groups operating in the state but not directly under the FCPN include the Florida Harm Reduction Collective, the Florida Black Leaders Group, and the Florida HIV Justice Coalition. The Department will develop a plan to ensure these groups have a representative at the FCPN table.

For the workgroups that report directly to the FCPN—the Florida Gay Men’s HIV Workgroup, the HIV Section Medication Formulary Workgroup, and the Community HIV Advisory Group—each group consists of PWH who use HIV services and community members selected through an application process and reflective of the profile of the HIV/AIDS epidemic in Florida. Members are appointed for a period of two years and may reapply for subsequent terms. These groups exist to provide a mechanism in which PWH and the community have meaningful input into the development of policies and programs to address their needs with and under the auspices of the Department and the HIV/AIDS Section.

Local Area Interview Results

To better understand the process of community engagement at the local level, interviews were held with each HIV partnership area, with a total of 72 participants. Participants included local Department staff, RWHAP Part A and B representatives, lead agencies, and other community planning body members. During each interview, participants were asked to report on membership, community engagement, outreach activities and keys to success.

Membership: Membership in area partnerships is consistent with all 14 partnership areas having county health departments and CBOs serving populations affected by HIV, as well as HIV service providers. Thirteen out of 14 areas include populations at risk for or with HIV representing priority populations, STD clinics and programs, and HIV clinical care providers and clinicians as part of their voting membership. Only 3 out of 14 partnership areas have epidemiologists and only 4 have representatives from state or local law enforcement or correctional facilities among voting members.

When asked about entities or organizations they would like to have in their planning body, but have not yet been able to secure, areas reported: pharmacists, a school system representative, local school-based clinics, elected officials, representatives from youth organizations, colleges and universities, health promotion groups, an epidemiologist, transportation agencies; faith-based organizations, the Association of Free and Charitable Clinics, and more staff to coordinate the planning body.

Community Engagement: All partnership areas report robust, comprehensive community engagement in each of their counties. All but one area reports challenges with maintaining representation from PWH receiving HIV care services (e.g., RWHAP Part A or B services). Most local areas report having PWH represent approximately 33% of their voting membership; however, these individuals may be staff at local community- and faith-based organizations or on local boards and not necessarily receiving HIV care services through the RWHAP. Several strategies have been used to try and encourage “everyday PWH” to become part of the local planning bodies. Many areas offer incentives and others send out mailers to PWH emphasizing the opportunity to have their voice heard and help the greater good. Other members that areas have difficulty recruiting and keeping are elected officials, faith-based leaders, hospital and health care planning agencies, and law enforcement.

One area restructured planning body meetings from formal events to more informal meetings using lay language and fewer acronyms. They reported that building planning activities around less structure

creates more freedom to speak. Additionally, the planning body keeps meetings to no longer than two hours, food is provided, and agenda items are suggested by members, so they drive future meetings.

To incorporate the perspective of PWH, almost every area sends surveys to clients about services they received and how satisfied they were with those services. This information is used to determine whether some services need to be enhanced, reworked, or streamlined. It is also used for gap analysis purposes and to determine future funding.

About half of the areas report a working relationship with local prisons and jails but felt more could be done to increase testing and treatment efforts. Areas overwhelmingly found value in monthly calls hosted by the Department's HIV/AIDS Section and saw them as a chance to exchange best practices.

Outreach Activities: Partnership areas report hosting focus groups and town hall meetings. Twelve areas held topic-focused community discussions and collaboration building meetings with new partners. Areas also rely on social media to reach PWH engaged in services; however, three areas report that different local restrictions present challenges. Some examples of outreach activities include harm-reduction events, annual surveys to RWHAP recipients, surveys to funded providers, local street fairs and block parties, and events planned around World AIDS Day and other key HIV observance days.

Keys to Success: Partnership areas identified several different ways they have built successful programs:

- Ability to work together to make service delivery appear seamless to clients, regardless of what organization was providing the service.
- Longevity in leadership positions and the sharing of funds between services.
- Consulting with adjacent partnership areas and assisting when possible.
- Having a continuous calendar of events and meetings.
- Participation in statewide calls.
- Collaboration and cohesiveness among partners.
- Cultivating a culture of trust and transparency.

Department Collaboration with RWHAP Parts

RWHAP Parts A, B, C, and D and ADAP programs are key local partners and are at the table as planning activities are performed since no single RWHAP part can meet the needs for all services. The RWHAP Part F program collectively funds Special Projects of National Significance (SPNS), as well as the AIDS Education and Training Centers (AETC) that provides support and training to the medical community in treating patients, and dental programs for PWH.

The planning process is guided by local resource inventories, demographics, satisfaction surveys and service needs expressed locally by PWH who use services. Given the multitude of RWHAP parts, as well as programs funded by other federal, state, and local sources, funding allocation necessitates collaboration and coordination at the local planning body level. Therefore, consortia and planning councils require coordination in RWHAP planning, which involves consideration of other programs in

such areas as assessment of needs, priority setting and resource allocation. Planning bodies must analyze existing resources, regardless of funding stream, to identify areas of unmet need. Likewise, in setting priorities, other resources must be considered in terms of how they help meet service demands so that RWHAP resources can be used to fill gaps.

The Department's HIV/AIDS Section routinely communicates with the RWHAP Part A administrators to ensure they are informed of program activities and have an opportunity to comment and contribute to various projects. Regular monthly calls are used to communicate program updates and policy changes, opportunities for collaboration, and solicitation of feedback. The hosting of the calls rotates, with one of the six RWHAP Part A areas leading the call each month. Examples of collaboration include the transition of RWHAP clients to the Marketplace®, work on the statewide IPC Plan, developing the ADAP HCV treatment project, developing reciprocal eligibility and Notice of Eligibility, data sharing, coordination with ADAP related to the changes in the pharmacy benefits manager, and ADAP formulary updates.

The Department's HIV/AIDS Section allocates RWHAP Part B funding for administration, planning and evaluation, clinical quality management and core medical and support services to 14 lead agencies annually to perform planning activities in their respective areas. Upon receiving RWHAP Part B funds from the Department, each lead agency is required to provide administrative assistance to the planning body (consortium) in the program area. The planning bodies serve as the entities that meet the RWHAP planning requirements for the program area and advise the lead agencies during the priority setting and resource allocation process. Lead agencies facilitate a provider selection process (internal services, external vendors, or competitive procurement process) through a network of local partners (CBOs, CHDs, consumers, planning bodies, and others).

There has also been collaboration with RWHAP Part A partners through EHE initiatives, as RWHAP Part A partners receive EHE funding directly from HRSA to address pillars 2 and 4 (Treat and Respond). The Department receives EHE funding directly from CDC and distributes the funds to the seven EHE counties (county health departments and community and faith-based organizations). Throughout the EHE planning and implementation process (2019 to present), it has been imperative that the Department and RWHAP partners coordinate to maximize efforts, promote information sharing, and ensure resources are used efficiently.

As the recipient of RWHAP Part B funds, the Department is required to develop and maintain a clinical quality management (CQM) program to ensure quality health care services are provided to persons living with HIV. The purpose of the HIV/AIDS Patient Care CQM Program is to provide a systematic approach for planning, measuring, implementing, evaluating, and improving the quality of RWHAP-funded care services delivered to PWH in Florida. Routine review of established performance measures leads to the identification of specific CQM goals for each quality improvement project. Stakeholders who are internal and external to the CQM committee review measures through formally established mechanisms using evidence-based quality improvement methods. This CQM requirement is also mandated by HRSA for each sub-recipient, at the local level. This includes having a formal quality committee and a local CQM plan. For 2019–2022, the following CQM goals were identified:

- **Percentage of Patients on ART (Antiretroviral Therapy)**—Ensure equitable access to RWHAP-funded HIV services in the state for PWH and ensure equitable results in HIV health outcomes; patients receiving ambulatory outpatient care are also on ART.
- **Improving Viral Suppression for PWH**—Drive maximum viral suppression for PWH in the state, with 90% of PWH achieving viral suppression by 2022.
- **Eligibility**—Ensure PWH in the state have complete eligibility documentation for all services received. Complete eligibility documentation prevents gaps in care and can help identify additional services for which the client has need. The goal is 90% of all clients having accurately completed eligibility documentation by 2022.

2.3 Engagement of People with HIV

Florida strives to actively involve key partners, stakeholders, and PWH and, in doing so, incorporates feedback received, for the IPC Plan, on an ongoing basis. The jurisdiction understands that to best serve those most marginalized, their voices must be involved in all aspects of the process. “Nothing about us, without us” is a call to action that informs the need for cultural shifts in programming, provisions of services, and community engagement. Changes have already been made to the planning process with a greater focus placed on creating an environment that is more welcoming to prospective members who represent communities most affected by HIV.

PWH were influential in the development of the statewide IPC Plan. PWH contributed by participating in the Statewide Needs Assessment and serving on local RWHAP Part B consortia, local prevention planning bodies, RWHAP Part A planning councils as well as RWHAP Parts C and D consumer advisory boards. There are also many robust peer-driven navigation and prevention programs that contribute greatly to PWH involvement on many different levels. They have helped identify what is working well (or not), barriers to care, and in accessing prevention and patient care services, and helping to develop the state’s unmet need matrix.

Further, PWH have participated widely in providing feedback to the Department by attending various town hall meetings that have helped develop goals and improve service delivery around eligibility, medical case management guidelines, HIP, PrEP, post-exposure prophylaxis (PEP), ADAP and many of the other programs overseen by the state. They have also played a key role in the success of the medical monitoring project (MMP) in Florida by willingly volunteering their time to be interviewed for this significant program. Florida has a very active Community HIV Advisory Group (CHAG) which also serves as the MMP’s Community Advisory Board. Proposed changes in policy are reviewed and feedback is provided by this group of dedicated individuals. Table 4 shows some of the community engagement and planning efforts across the state.

TABLE 4: COMMUNITY ENGAGEMENT EFFORTS

Location	Involvement
Statewide	Community engagement activities including: five ad-hoc consultations with representatives from priority populations (30+ participants per session) and launched Florida’s Undetectable=Untransmittable (U=U) campaign. The Department’s HIV/AIDS Section hosted virtual meetings (180+ reached) for FCPN and community guests to refine the elements of the unified EHE plan from a statewide perspective.
Area 1 Counties: Escambia, Santa Rosa, Okaloosa, Walton	Community engagement activities were conducted, including the implementation of a U=U campaign, launched with a press conference inviting local civic leaders and community partners. A meeting was also held with the superintendent of schools and a school board member to provide information on local HIV data.
Area 2A Counties: Bay, Calhoun, Gulf, Holmes, Jackson, Washington	Partnered with BASIC NWFL for HIV and HCV testing and condom distribution. PanCare of Florida (FQHC) conducted mobile HIV testing.
Area 2B Counties: Franklin, Gadsden, Jefferson, Leon, Liberty Madison, Taylor, Wakulla	Partnered with 4 community resources for the provision of ART, 3 community resources for HIV testing and diagnosis, 1 partner for HIV education/community outreach, town hall meeting (10 clients attended), and mailed 14 surveys
Area 3/13 Counties: Alachua, Citrus, Lake, Marion, Putnam, Hamilton, Suwannee, Columbia, Lafayette, Gilchrist, Dixie, Levy, Bradford, Sumter	Conducted a town hall meeting in Area 3/13 and results were shared at the April 2022 FCPN meeting. Draft goals and objectives were sent out to the local consortium via email for review and then discussed at the June 2022 consortia meeting.
Area 4 Counties: Nassau, Baker Duval, Clay, St Johns	Community engagement activities such as: 2 provider meetings and town halls, the creation of a local EHE committee, provider survey (68 reached), community-wide listening sessions (115+ reached), faith-based workshops to address stigma and the social justice aspect of the HIV epidemic, and exclusive focus groups (50+ reached) with priority populations.
Area 5/6/14 Counties: Hernando, Pasco, Pinellas, Hillsborough, Manatee, Polk, Hardee, Highlands	Community engagement activities such as: an online community survey (72 reached), focus groups (8 reached) with youth, community members, and private sector leaders; individual phone interviews (39 reached); virtual town hall meetings per pillar (34 across all meetings); and an HIV care needs survey (600+ reached). Additional activities included: focus groups facilitated by representatives of key priority populations (55 reached across all sessions); a virtual interview with local radio station to engage the community (1,000+ reached); virtual EHE Advisory Council meetings to engage new and existing stakeholders; Teen Talk Thursdays, monthly webinars facilitated by representatives revered by youth (50+ reached per meeting) and listening sessions with HIV service providers (45 reached).

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Area 7 Counties: Seminole, Orange, Osceola, Brevard	Community engagement activities such as: conducted 3 town hall meetings; key informant interviews (27 reached); EHE and HIV stigma conversations on Facebook Live with iHeart Media; 8 virtual town hall meetings with key priority populations (98 individuals participated across all town halls, viewed by 3,356 individuals on Facebook Live); quarterly provider meetings to discuss EHE plans and implementation; 8 pop-up HIV testing events; listening sessions with HIV service providers; and community-wide surveys (300+ reached)—one tailored to the community members and the other tailored to providers.
Area 8 Counties: Sarasota, Desoto, Charlotte, Glades, Lee, Hendry, Collier	Community engagement activities were conducted throughout the area, including health education and outreach, community forums and meetings, and testing events.
Area 9 County: Palm Beach	Community engagement activities such as: service provider interviews (19 reached); focus groups with PWH (10 reached); and Palm Beach resident phone interviews in English, Haitian-Creole, and Spanish (253 reached).
Area 10 County: Broward	Community engagement activities such as: 28 community presentations; community-wide listening session; listening session with youth (9 reached); outreach sessions with college students (40+ reached); 5 focus groups with providers, transgender individuals, men who have sex with men (MSM), Black heterosexual women, and Latino individuals; student survey (130 reached); 40 key informant interviews with community members and service providers; and needs-based surveys for providers (430 reached) and community members (1,780 reached) in multiple languages.
Area 11A County: Miami-Dade	Community engagement activities including: several listening sessions at different venues; met with workgroups; and focus groups outside the RWHAP or the Miami-Dade CHD. Additional activities included: key informant interviews with local CBOs and local government (23 reached); 2 needs-based surveys tailored to HIV service providers (37 reached) and community members (1,158 reached) in multiple languages; online community forums and focus groups representing priority populations (250+ reached); 11 community listening sessions with community mobilization groups that primarily serve Black and Latino populations. Mobilization also occurred among transgender individuals.
Area 11B County: Monroe	Engagement activities including quality management patient surveys in ADAP, customer satisfaction surveys in RWHAP Part B, focus group activities in the Client Advisory Board, multiple discussions in the Florida Keys Community Planning Partnership, and monthly Teams meetings, in which all prevention providers meet to discuss awareness day activities, nationally recognized testing day activities and ongoing local prevention activities (e.g.,

	testing sites, outreach activities and involvement and partnership with the Gay Men's Health Summit and Miami-Dade County).
Area 12 Counties: Volusia, Flagler	Various community engagement activities were conducted throughout the area and included numerous health fairs and HIV observance day events (e.g., health fairs at Bethune Cookman University, Stetson University and Daytona Beach College; HIV Testing Day; World AIDS Day; New Smyrna Beach Senior Summit; One Voice Volusia Health Summit; and HOPE Fest Community Outreach with Hope Church).
Area 15 Counties: Indian River, Okeechobee, St. Lucie, Martin	Conducted focus groups with PWH (25 reached); facilitated HIV needs assessment survey (175 reached); partnered with United Against Poverty St. Lucie County for HIV and sexually transmitted infection (STI) screenings and condom distribution (20+ reached); facilitated an HIV/AIDS symposium where attendees were community members, PWH, and service providers (100 reached); participated in Annual Showcase of Services community event and provided resource information to local social service agencies and community members (70 reached); conducted HIV and STI screening at local substance use disorder treatment centers (20 reached); participated in community health resource fair and provided HIV and STI screenings as well as condom distribution (100+ reached); hosted National Latino AIDS Awareness Day testing event (6 reached); and facilitated weekly HIV and STI testing and awareness events in 4 area counties (number reached varied), where all events were conducted in multiple languages.

2.4 Social Determinants of Health

To reduce new HIV diagnoses in Florida, it is critical to ensure that everyone with HIV is aware of their status, is linked to and retained in HIV medical care, and maintains viral suppression. Collaborative efforts from prevention and patient care programs at the state and local levels, including by CHDs, RWHAP partners, CBOs, and health care providers are an integral part of ending the HIV epidemic in Florida. There must also be a focus on the social determinants of health that preclude people from engaging in prevention activities, seeking treatment, and acquiring an adequate level of health literacy. Lower health literacy has been tied to poorer health outcomes in PWH; therefore, ensuring basic levels of health literacy is essential to ensure medication and treatment adherence and ultimately, viral suppression. Social determinants of health (as shown in Figure 6) include food and housing insecurity, geographic location, educational status, poverty, racism, violence, and stigma.

FIGURE 6: DEMOGRAPHIC HIV STATISTICS

In the past decade, Florida has seen a general decline in HIV diagnoses in Florida; however, Black and Hispanic/Latino populations are disproportionately impacted with higher rates of new diagnoses compared to the White population. Additionally, late-stage HIV or AIDS is also higher in the Black population. For males diagnosed with HIV in 2021, Black males were 6 times more likely to be diagnosed with HIV compared to the White males; additionally, Hispanic/Latino males were 4 times more likely to be diagnosed with HIV compared to White males. Similar trends are observed for females, where Black and Hispanic females were 12 and 3 times, respectively, more likely to be diagnosed with HIV compared to White females.

With respect to mode of transmission, in 2021, the majority (61%) of new HIV diagnoses were a result of male-to-male sexual contact (MMSC), followed by 31% who were persons who had heterosexual contact, and 4% who were persons who inject drugs (PWID). Through the identification of priority populations disproportionately impacted by HIV, Florida will continue to engage with and seek input from members of those communities to address health disparities and social determinants of health.

Florida's incorporation of the status-neutral approach and Undetectable=Untransmittable (U=U) into HIV prevention and care service delivery is a key component in addressing social determinants of health and stigma that may prevent individuals from engaging in HIV care services. In June 2020, the Department announced its endorsement of the Prevention Access Campaign's U=U. In becoming a U=U partner, the Department joined nearly 1,000 organizations around the world supporting the science-backed message that PWH who use antiretroviral therapy and have an undetectable viral load in their blood have effectively no risk of sexually transmitting HIV.

Florida will work to ensure programs and services for PWH and those at increased risk for acquiring HIV align with the National Culturally and Linguistically Appropriate Services (CLAS) Standards

(<https://thinkculturalhealth.hhs.gov/Assets/Pdfs/EnhancedNationalCLASStandards.Pdf>), which provide a structure to implement culturally and linguistically appropriate services, and increase the ability of the state to address health care disparities.

2.5 Priorities

The IPC Plan priorities are based on the four goals of the NHAS, 2022–2025:

1. Prevent new HIV infections.
2. Improve HIV-related health outcomes for people with HIV.
3. Reduce HIV-related disparities and promote diverse community wellness.
4. Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and stakeholders.

For the complete list of unique activities to support each strategy, please refer to Appendix Section 9.1 Strategy and Activity Table.

Additionally, the RWHAP Part A's local priorities align with the NHAS, and the four pillars outlined in the EHE: diagnose, treat, prevent, and respond. All goals and objectives include various local initiatives with some overlap between several CDC and HRSA grants.

Based on the most recent HIV data trends for the state (2017–2021) and feedback from community engagement activities conducted in preparation for the IPC development, Florida's integrated HIV prevention and care planning body (FCPN), along with the RWHAP Part A partners, has determined to focus on PWH, Black and Latino populations, LGBTQ communities, PWID, and youth populations.

The planned outcomes of the IPC include reducing HIV-related disparities and promoting diverse community wellness by expanding targeted efforts to prevent HIV transmission using innovative and evidence-based approaches, decreasing the annual HIV diagnosis rate, ensuring early linkage to care, and increasing the number of PWH who are retained in care and virally suppressed. Progress on these outcomes will be ongoing throughout the project period and will benefit the overall community by improving population-level health and reducing the incidence of HIV/AIDS.

While setting goals and priorities, *Demanding Better: An HIV Federal Policy Agenda by People Living with HIV* (<https://www.pwn-usa.org/wp-content/uploads/2021/07/Networks-Policy-Agenda-FINAL.pdf>) was referenced to ensure the Meaningful Involvement of People with HIV/AIDS (MIPA) in decision-making, at every level of the response. In *Demanding Better*, the U.S. People Living with HIV Caucus outlines five recommendations which must be included in every aspect of the federal HIV response:

1. Concretely elevating the meaningful involvement of people living with HIV and disproportionately impacted communities in the HIV response.
2. Proactively creating an affirming human rights environment for people living with HIV.

3. Addressing inequities in the federal response by attending to racial and gender disparities.
4. Adding sex workers and immigrants living with HIV as priority populations.
5. Affirmatively committing to improving quality of life for people living with HIV.

MIPA requires dedication, planning and assessment, organizational buy-in, and a champion to help usher its development and continued assessment. Although the U.S. Department of Health and Human Services (HHS) *National Strategic Plan: A Roadmap to End the Epidemic for the United States, 2021–2025* (<https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>) largely did not address these recommendations in the final version, Florida’s statewide IPC Plan will do so to the greatest extent possible, as they were created by and for people living with HIV.

2.6 Updates to Other Strategic Plans Used to Meet Requirements

Local jurisdictions perform an annual needs assessment, based on core questions developed through the FCPN Needs Assessment Committee. The needs assessments are created using multiple sources of information from PWH and other stakeholders. Interviews are conducted with PWH and stakeholders to incorporate their feedback and needs. Additionally, surveys are sent out to clients and focus groups are held with the community to understand any changing of needs and priorities. Ongoing feedback of PWH and stakeholders is accomplished by broadly advertising public meetings, allowing public access to all draft, and completed reference documents through online postings, and encouraging participation by members and guests at all meetings. Following completion, the IPC Plan will be presented to the groups who contributed to ensure ongoing community engagement. With greater representation comes additional perspectives that are pivotal to evaluating and improving all planning processes, including the IPC Plan.

Florida’s new IPC Plan for 2022–2026 was built upon the foundational goals, strategies, and activities from the Florida Statewide Integrated HIV Prevention and Care Plan, 2017–2021, Florida’s Unified Ending the HIV Epidemic Plan, 2020, the National HIV/AIDS Strategy, and input from local planning bodies and community members.

3 Contributing Data Sets and Assessments

In analyzing contributing data sets and assessments used to describe how HIV impacts the jurisdiction, the subsequent sections will detail HIV prevention services, barriers to accessing those services, and gaps in the service delivery system:

- Epidemiological Snapshot (Section 3.1)
- Data Sharing and Use (Section 3.2)
- HIV Prevention, Care and Treatment Resource Inventory (Section 3.3)
- Gaps, Needs and Barriers (Section 3.4)
- Needs Assessment including Methodology, Approach, Priorities, and Actions Taken (Section 3.5)

3.1 Epidemiologic Snapshot

The full Epidemiological Profile of HIV in Florida, 2017-2021 will be provided separately. Below is a brief snapshot of the key points.

According to the CDC, in 2020,⁴² Florida had the third highest number of HIV diagnoses and was the third highest for new HIV diagnosis rates per 100,000 population in the U.S., including the District of Columbia. In 2021, 4,708 persons received an HIV diagnosis in Florida, a 37% increase from the 3,441 HIV diagnoses in 2020; however, these data should be interpreted with caution due to impacts from the COVID-19 pandemic which impacted testing, access to care and surveillance activities. In 2021, 83% of those newly diagnosed were linked to HIV-related care in 30 days of diagnosis. There were 120,502 PWH, regardless of AIDS status, living in Florida through 2021 which represents only 86% of all the PWH in Florida. The remainder of whom are living with the disease but are unaware of their HIV status. Among the PWH, 73% were retained in care and 69% had a suppressed viral load at the end of the year. Twenty percent (20%) of PWH had no care in 2021.

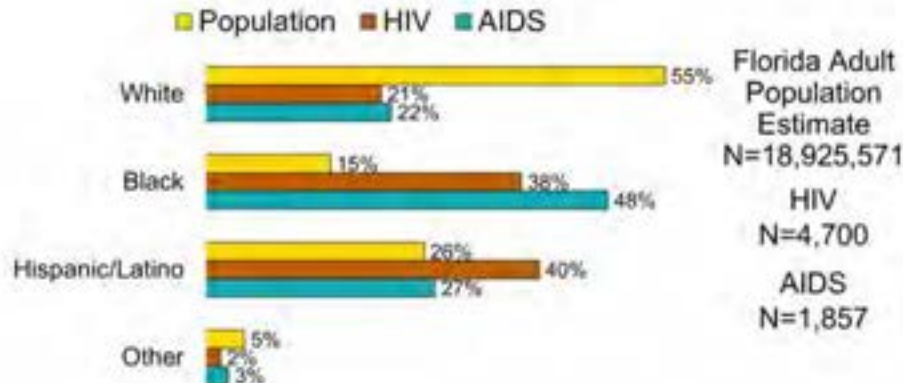
Geographical Region and Socio-Demographic Characteristics of Florida

Florida is a southern state that spans a geographic region of 53,624 square miles, comprises 67 counties and 283 cities, and has a mix of urban, suburban, and rural areas. The 2021 population in Florida was 22.0 million residents, with an average of 410 residents per square mile. Approximately 20% of the population is under the age of 18 and 21% is over the age of 65. According to the U.S. Census Bureau, in 2020, 12.4% of Floridians were living in poverty and 16% of Floridians under the age of 65 were without health insurance. The population of Florida is very diverse, with approximately 20.8% of persons residing in the state being foreign born (born outside the continental U.S.). Although most new HIV diagnoses in 2021 were among those born in the U.S. (58.1%), 41.9% of people newly diagnosed with HIV in Florida were born outside the U.S. mainland.

The racial distribution among the adult population (age 13 and above) in Florida in 2021, was 55% White, 15% Black, 26% Hispanic/Latino, and 5% other races including American Indian, Asian, or

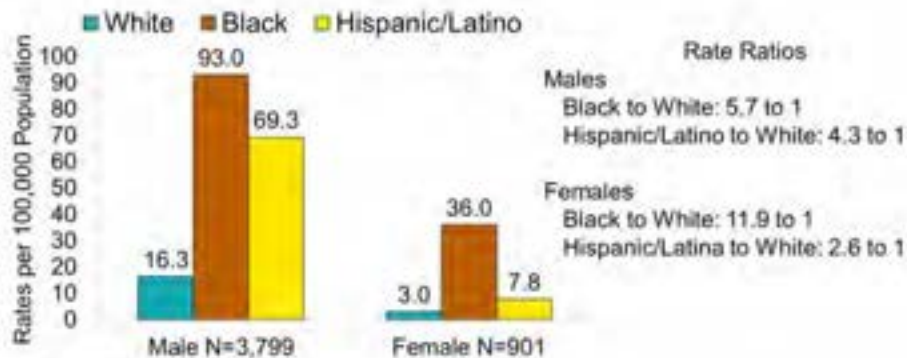
multiracial. There were 4,708 HIV diagnoses among adults in 2021. The greatest burden was among the Black population, which received 38% of the new HIV diagnoses in 2021 despite only representing 15% of the adult population in Florida. Hispanic/Latino people were also disproportionately represented for new HIV diagnoses, with 40% of the new HIV diagnoses, compared to 21% among White people as shown in Figure 7.

FIGURE 7: ADULT (AGE 13+) HIV AND AIDS DIAGNOSES AND POPULATION BY RACE/ETHNICITY, 2021, FLORIDA



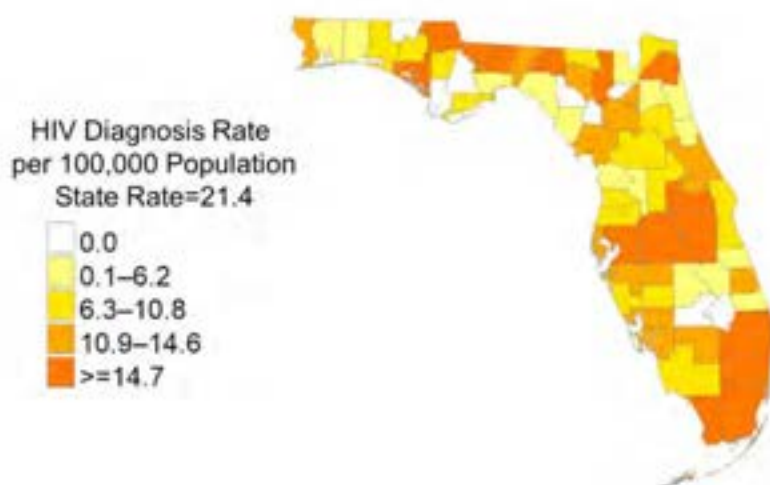
In 2021, Florida continued to see disparities in HIV diagnoses among adults, despite an annual decrease in the HIV diagnosis rate among Black persons in the past five years. The HIV diagnosis rate per 100,000 population among Black males (93.0) was nearly six times higher than for White males (16.3) and the rate for Hispanic/Latino males (69.3) was more than four times higher than for White males. The HIV diagnosis rate among Black females (36.0) was 12 times higher than for White females (3.0); the rate for Hispanic/Latina females (7.8) was more than two times higher than for White females (see Figure 8). Black persons had a lower statewide viral suppression (<200 copies/mL) rate of 64% compared to 77% for White persons and 71% for Hispanic/Latino persons.

FIGURE 8: ADULT (AGE 13+) HIV DIAGNOSIS RATES BY SEX AND RACE/ETHNICITY, 2021, FLORIDA



In 2021, there was at least one HIV diagnosis in all but 7 counties in Florida and the state HIV diagnosis rate was 21.4 per 100,000 population (see Figure 9). Miami-Dade (42.1), Broward (33.5), Orange (30.3), Duval (30.2), and Palm Beach (21.7) counties had rates higher than that for the state in 2021. The greatest numbers of HIV diagnoses were from the seven counties identified in the national EHE initiative: Miami-Dade (N=1,204), Broward (N=652), Orange (N=439), Hillsborough (N=323), Duval (N=300), Palm Beach (N=322) and Pinellas (N=130). These seven counties diagnosed a combined total of 3,370 cases in 2021, or 72% of the statewide total.

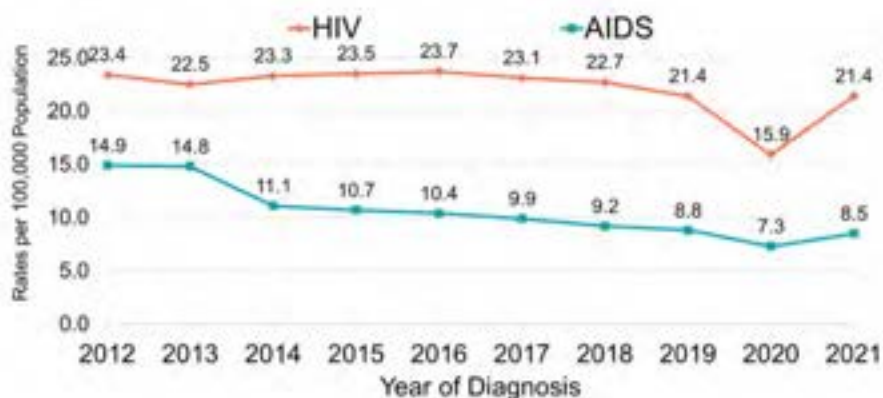
FIGURE 9: HIV DIAGNOSIS RATE BY COUNTY IN 2021, FLORIDA



Trends in HIV Diagnosis

Data for 2020 and 2021 should be interpreted with caution due to the impact of COVID-19 on HIV testing, care-related services, and case surveillance activities in state and local jurisdictions. Figure 10 shows that over the past 10 years (2012–2021), the rates of diagnosed HIV and AIDS in Florida have decreased 9% and 43%, respectively.

FIGURE 10: TEN-YEAR TREND (2012–2021) OF HIV AND AIDS RATES PER 100,000 POPULATION IN FLORIDA



The number of HIV diagnoses decreased by 4% from 2018 to 2019 and increased by 3% from 4,556 (2019) to 4,708 (2021). Additionally, the number of new HIV diagnoses increased by 6% among adult men and decreased by 6% among adult women from 2019 to 2021. The number of new HIV diagnoses over the past 5 years (2017–2021) decreased among all but two age groups: persons aged 30 to 39 (15% increase) and persons aged 40 to 49 (2% increase). The number of new HIV diagnoses over the past five years decreased among all race/ethnicity groups except Hispanic/Latino persons, where a 25% increase was observed.

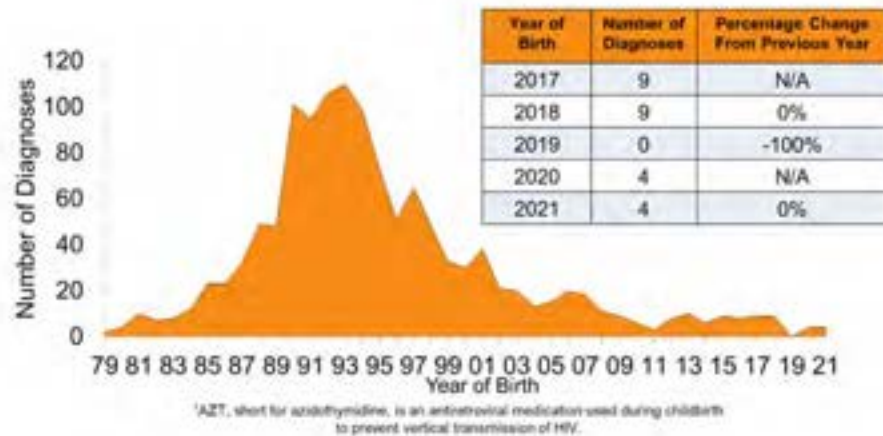
With respect to mode of exposure, male-to-male sexual contact continues to be the primary mode of exposure for HIV among males (77% in 2021), followed by heterosexual contact (18%) and injection drug use (IDU) (3%). Over the past five years (2017–2021), transmissions among males that observed an increase in HIV diagnoses were MMSC (1%) and IDU (28%), whereas transmissions that decreased were MMSC/IDU (12%) and heterosexual contact (1%).

Among females, heterosexual contact is the primary mode of exposure for HIV (92% in 2021), followed by IDU (8%). Over the past five years (2017–2021), decreases in HIV diagnoses among females were observed among both transmissions: heterosexual contact (11%) and IDU (13%).

Thirty-eight out of the 67 counties (57%) saw a decrease in new diagnoses of HIV from 2018 to 2019. Twenty-eight out of the 67 counties (42%) saw a decrease in new diagnoses of HIV from 2019 to 2021. All but two of the seven EHE counties in Florida saw a decrease in HIV diagnoses from 2019 to 2021 (Pinellas [32%], and Orange [5%]). Palm Beach County saw a 31% increase from 2019 (N=245) to 2021 (N=322), and Hillsborough County saw a 12% increase from 2019 (N=288) to 2021 (N=323). The three remaining EHE counties (Duval, Miami-Dade, and Broward) all saw a 3% increase from 2019 to 2021. Challenges exist with many new HIV diagnoses being among people who may be new to the county, state, or country and who may not have benefited from the robust prevention activities available throughout Florida; yet the new (or re-diagnoses) count toward new HIV diagnoses for local jurisdictions and the state.

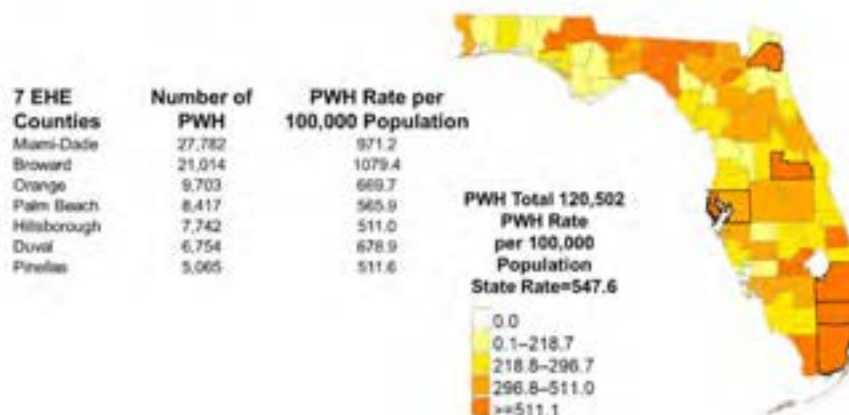
Perinatal HIV Transmission

A strategic long-term goal in Florida is to reduce or eliminate the annual number of babies born in Florida with perinatally acquired HIV. Since the introduction of azidothymidine (AZT) in 1994, perinatally acquired HIV diagnoses have drastically declined (see Figure 11). Over the past three years (2019 to 2021), there were eight perinatally acquired HIV diagnoses with an average transmission rate of 0.006. For the first time in the history of the HIV epidemic, there were no perinatally acquired HIV diagnoses born in Florida in 2019. There were four in 2020, and four in 2021.

FIGURE 11: PERINATALLY ACQUIRED HIV DIAGNOSES, 1979–2021, BABIES BORN IN FLORIDA

Prevalence of PWH in Florida

The rate of PWH in Florida in 2021 was 547.6 per 100,000 population, with the majority of PWH living in the large metropolitan areas and the seven counties outlined in the EHE plan. However, there is also a high rate of PWH living in smaller, more rural counties, such as those in northern Florida (see Figure 12). There were 120,502 PWH living in Florida in 2021. Among the adult PWH (N=120,379), 44% were Black, 28% were White, 26% were Hispanic/Latino, and 2% were American Indian, Asian, or multiracial. More than one-half (57%) were over the age of 50. MMSC was the mode of exposure for 71% of males. Heterosexual contact was the mode of exposure for 86% of females. Ten percent (10%) of PWH had a history of IDU. Among the PWH in 2021, 503 (0.4%) were transgender individuals and the primary mode of transmission was sexual contact (90%).

FIGURE 12: PWH, LIVING IN FLORIDA, BY COUNTY OF RESIDENCE, YEAR-END 2021

Late HIV Diagnosis and Resident Deaths Due to HIV/AIDS

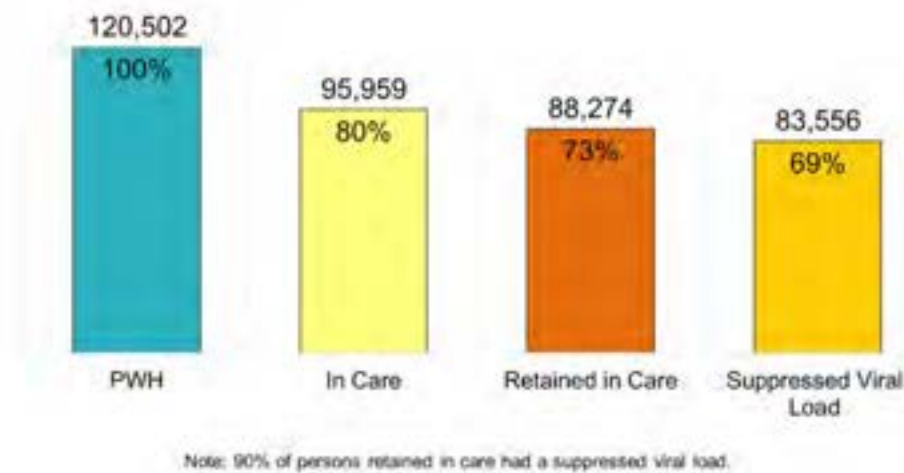
HIV/AIDS-related deaths in Florida decreased markedly (30%) from 1995 (N=4,004) to 1996 (N=2,796) after the advent of highly active antiretroviral therapy (HAART) in 1996. Furthermore, HIV-related deaths in Florida from 2012 to 2021 decreased 34% over the past 10 years, 16% over the past five years, and 7% in the past year from 659 in 2020 to 612 in 2021. The Black community has been disproportionately affected by HIV in Florida since the epidemic began in 1981 and despite a large decrease in the rate of HIV-related deaths among Black persons (43% since 2012), HIV disparities still exist among Florida's Black population. In 2021, rates of HIV-related deaths were five times higher for Black males (11.9 per 100,000 population) compared to White males (2.6 per 100,000 population) and nearly 11 times higher for Black females (7.5 per 100,000 population) compared to White females (0.7 per 100,000 population) with HIV.

Of the 4,708 HIV diagnoses in 2021, 19% (N=895) were late diagnoses, which are defined as persons receiving an AIDS diagnosis within 90 days of their confirmed HIV diagnosis. By race/ethnicity, 20% of Black persons, 21% of White persons, and 16% of Hispanic/Latino persons were late diagnoses. Among adults (age 13+), the two groups with the highest proportion of late diagnoses by age and mode of exposure were persons aged 50 and over (29%) and males with a history of IDU (29%), respectively.

HIV Care Continuum

The HIV Care Continuum is a diagnosis-based model that reflects the series of stages from initial diagnosis to being retained in care and achieving viral suppression. The HIV Care Continuum has four main stages: HIV diagnosis, linkage to care, retention in care, and viral suppression. It demonstrates the proportion of individuals diagnosed and living with HIV who are engaged at each stage. This model is used by federal, state, and local agencies to identify issues and opportunities related to improving the delivery of services to PWH across the entire continuum.

In 2021, despite the COVID-19 pandemic, of the 120,502 PWH in Florida, 80% (N=95,959) were reported to be in care (received at least one documented VL (viral load) or CD4 lab, medical visit, or HIV-related prescription in 2021), 73% (N=88,274) were retained in care (had HIV-related care two or more times at least three months apart), and 69% (N=83,556) were virally suppressed. As Figure 13 shows, of the persons retained in care, 90% had a suppressed viral load (<200 copies/mL). Twenty percent (20%) (N=24,543) did not receive any HIV-related care in 2021.

FIGURE 13: PWH LIVING IN FLORIDA ALONG THE HIV CARE CONTINUUM, YEAR-END 2021

The seven EHE counties make up approximately 11% of the total national HIV burden as outlined in the EHE plan and represent 72% of the total persons living with an HIV diagnosis in Florida.

Five of the EHE counties, Pinellas (77%), Hillsborough (71%), Orange (72%), Broward (70%) and Duval (69%) had a viral suppression rate equivalent to or greater than the state rate of 69%, while Palm Beach (65%) and Miami-Dade (63%) had lower viral suppression rates than the state at the end of 2021. It's important to note that PWH who receive services from the RWHAP and ADAP tend to have better results of viral suppression. For example, although Miami's overall viral suppression rate was 63%, approximately 82% of the 8,418 clients served by Miami's RWHAP Part A and Minority AIDS Initiative (MAI) program in fiscal year 2021 were virally suppressed.

The five populations ranked lowest in the percentage of suppressed VL (<200 copies/ml) in 2021, in descending order, were as follows:

1. Male PWID (58%)
2. Black Males with Heterosexual Contact (59%)
3. Black Males with MMSC (65%)
4. Persons 25–39 years of age (66%)
5. Persons 13–24 years of age (67%)

When compared with the HIV Care Continuum for Florida, the above five populations demonstrated disparities, particularly in the last stage, suppressed VL (<200 copies/ml). In 2021, 69% of PWH in Florida had a suppressed viral load. The five populations of concern in this section show suppressed VL percentages below 69%. This is significant to note in observing the ultimate health outcome of treatment adherence and an individual living with HIV leading a healthier life.

HIV-Related Co-Morbidities

STIs and hepatitis B virus (HBV) and (HCV have been steadily increasing in Florida over the past five years, including a 4% increase in chlamydia, a 40% increase in gonorrhea, and an 88% increase in early syphilis. Co-infection of PWH with STIs also increased during this same time period, with an increase of 67% for HIV/gonorrhea, 72% for HIV/chlamydia, and 76% for HIV/early syphilis. In 2021, there were 302 adults who were also co-infected with HBV, 86% of whom were male; 59% of the males reported MMSC exposure, and 30% of females reported IDU exposure. There were 537 PWH who were coinfecting with HCV in 2021, the majority of whom were males (82%) with MMSC (66%), IDU (13%), or heterosexual (11%) exposure. Forty-eight percent (48%) of female PWH with a co-occurring HCV diagnosis had IDU exposure. An increase in routine screening of all STIs, HIV, and hepatitis is needed to capture and prevent disease burden.

HIV Transmission Clusters and Networks

One aspect of the Florida IPC and the Florida EHE plans is to detect and respond to rapidly growing HIV transmission clusters and networks and prevent future HIV diagnoses using data and laboratory results collected through routine public health surveillance. Transmission cluster network analyses are conducted using data from point-of-care HIV-1 genotypic resistance testing to identify genetic (molecular) links of similar virus strains by comparing those with similar HIV genetic sequences. Those data are then used to identify networks of recent and rapid transmission for prevention and linkage-to-care interventions. The observed HIV transmission rate in molecular clusters identified across the U.S. is, on average, 11 times higher than the transmission rate in the general HIV population, thus indicating the importance of quickly using proven interventions to stop further transmission of HIV. HIV molecular clusters are considered rapidly growing when there have been five or more new HIV diagnoses in the previous 12 months. The Department is actively conducting surveillance and investigation for HIV clusters. The Department routinely conducts monthly analysis to detect rapidly growing molecular clusters and time-space clusters of public health significance. Additionally, a state level HIV cluster review committee is convened monthly to review cluster data, discuss challenges, and brainstorm strategies to improve the statewide response. Since fall 2021, the Department's Bureau of Communicable Diseases has established routine communication with CHDs experiencing clusters to coordinate and guide local responses to investigate and respond to clusters. Florida's updated HIV Cluster Detection and Response plan was submitted to CDC in fall 2021 and will be updated in 2023.

Since the beginning of the Department's HIV transmission cluster detection program in November 2017, the HIV/AIDS Section has identified 64 clusters at a 0.5% genetic distance between strain of HIV demonstrating rapid growth. These molecularly linked transmissions comprise a total of 772 persons receiving an HIV diagnosis in Florida with a much larger, often underdefined transmission and risk network. Though members of molecular clusters live across the state, 554 (72%) have a current residence in one of the seven EHE counties. The state has also taken a collaborative approach to responding to other outbreaks that impact the care and treatment of PWH (e.g., COVID-19, Mpox, hepatitis A, and meningococcal disease), providing trainings, developing messaging, and promoting health resources and services.

3.2 Data Sharing and Use

De-identified HIV, viral hepatitis, STD, and TB data are routinely shared via ad-hoc requests to surveillance programs with outside entities including, but not limited to, academic institutions, community partners, RWHAP parts, internal agency partners and collaborators, and the public. Each of these programs provide annual data which are uploaded into FLHealth CHARTS (Florida Community Health Assessment and Resource Tool Set) (<https://www.flhealthcharts.gov/charts/CommunicableDiseases/default.aspx>). In addition, the Department is updating the FLHealth CHARTS website (a web-based platform that provides easy access to health indicator data at the community and statewide level for the state of Florida from a multitude of sources) with a new dashboard (at the county level) that will incorporate a multitude of HIV/AIDS indicators including but not limited to, demographic and socio-economic indicators, partner services data, testing and treatment facilities, PrEP, and other data not previously included on FL Health CHARTS.

By ensuring all these data and information are made readily accessible and user-friendly, the new dashboard will help local and state planning bodies develop more effective and efficient programs and corresponding activities and monitor progress of IPC strategies and activities. All data are protected securely and confidentially, adhering to the Department's internal policies and strictly adhering to CDC's, *National Centers for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Data Security and Confidentiality Guidelines*.

Summarized ad-hoc data requests are honored based on the ability of the program to generate the requested data within the time constraints of the request. Data requests for ZIP code data will receive suppressed data (data by ZIP code with three or more cases) based on internal Department ZIP code suppression rules.

Epidemiologic Data

Summarized annual data are uploaded to the Department's HIV/AIDS Section web page (<http://floridaaids.org>) and are also available on a SharePoint site for internal use at the state and CHD level. Annual data releases include a comprehensive epidemiological profile for the state and for each partnership area, a state slide set presented annually to FCPN, and other annual data products. The epidemiological profiles are an expanded Excel workbook with multiple tabs containing 5-year trend analyses of HIV (demographics, diagnosis, AIDS, deaths, and continuum of care), STIs, HBV, HCV, and TB.

Factsheet and Slide Sets to Support Stakeholder Engagement and Planning

Various factsheets are generated to portray epidemiology and disease highlights for a demographic population. These fact sheets address various HIV/AIDS awareness day topics as well as highlight summary data for high-risk population groups. These fact sheets are updated annually, shared with community stakeholders, and uploaded to the Department's external web and internal SharePoint sites. Integrated slide sets and epidemiological profile tables are generated to support stakeholder engagement and planning. The Department's HIV/AIDS Section has generated comprehensive slides sets

and epidemiologic profiles specifically for each of the 14 partnership areas each year since the 1990s. These slide sets and profiles are shared with the RWHAP Part A entities, community stakeholders, field surveillance staff, and others who may request these data. These data are frequently used as tools for program planning and evaluation.

Other Data Sources

Along with HIV data, the Department summarizes data from MMP and CDC's National HIV Behavioral Surveillance (NHBS) surveillance project, along with Department PrEP, Test and Treat, and HIV counseling and testing data. Data from the needs assessments are also shared in reports sent out to FCPN membership. Other data sources include the RWHAP Eligibility Portal, CAREWare, and Provide Enterprise (an online care management system).

Data Sharing Agreements

For persons requesting de-identified data in a database format that can be analyzed for public health research purposes, the researcher must first submit a concept proposal with research aims, benefit to public health, and required data variables and time frame for the requested data. An internal Department research committee reviews the feasibility of the project, including for potential human subjects impacts and ethical considerations. Once approved, the requestor must complete a Data Use Agreement (DUA) and obtain a study approval or study exemption letter from the Department's Institutional Review Board. Once received, the DUA is routed for legal review and signatures. Data are provided via secure FTP format and can only be housed on secure servers as part of the DUA.

Any program outside of the Department that is approved to receive HIV data through a Data Sharing Agreement (DSA) for the purpose of linking or re-engaging HIV clients into care must be in full compliance with the NCHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD, and TB Programs, Department security and confidentiality policies, Health Insurance Portability and Accountability Act (HIPAA) guidelines and have documented active-client consent to share. Data sharing with programs outside the Department requires approval of the overall responsible party, HIV/AIDS Section administrator and legal counsel. A memorandum of understanding or DSA must be completed between the Department and the program requesting data. The HIV Surveillance Program will provide only the minimum data required to conduct linkage and reengage to HIV care and services.

In partnership with the six RWHAP Part A programs located in the seven EHE counties and through funding received by Georgetown University, the Department has developed and is preparing to implement a data sharing and Data to Care (D2C) effort to improve linkage to HIV care for persons out of care in those jurisdictions.

Some challenges exist with data sharing; for example, the Department's data sharing agreement with the Florida Agency for Health Care Administration (AHCA) for Medicaid does not allow the Department to share data on Medicaid enrollments of the same clients receiving services in and from the RWHAP

Part A jurisdictions. This leads to duplicative and sometimes costly efforts for the RWHAP Part A programs to run Medicaid verification checks on the clients for eligibility assessments.

3.3 HIV Prevention, Care, and Treatment Resource Inventory

To ensure that the state is meeting the goals and objectives set forth to best address the needs of PWHs, Florida must prioritize the financial resources and assess the capacity to provide the services outlined. The following section provides a comprehensive HIV financial resources inventory for Florida. Components include, but are not limited to, statewide public and private funding sources for HIV prevention, care, and treatment services; the dollar amount and the percentage of the total available funds for each funding source; program or service delivery; and what step of Florida's HIV Care Continuum is impacted.

Resource inventories have been provided by all 14 HIV partnership areas in the state of Florida. Each partnership area provided separate inventories for prevention and patient care, which can be found in Appendix Section 9.3 Partnership Area Resource Inventories. Table 5 represents Florida-specific funding from various sources for HIV-related services statewide, where available, for FY 2021.

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TABLE 5: FUNDING RESOURCE INVENTORY

Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
HRSA RWHAP Part A (EMA/TGA)²	\$76,146,512	12.67%		
Fort Lauderdale	\$15,724,848		Medical case management (including treatment adherence), oral health care, EIS, mental health services, substance abuse treatment (outpatient), case management (nonmedical), food bank/home-delivered meals, health education/risk reduction, housing services, legal services, medical transportation services, psychosocial support services	2,3,4,5
Jacksonville	\$5,886,669			
Miami	\$26,432,895			
Orlando	\$10,445,207			
Tampa	\$10,352,255			
West Palm Beach	\$7,304,638			
HRSA EHE–RWHAP Part A Jurisdictions²	\$10,780,783	1.79%		
Fort Lauderdale	\$2,075,933		Linkage services for PWH who are either newly diagnosed or are diagnosed but currently not in care, to essential HIV care and treatment and support services.	2,3,4,5
Jacksonville	\$1,086,820			
Miami	\$2,887,384			
Orlando	\$1,667,000			
Tampa	\$1,667,000			
West Palm Beach	\$1,396,646			
HRSA RWHAP Part B³	\$282,240,453	46.96%		
Base	\$30,031,995		Medical case management services (including treatment adherence), case management (non-medical), food bank/home-delivered meals, health education/risk reduction, psychosocial support services, quality management, and evaluation	2,3,4,5
MAI	\$1,253,307			
ADAP Earmark	\$84,839,389			
ADAP Rebates	\$165,647,438			
Emerging Communities	\$468,324			
HRSA RWHAP Part B³ – Supplemental	\$2,888,725	0.48%	ADAP medications	3,4,5
HRSA RWHAP Part B³ – ERF	\$5,211,950	0.87%	ADAP medications	3,4,5

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
HRSA RWHAP Part C -Early Intervention	\$10,668,448	1.78%		
Borinquen Health Care Center, Inc. (Miami)	\$699,183		EIS (management and administration EIS), core medical services, support services, quality management and administration.	1,2,3,4,5
Empower U (Miami)	\$679,903			
University of Miami (Miami)	\$933,332			
Charlotte De Soto County Health Department (Arcadia)	\$273,835			
Collier Health Services (Immokalee)	\$468,290			
Duval County Health Department (Jacksonville)	\$300,912			
Hendry County Health Department (Labelle)	\$317,459			
Manatee County Rural Health Services, Inc. (Palmetto)	\$499,050			
Monroe County Health Department (Key West)	\$521,839			
Neighborhood Medical Center, Inc. (Tallahassee)	\$545,577			
North Broward Hospital District (Fort Lauderdale)	\$875,925			
Okaloosa County Health Department (Fort Walton Beach)	\$306,167			
Orange County Health Department (Orlando)	\$1,072,229			
Pancare of Florida, Inc. (Panama City)	\$300,000			
Polk County Health Department (Bartow)	\$546,633			
St. Johns County Health Department (St. Augustine)	\$357,926			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
The McGregor Clinic, Inc. (Fort Myers)	\$339,544			
Unconditional Love, Inc. (Melbourne)	\$346,828			
University of Florida (Gainesville)	\$350,484			
HRSA RWHAP Part D	\$7,593,769	1.26%		
Bond Community Health Center, Inc. (Tallahassee)	\$493,499		Medical services, clinical quality management, support services, and administration.	1,2,3,4,5
Children's Diagnostic & Treatment Center, Inc. (Fort Lauderdale)	\$2,016,919			
Florida Department of Health (Tallahassee)	\$829,678			
University of Florida (Gainesville)	\$729,616			
University of Miami (Miami)	\$2,058,949			
University of South Florida (Tampa)	\$1,465,108			
HRSA RWHAP Part F				
NOVA Southeastern University, Inc. (Fort Lauderdale)	\$219,230	0.04%	Assistance for accredited dental schools, post-doctoral dental programs, and dental hygiene education programs for uncompensated costs incurred in providing oral health treatment to patients with HIV infection.	3
CDC Integrated Prevention and Surveillance	\$38,756,445	6.45%		
Florida Department of Health in Tallahassee (State Health Office)	\$30,671,550		Core prevention and surveillance programs including HIV testing and linkage to care; comprehensive prevention services for HIV-positive individuals; condom distribution; policy initiatives; interventions for at-risk populations; social marketing, media, and mobilization; HIV prevention planning; PrEP and PEP initiatives; capacity-building and technical assistance; program planning, monitoring, and evaluation; and quality assurance.	1,2,3,4,5
The Department's Statewide total distribution (counties)	\$8,084,895			
CDC Ending the HIV Epidemic (EHE)	\$11,280,419	1.88%		
State Health Office	\$2,613,537			1,2,3,4,5

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Broward	\$1,949,187		Prevention and surveillance programs which complement existing work under the state's HIV prevention and surveillance cooperative agreement (CDC-PS18-1802) and use innovative strategies addressing ending the HIV epidemic.	
Duval	\$615,372			
Hillsborough	\$674,419			
Miami-Dade	\$2,624,940			
Orange	\$880,968			
Palm Beach	\$794,010			
Pinellas	\$457,986			
CDC Medical Monitoring Project	\$861,929	0.14%	Population-based project which provides information about the behaviors, clinical outcomes, quality of care, and barriers to care and viral suppression among people with diagnosed HIV.	4,5
CDC National HIV Behavioral Surveillance (NHBS)	\$433,710	0.07%	National HIV Behavioral Surveillance Study (Miami)	1,2
CDC Integrated Hepatitis Surveillance Prevention	\$774,500	0.13%	Improve hepatitis surveillance data collection systems to systematically collect, analyze, interpret, and disseminate data. Increase hepatitis testing and vaccination for high-risk populations.	1,2
CDC STD Grants	\$35,813,552	5.96%		
Strengthening STD Prevention and Control for Health Departments (STD PCHD)	\$5,696,617		Surveillance, investigation and intervention for syphilis, gonorrhea, chlamydia, and HIV. Limited clinical support.	1,2,3
DIS Workforce Development Supplement	\$29,068,863		Expanding public health workforce capacity to respond to infectious disease outbreaks.	1,2,3,4
STD Surveillance Network (SsuN)	\$340,000		Enhanced surveillance of gonorrhea via extended patient and provider interviews.	1,2
Epidemiology and Laboratory Capacity (ELC)	\$633,071		Routine syphilis screening at non-traditional venues (hospital emergency department and syringe services program) to reduce congenital syphilis rates.	1,2
Childbearing Capacity in Jails (NACCHO)	\$75,000		Routine syphilis screening for women of child-bearing age to reduce congenital syphilis rates.	1,2
State General Revenue	\$42,210,855	7.02%		

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
State Health Office	\$22,748,209		HIV prevention and care staff, services, and supplies.	1,2,3,4,5
County Health Departments ⁴	\$12,427,076			
Pharmacy	\$7,035,570		HIV prevention and treatment medications	4
State Line-Item Appropriations	\$1,739,000	0.29%		
UM Center for AIDS Research	\$1,000,000		HIV cure research.	
TOPWA	\$500,000		Perinatal HIV prevention services.	1,2,3,4,5
Hispanic & Haitian Outreach	\$239,000		HIV outreach and education to Hispanic and Haitian communities.	1,2
HOWPA (HUD)-State				
The Department Statewide	\$8,364,929	1.39%	Housing assistance and related support services for low-income persons with HIV/AIDS and their families.	3,4,5
HOWPA (HUD)-Direct Funding to Cities	\$34,257,931	5.70%		
Fort Lauderdale	\$7,088,032		Housing assistance and related support services for low-income persons with HIV/AIDS and their families.	3,4,5
Jacksonville	\$2,601,336			
Miami	\$11,924,914			
Orlando	\$4,586,699			
Tampa	\$4,378,068			
West Palm Beach	\$3,202,608			
Key West (competitive)	\$476,274			
DIRECTLY-FUNDED ORGANIZATIONS				
CDC Directly-Funded HIV Service Providers				
CDC-PS21-2102 ⁵	\$4,857,875	0.81%	Comprehensive high-impact HIV prevention programs for community-based organizations	1,2,3,4,5
AIDS Service Association of Pinellas, Inc. dba EPIC (Clearwater)				
BASIC NWFL, INC. (Panama City)				
Borinquen Health Care Center, Inc. (Miami)				
Care Resource Community Health Centers, Inc. (Miami)				

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
FoundCare Inc. (West Palm Beach)		0.18%	Comprehensive high-impact HIV prevention programs for young MSM and transgender individuals of color.	1,2,3,4,5
Health Care Center for the Homeless, Inc. dba Orange Blossom Family Health (Orlando)				
Hope and Help Center of Central Florida, Inc. (Winter Park)				
Latinos Salud, Inc. (Wilton Manors)				
Metropolitan Charities dba METRO Inclusive Health (St. Petersburg)				
Treasure Coast Health Council, Inc dba Health Council of Southeast Florida (Palm Beach Gardens)				
Village South, Inc. (Pembroke Pines)				
CDC-PS17-1704	\$1,063,791	0.18%	Comprehensive high-impact HIV prevention programs for young MSM and transgender individuals of color.	1,2,3,4,5
Care Resource Community Health (Miami)	\$354,597	0.35%	Promoting adolescent health through school-based HIV prevention through HHS, CDC, NCHHSTP.	1
Jacksonville Area Sexual Minority Youth Network (JASMYN) (Jacksonville)	\$354, 597			
Latinos Salud (Miami Beach)	\$354, 597			
CDC Division of Adolescent School Health (DASH), CDC-PS-18-1807 ⁶	\$2,100,000	0.35%	Promoting adolescent health through school-based HIV prevention through HHS, CDC, NCHHSTP.	1
Broward County		0.35%	Promoting adolescent health through school-based HIV prevention through HHS, CDC, NCHHSTP.	1
Duval County				
Hillsborough County				
Orange County				
Pasco County				
Palm Beach County				
HRSA Directly-Funded HIV Service Providers				

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
HRSA EHE Primary Care HIV Prevention	\$6,361,483	1.06%	Funding provided to health centers to expand access to medication to prevent HIV (including PrEP and related services), connect people to care, and ensure care services are well coordinated.	1,2,3,4,5
Agape Community Health Center, Inc. (Jacksonville)	\$254,811			
Borinquen Health Care Center, Inc. (Miami)	\$284,779			
Broward Community and Family Health Centers, Inc. (Hollywood)	\$266,341			
Care Resource Community Health Centers Inc. (Miami)	\$269,322			
Citrus Health Network, Inc. (Hialeah)	\$270,825			
Community Health Centers of Pinellas, Inc. (St. Petersburg)	\$286,640			
Community Health South Florida, Inc. (Miami)	\$300,697			
Empower U, Inc. (Miami)	\$253,689			
Florida Community Health Centers, Inc. (West Palm Beach)	\$276,697			
FoundCare Inc. (West Palm Beach)	\$268,470			
Health Care Center for the Homeless, Inc. (Orlando)	\$263,810			
I.M. Sulzbacher Center for the Homeless, Inc. (Jacksonville)	\$254,995			
Jessie Trice Community Health System, Inc. (Miami)	\$284,758			
Miami Beach Community Health Center, Inc. (Miami)	\$308,991			
North Broward Hospital District (Fort Lauderdale)	\$251,614			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Pinellas, County of (Clearwater)	\$162,412			
Tampa Family Health Centers, Inc. (Tampa)	\$305,605			
Banyan Community Health Center (Miami, FL)	\$343,379			
Central Florida Family Health Center (Sanford, FL)	\$361,799			
Community Health Centers (Winter Garden, FL)	\$373,076			
Genesis Community Health (Boynton Beach, FL)	\$340,385			
Suncoast Community Health (Ruskin, FL)	\$378,388			
Substance Abuse and Mental Health Services Administration (SAMHSA) FUNDING				
Florida Department of Children and Families (FDCF)				
Substance Abuse Prevention and Treatment Block Grant, HIV Early Intervention Services Set Aside	\$ 5,569,266	0.93%	Funding for HIV testing in substance use disorder treatment facilities.	1,2,3
SAMHSA-Directly Funded Organizations	\$9,814,811	1.63%		
Broward House, Inc. (Fort Lauderdale)	\$485,000		Minority AIDS Initiative-service Integration	1,2,3,4
FoundCare Inc. (West Palm Beach)	\$445,987		Minority AIDS Initiative-service Integration	
Guidance/Care Center, Inc. (Key West)	\$479,325		Minority AIDS Initiative-service Integration	
Banyan Community Health Center, Inc. (Miami)	\$257,354		Capacity Building Initiative (CBI-HIV) for substance abuse and HIV prevention services for at-risk racial/ethnic minority youth and young adults.	1,2,3,4
BASIC NWFL, Inc. (Panama City)	\$255,000		CBI-HIV	
Bethel Family Enrichment Center, Inc. (Miami Gardens)	\$257,166		CBI-HIV	

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Gang Alternatives, Inc. (Miami)	\$257,245		CBI-HIV	
26 Health, Inc. (Orlando)	\$199,774		Substance Abuse (SA) and HIV Prevention Navigator Program	1,2,3,4
Aspire Health Partners, Inc. (Orlando)	\$200,000		SA and HIV Prevention Navigator Program	
Borinquen Health Care Center, Inc. (Miami)	\$200,000		SA and HIV Prevention Navigator Program	
Community Rehabilitation Center, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Orange County (Orlando)	\$200,000		SA and HIV Prevention Navigator Program	
Gang Alternatives, Inc. (Miami)	\$199,996		SA and HIV Prevention Navigator Program	
New Breed Creation Life Center, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Pridelines Youth Services, Inc. (Miami)	\$200,000		SA and HIV Prevention Navigator Program	
River Region Human Services, Inc. (Jacksonville)	\$200,000		SA and HIV Prevention Navigator Program	
Aspire Health Partners, Inc. (Orlando)	\$525,000		Targeted Capacity Expansion (TCE-HIV) HIV Program: substance use disorder treatment for racial/ethnic minority populations at high risk for HIV/AIDS	1,2,3,4
Bethel Family Enrichment Center, Inc. (Miami Gardens)	\$461,175		TCE-HIV	
Borinquen Health Care Center, Inc. (Miami)	\$525,000		TCE-HIV	
Broward House, Inc. (Fort Lauderdale)	\$520,693		TCE-HIV	
Community Rehabilitation Center, Inc. (Jacksonville)	\$425,000		TCE-HIV	
Gateway Community Services, Inc. (Jacksonville)	\$525,000		TCE-HIV	
Guidance/Care Center, Inc. (Key West)	\$499,179		TCE-HIV	
Health Care Center for the Homeless, Inc. (Orlando)	\$525,000		TCE-HIV	
Lakeview Center, Inc. (Pensacola)	\$521,965		TCE-HIV	

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Metropolitan Charities, Inc. (dba Metro Inclusive Health) (St. Petersburg)	\$525,000		TCE-HIV	
The Village South, Inc. (Miami)	\$524,952		TCE-HIV	
Veteran's Affairs⁷	—		Funding to support services for Florida veterans	1,2,3,4,5
Medicaid-funded HIV Services⁷	—		Funding to support PWH medical services	1,2,3,4,5
Indian Health Service		0.16%	Funding to support services for Florida's federally-recognized tribes and tribal organizations	1,2,3,4,5
Seminole Tribe of Florida (HHS Substance Abuse and Mental Health Services Projects of Regional and National Significance)	\$402,265		Funding to support services for tribal opioid response.	
Seminole Tribe of Florida (HHS, CDC Funds for Public Health Response, COVID-19)	\$311,730		Funding to support tribal response to public health or health care crises (COVID-19 response funds).	
Miccosukee Tribe of Indians of Florida (HHS, CDC Funds for Public Health Response, COVID-19)	\$259,456		Funding to support tribal response to public health or health care crises (COVID-19 response funds).	
PRIVATE FOUNDATIONS⁸				
The Campbell Foundation	\$20,000	0.003%		
AH Monroe, Inc. (Key West)	\$2,000		HIV-related services	
Broward House, Inc. (Fort Lauderdale)	\$2,000			
Care Resource, Inc. (Miami, Fort Lauderdale)	\$2,000			
Children's Diagnostic & Treatment Center, Inc. (Fort Lauderdale)	\$2,000			
Compass, Inc. (West Palm Beach)	\$2,000			

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Funding Source and Area/Jurisdiction	Funding Amount (\$)	Percentage of Total Funding (%)	Services Delivered	HIV Care Continuum Steps Impacted ¹
Empath Health/EPIC, Inc. (St. Petersburg)	\$2,000			
Latinos Salud, Inc. (Wilton Manors, Miami)	\$2,000			
McGregor Clinic, (Fort Myers)	\$2,000			
Poverello, Inc. (Wilton Manors)	\$2,000			
SunServe, Inc. (Wilton Manors)	\$2,000			
TOTAL	\$601,003,817			

¹ HIV Care Continuum: 1 = HIV Testing and Diagnosis: Staff, services and systems that help to identify and test persons who are unaware of their HIV status; 2 = Linkage to Care: Staff, services, and systems that help connect newly diagnosed PWHA to care; 3 = Retention in Care: Staff, services, and systems that help PWH remain engaged in care and treatment services; 4 = Provision of ART: Staff, services, and systems that help PWH access and remain adherent to antiretroviral medication; 5 = Viral Suppression: Staff, services and systems that help PWH achieve and maintain viral suppression.

² RWHAP Part A figures represent FY2021 funding amounts.

³ The State Health Office is the recipient of HRSA RWHAP Part B funds.

⁴ State General Revenue to County Health Departments includes 4B000, 4BNWK, and 4BAPS.

⁵ CDC-PS21-2102: Unable to obtain exact funding amounts. Average funding award for each provider was approx. \$441,625.

⁶ CDC-PS18-1807: Unable to obtain exact funding amounts. Average funding awards approx. \$350,000.

⁷ Unable to obtain Florida-specific funding levels.

⁸ Additional private foundation awards exist; however, recipients and award amounts are unknown.

Other sources of funding include funds from the state of Florida general revenue, Housing Opportunities for Persons with AIDS (HOPWA), U.S. Department of Housing and Urban Development (HUD), RWHAP all parts, CDC Integrated HIV Prevention and Surveillance, CDC MMP, CDC NHBS, CDC and HRSA EHE funds, SAMHSA, tribal organization funding, and private foundation funding, where available. More work is needed to identify Florida-specific funds related to HIV services from the Veteran’s Administration (VA) and Medicaid.

The Florida HIV Care Continuum Dashboard Tool was developed as a mechanism to gather information related to how funds are distributed statewide and RWHAP services are delivered by geographic area. The purpose and goal of the tool was to provide a snapshot of HIV prevention and patient care funding and assess HIV prevention and patient care activities across the care continuum by each of the 14 HIV partnership areas.

The tool provides a listing of resources in CHDs and local communities, as well as illustrating gaps and unmet needs by contrasting regional differences and highlighting areas of need. The information in the Florida HIV Care Continuum Dashboard Combined Tool was self-reported by each local area; therefore, slight differences may appear in terms of funding or data reported. Additionally, specific caveats may apply since they may have alternate funding streams coming into their local areas or enhanced best practices or collaborative efforts which result in increased funding as reported by the state.

The purpose of this inventory is to provide a snapshot of HIV prevention and patient care funding by area. The goal of this inventory is to help assess HIV prevention and patient care activities across the continuum of care by area. The inventory provides a snapshot of resources in CHDs and communities. Individual area resource inventories can be found in Appendix Section 9.3 Partnership Area Resource Inventories.

3.4 Gaps, Needs and Barriers

Through the development of Florida’s Unified EHE Plan and through local community engagement activities, additional gaps, needs, and barriers were identified which span across all pillars as described in Table 6:

TABLE 6: GAPS, NEEDS AND BARRIERS

Summary	Description
Meaningful Community Engagement with Priority Populations	The Department received feedback from community partners on the perceived effectiveness of current public health initiatives. Partners identified across all IPC pillars determined there is a need for increased and meaningful community engagement with all of Florida’s populations that are disproportionately affected by and living with HIV, including Black and Hispanic/Latino populations and the LGBTQ community. The Department recognizes that Florida’s racial/ethnic minority populations continue to increase in size and continues to address gaps in diverse community

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Summary	Description
	wellness throughout the state. Improvements in HIV outcomes over the last decade have had great strides. However, populations of racial and ethnic minorities should continue to be prioritized to improve prevention and care access. For Florida’s racial/ethnic minority populations, HIV outcomes should improve among all populations at the same rate – especially among Florida’s diverse population. While Florida has maintained the Business Responds to AIDS (BRTA) and Faith Responds to AIDS (FRTA) initiatives for over a decade, additional efforts are needed to involve faith-based and business leaders. Faith-based leaders, as trusted members of their communities, are well-poised to educate and mobilize Black and Hispanic populations around HIV/AIDS. Feedback indicates there would be a benefit for leaders of faith-based institutions to engage in HIV education and awareness. Challenges exist around maintaining community engagement with and representation from PWH who receive services directly through the RWHAP, both at state and local levels.
Geography and Transportation	Whereas there are major metropolitan areas in the state, 30 of Florida’s 67 counties (45%) are designated as rural per the 2010 U.S. Census.³⁹ Many Floridians live in areas that have both rural and urban characteristics, which makes addressing the needs of these communities challenging. Transportation is often a barrier for clients attempting to access HIV care services and can lead to missed appointments, decreased medication adherence, and disengagement from care.²⁰ County size and lack of affordable, safe, and timely transportation options are also factors contributing to barriers in accessing care. For example, in Miami-Dade County, some clients who live in far south Dade, and fear stigma of accessing HIV care closer to home, opt to ride hours on public transportation, often in inclement weather, to access services near downtown Miami.
Poverty and Education	In 2020, 13% of people living in Florida reported living below the federal poverty level.²⁰ Counties with the highest poverty rates included DeSoto, Hamilton, Hardee, Hendry, and Madison. In 2016–2020, 88.5% of people aged 25 years and older living in Florida had at least graduated from high school (compared to 89.4% for the U.S.).²⁰ Counties with the fewest individuals with at least a high school diploma included DeSoto, Glades, Hamilton, Hendry, and Lafayette. Counties with the lowest education levels were found in central and northern Florida.
Mental Health and Substance Use Disorders	Persons experiencing mental health and substance use disorders are at increased risk for HIV and frequently lack access to HIV and STI education, prevention, and care services.²² In 2020, nearly 18% (7,842) of the 44,577 reported drug overdose deaths in Florida involved opioids.²³ There was an approximate 28% increase in the number of persons treated for addiction with self-reported IDU between 2014 and 2018.²⁴ There was a 2% increase in HIV diagnoses from 2017–2021 among persons with an IDU-related mode of exposure.⁶ Over that same time period, acute HCV infections

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Summary	Description
	increased by 366% in Florida; injection drug use is the primary mode of exposure among persons diagnosed with acute HCV. Efforts are needed to ensure organizations providing behavioral health and substance use treatment services are providing education around HIV, STIs, and HCV and are knowledgeable about local testing and treatment resources. According to the FDCF, 2020 Florida Youth Substance Abuse Survey (FYSAS) State Report, substance use among students in Florida continues to decline. Among middle and high school students in Florida, between 2010 and 2020, the prevalence of lifetime alcohol use decreased from approximately 52% to 35% and the past-30-day prevalence of alcohol use decreased from 29% to 15%. Regarding marijuana use, the prevalence of lifetime and past 30-day marijuana use among middle and high school students also decreased between 2010 and 2020. According to estimates from the 2022 FYSAS among high schoolers, the lifetime prevalence is 2.8% for opioid misuse, 4.1% for stimulant misuse, and 5.7% for opioid and stimulant misuse.⁴⁵ Methadone- or buprenorphine-assisted maintenance treatment (including psychosocial support as needed and if desired) is the evidence-based standard of care used to treat opioid use disorders. According to an analysis of 25,866 Florida Medicaid enrollees diagnosed with opioid use disorders only about 28% go on to initiate medication-assisted treatment. About 56% of newly diagnosed individuals who began methadone treatment continued for 180 days, compared about 19% of newly diagnosed individuals who began treatment with buprenorphine.⁴⁶
Multicultural and Multilingual Issues	Florida population estimates for 2020 show racial/ethnic distributions as follows: 51.5% White (non-Hispanic), 14.5% Black (non-Hispanic), 3.0% Asian American, and 0.2% Native American. Hispanic/Latino persons make up over a quarter (26.5%) of the population. Florida ranks in the top five states with the highest Hispanic/Latino populations in the U.S. and has one of the largest Black/African American populations in the country. Florida's Asian population is growing, particularly in Gulf Coast locations. The state is home to two federally recognized American Indian tribes (the Seminole and the Miccosukee in South Florida) and many more non-federally recognized tribes, bands, and clans. The Miami metropolitan area (along with New York City) maintains one of the highest populations of Caribbean immigrants, with approximately 63% of Caribbean immigrants in the U.S. living in these two metro areas. Just over 20% of Florida's population is foreign-born and nearly 30% of households in Florida speak a language other than English.⁵ There is a lack of bilingual and multilingual health care providers and media and marketing messages in certain regions of the state.²⁵ Florida works to ensure programs and services for PWH and those at increased risk for acquiring HIV align with the National CLAS Standards and that translation services are made available to all clients receiving services at CHD clinics and through funded HIV prevention and care service providers.

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Summary	Description
Racism, Discrimination, and Medical Mistrust	Persons experiencing racism and discrimination are less likely to remain adherent to care and more likely to have poorer health outcomes.²⁶ Medical mistrust tends to be higher among Black and American Indian populations in Florida. The Tuskegee Study conducted by the U.S. Public Health Service left lasting impacts on the way Black persons view health care, particularly public health.²⁷ Similarly, studies have shown the sterilization of American Indian women by the Indian Health Service in the 1960s and 1970s created a culture of distrust of government-funded health care services.²⁸
In-Migration, Tourism, Seasonal, and Mobile Populations	Florida sees more than one-hundred million tourists each year, many of whom are drawn to popular beach towns and cities like Miami, Fort Lauderdale, and Key West.²⁹ Its many theme park attractions and over 8,400 miles of coastline make Florida a destination for tourists from around the world. According to VISIT FLORIDA's latest estimates, during Quarter 1 of 2022 (January–March), Florida saw a total of 36 million visitors. This represents a 14% increase from Q4 2021, and the third consecutive quarter that overall visitation has surpassed pre-pandemic levels. Approximately 34.1 million domestic visitors traveled to Florida in Q1 2022, and there were approximately 1.3 million travelers from overseas who visited the state during that same time period (represents an increase of nearly 169% from Q1 2021).⁴⁷ The state also has a large population of seasonal residents—students, seasonal workers (in industries such as hospitality, agriculture, and tourism), and persons who reside here part time to avoid harsh winters. In addition, Florida is home to several state and private higher-learning institutions, including Historically Black Colleges and Universities (HBCUs). These colleges and universities are often located in Florida's major metropolitan areas, which have higher than average HIV incidence. If tourists, visitors, and persons migrating into the state receive their original HIV diagnosis in Florida, that case counts toward Florida's overall HIV prevalence. The Department's surveillance unit works with other states and jurisdictions to perform deduplication efforts to ensure that persons initially diagnosed in another state or jurisdiction are not counted toward Florida's overall prevalence.
Immigration and Refugee Services	Over the past few years, foreign-born individuals and individuals born in U.S.-dependent areas immigrating to Florida have accounted for roughly half of the population's growth; more than one in five Florida residents is an immigrant.³⁰ Individuals born outside the continental U.S. comprise roughly 20% of the state's population, and in Miami-Dade County, more than 60% of the population is foreign-born. Among non-U.S. born residents in Florida, persons born in Haiti, Cuba, Venezuela, and Colombia experienced the highest numbers of HIV diagnoses in 2021. This presents a need for increased cultural humility to ensure health education, prevention, and care services are delivered in a culturally and linguistically appropriate manner (i.e., National CLAS Standards).

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Summary	Description
	FDCFs Refugee Services Program is federally funded by the Office of Refugee Resettlement in HHS to assist refugees to achieve economic self-sufficiency and social adjustment in the shortest possible time after their arrival in the United States. While in recent years the number of arrivals has decreased nationwide, the state of Florida's refugee program is the largest in the nation, receiving more than 5,000 refugees, asylees, and Cuban/Haitian entrants each year. Eligibility for programs of Refugee Services is determined by federal law and includes the following: Refugees; Cuban/Haitian Entrants; Asylees; Afghan and Iraqi Special Immigrants; and Certified Victims of Human Trafficking.⁵¹ FDCF Refugee Services currently manages more than a dozen refugee services contracts with state agencies, local governments, and community-based organizations. Through their Refugee Health Program, the Department's CHDs provide health screenings to ensure newly arrived refugee clients do not have communicable diseases and to identify health issues. AHCA provides payment for Refugee Medical Assistance services with federal funding and in accordance with Medicaid rules. Of Florida's 67 counties, approximately 32 counties receive refugees for health services on a regular basis. Geographically, new arrivals tend to resettle more frequently in one of the nine following Florida counties: Miami-Dade, Hillsborough, Duval, Palm Beach, Broward, Orange, Collier, Lee, or Pinellas.⁵² From the latest data available from FDCF, in 2021, 30,092 refugees arrived or became eligible for Refugee Services in Florida. Additionally, over the last five years (2017–2021), 97,492 refugees arrived or became eligible for Refugee Services. Florida received refugees from 47 different countries last year, of which 72% of refugees were Cubans, and 50% of refugees settled in Miami-Dade County. Cuban, Haitian, Afghan, Mexican, and Chilean were the top nationalities of new refugees in 2021.⁵³
Criminal Justice	According to the National Corrections Institute, Florida's incarceration rate (prisons and jails) was 371 per 100,000 population in 2020.⁴⁸ In 2020, the U.S. Bureau of Justice Statistics ranked Florida eleventh among states in terms of incarceration rates.³² Most incarcerated PWH were diagnosed prior to entering the correctional system; however, HIV testing in a correctional setting may be the first time persons who are incarcerated take advantage of testing and prevention education. Although condom provision is one of the simplest harm-reduction interventions to control HIV, STIs, and viral hepatitis, condoms are prohibited in correctional settings. Section 945.355, Florida Statutes (F.S.), requires inmates of FDC to be offered HIV testing prior to release, while jails (which are governed by each county) do not have uniform statewide HIV testing policies. Over time, the Department has built relationships with county jails to establish HIV testing and linkage programs. Increased partnerships with county jails are needed to expand HIV, STI, and HCV testing.

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Summary	Description
HIV Criminalization	Established in 1990, section 384.24, F.S., criminalizes non-disclosure of STI status, and separately HIV status, prior to sex. The offense requires the person to be aware of their STI and HIV status, to be informed of the risks of transmission through sex, and to go on to have sex with another person. At the time the law was established there was a modest understanding of how HIV transmission occurred, and treatment options were limited. After 30 years of research and advancements in HIV treatment, the law does not take into account the latest science and measures to prevent transmission (e.g., viral suppression, U=U). Persons with HIV and other community members have reported that criminalization laws may be discouraging HIV testing and perpetuating stigma against persons with HIV.
Environmental Impacts	Severe weather events can disrupt and interrupt HIV prevention and care delivery systems. Florida is a state particularly vulnerable to frequent hurricanes. When Hurricane Michael hit the Florida Panhandle in October 2018 as a category 5 storm, it caused mass destruction. Thousands of homes were destroyed, and many residents were displaced. PWH in the area had trouble accessing services and medications due to widespread devastation. Many people were forced to find housing elsewhere in Florida or even in other states. Emergency medication fills were available through the Department’s ADAP program; however, increased efforts are needed to identify PWH in need of reengagement in care and ancillary services following a natural disaster. Most recently, on September 28, 2022, Hurricane Ian made landfall on Florida’s southwest coast (Fort Myers area) as a category 4 storm, with Lee and Charlotte counties bearing the greatest impacts. More than 100 people lost their lives in Hurricane Ian, with most deaths being attributed to drowning—the record-breaking storm surge reached as high as 18 feet in some areas. Hurricane Ian is being categorized as the deadliest storm to hit Florida since the 1935 Labor Day Hurricane. The Department used the federal emergency declaration to ensure that ADAP clients had access to medication refills ahead of the storm and worked with ADAP staff statewide to communicate to clients that they had the ability to get prescriptions filled at any pharmacy location in their local areas.
Homelessness and Housing Instability/Insecurity	In 2021, the Florida Housing Coalition reported Florida having the third-highest homeless population of any state in the nation, with 27,640 people living in homeless shelters and on the streets. Before the COVID-19 pandemic, 875,259 very low-income Florida households—including hardworking families, seniors, and people with disabilities—paid more than 50% of their incomes for housing. For PWH, housing is one of the primary predictors of their access and adherence to treatment, other health outcomes, and life expectancy. There are several definitions of homelessness or unstable housing, such as lacking a fixed, regular, or adequate nighttime residence, but also including residing in a motel, doubling up with friends or family, or “couch-surfing.” People fleeing domestic violence are also considered unstably housed if they do not have the resources and support to obtain other

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Summary	Description
	permanent housing. Responses from Florida’s 2019 HIV Care Needs Assessment survey indicated that, of persons who experienced housing-related barriers, the top three barriers were not having money to pay rent, being afraid of others knowing their HIV status, and not having enough food to eat.⁵⁵
Food Insecurity	The latest data from Feeding America show that in 2020, Florida’s overall food insecurity rate was 10.6% (approximately 2.3 million people). Although Florida’s overall food insecurity rate is lower than the U.S. average of 11.8%, 42 out of 67 Florida counties (63%) have food insecurity rates at or above the national average (>11.8%). Florida’s 2019 HIV Care Needs Assessment Survey revealed that for PWH who reported experiencing housing-related barriers, one of the top three issues reported included not having enough food to eat. Many antiretroviral medications used to treat HIV require they be taken with food and ensuring proper nutrition for PWH is paramount to medication adherence and improved health outcomes.⁵⁶
Persons with HIV Aged 50+	Improvements in ART for HIV over the years have led to people with diagnosed HIV living longer and healthier lives, especially when diagnosed early, maintained on ART, and virally suppressed. In 2021, persons with HIV aged 50 and older living in Florida made up nearly 57% of the state’s total population of persons diagnosed and living with HIV. Persons aged 50 and older living with HIV face several health challenges—HIV-related and other comorbidities (e.g., cardiovascular and liver disease, neurocognitive impairment), concurrent use of multiple medications (i.e., polypharmacy), oral health problems (e.g., tooth loss), and mental health and substance use disorders.
Outbreak Response for Syndemics	Over the past several years, the state has taken a collaborative approach, with RWHAP and other community-based partners, to responding to other outbreaks that impact the care and treatment of PWH (e.g., COVID-19, Mpox virus, hepatitis A, and meningococcal disease), providing trainings, developing messaging, and promoting access to available health resources and services (e.g., vaccine promotion events for hepatitis A and meningococcal disease). Greater coordination is needed to ensure these intersecting conditions are addressed holistically (e.g., whole-person care).
HIV Workforce Infrastructure (public and private)	Current challenges exist with the HIV workforce—both public and private. The Department’s Bureau of Communicable Diseases experienced a high degree of turnover in key leadership positions in 2022, beginning in spring and continuing into fall 2022. Key positions such as the Bureau Chief of Communicable Diseases, HIV/AIDS Section Administrator, Statewide HIV Planning/EHE Coordinator, HIV Patient Care unit manager, Communications unit manager, and Clinical Quality Management Liaison all became vacant during that time. Other positions that had

Summary	Description
	been vacant prior to 2022 are still in need of being filled and include the Performance and Quality unit manager and Statewide Minority AIDS Coordinator. High turnover and staff reaching retirement age have led to gaps in historical program knowledge and staff having to assume interim roles or double-up on responsibilities. Staffing shortages and recruiting challenges have also been reported from CBOs and private sector agencies (e.g., difficulties recruiting health care professionals).
Vulnerable Populations—Human Trafficking, Domestic/Intimate Partner Violence	According to the Florida Alliance to End Human Trafficking, Florida ranks third in the nation for the number of human trafficking cases reported and ranks second in the nation for the number of labor trafficking cases reported. The majority (71.4%) of cases are sex trafficking cases, followed by labor trafficking (14.3%), unspecified trafficking (9.0%), and sex/labor trafficking (5.1%). Persons experiencing exploitation are particularly vulnerable to exposure to HIV, STIs and viral hepatitis due, in part, to substance use, lack of access to health care, lack of autonomy, and exposure to violence.⁵⁷ In 2020, 106,515 crimes of domestic violence were reported to Florida law enforcement agencies and during FY 2020–21 and Florida’s certified domestic violence centers provided 412,360 nights of emergency shelter to 10,287 survivors of domestic violence and their children. Many more survivors of domestic violence are not reporting their abusers to the police or accessing services at domestic violence services due to reasons such as shame, fear, or being prevented from doing so by their abusers. For this reason, the number of cases is thought to be underreported. Women in violent relationships are at a four times greater risk for contracting STIs, including HIV, than women in non-violent relationships and women who experience intimate partner violence are more likely to report risk factors for HIV.⁵⁸

3.5 Needs Assessment

The information gained from the 2019 HIV Care Needs Survey represents a statewide comprehensive assessment of the needs of PWH in Florida. Survey questions were designed to better understand the current demographics of PWH in Florida and the HIV medical care, patient care services, jail and prison release services, and housing services that were needed and delivered during the 12 months prior to the time the survey was taken.

To ensure that services provided through the Patient Care Program are appropriate and contribute to improving health outcomes for PWH, the HIV/AIDS Section conducted the 2019 HIV Care Needs Survey throughout the state. The primary focus of the survey was to determine met and unmet service needs for PWH in Florida. Data collected from this survey are intended to help statewide and local planning stakeholders determine the best ways to distribute funds and resources. This survey was launched on

May 28, 2019, and continued to completion on September 6, 2019. The survey was delivered via Survey Gizmo and paper to Floridians living with HIV who sought HIV care services in each of the 14 program areas of the Ryan White Patient Care Program.

Limitations

Using the convenience sampling method to collect input for this type of assessment has its advantages, disadvantages, and limitations. Surveys collected using this method can yield rich qualitative data for review and planning in a comparatively cost-efficient manner. Data are available relatively quickly to match the pace of planning needs and are useful to signal changes or shifts in attitudes, behaviors, and outcomes. Among the disadvantages of collecting assessment data via convenience sampling are the potential for bias in data collection and sampling errors that could introduce inaccuracies. Surveying processes that use the convenience sampling method have limitations. Survey participants were self-selected.

3.5.1 Methodology

Survey questions were grouped into sections that included general demographics, HIV medical care, and patient care, jail and prison release, housing, and prevention services. Questions were related to the past 12 months of service. Distribution of the survey was facilitated by the 14 consortia lead agencies throughout Florida. A sample size for each county was calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. RWHAP Part B lead agencies, in collaboration with RWHAP Part A recipients, worked with local providers, community members, and other stakeholders to obtain the survey responses. The survey was made available in three languages: English, Haitian-Creole, and Spanish. Paper surveys were collected locally and mailed to the HIV/AIDS Section for data entry and analysis.

A total of 4,114 surveys were conducted by the end of the survey period: 3,758 in English, 334 in Spanish, and 22 in Haitian-Creole. Of these, 3,777 were complete, 147 were partial, and 190 were disqualified. Respondents were required to answer the demographic questions about age, gender, race, and county.

This document presents the key findings of the 2019 HIV Care Needs Assessment. Results from this survey will be used to help guide service implementation and resource allocation in Florida's HIV/AIDS Patient Care Program.

Survey respondents' counties of residence were reported for 66 of Florida's 67 counties. Union County was not surveyed because there are no reported PWH in that county. A total of 3,879 respondents answered the question about residence. Table 7 lists the number of respondents from each county.

TABLE 7: FLORIDA COUNTY OF RESIDENCE

County	Count	Percent	County	Count	Percent
Alachua	20	0.52%	Lake	45	1.16%
Baker	3	0.08%	Lee	76	1.96%
Bay	29	0.75%	Leon	221	5.70%
Bradford	3	0.08%	Levy	5	0.13%
Brevard	244	6.29%	Liberty	4	0.10%
Broward	65	1.68%	Madison	11	0.28%
Calhoun	1	0.03%	Manatee	22	0.57%
Charlotte	24	0.62%	Marion	23	0.59%
Citrus	8	0.21%	Martin	22	0.57%
Clay	16	0.41%	Miami-Dade	765	19.72%
Collier	29	0.75%	Monroe	37	0.95%
Columbia	3	0.08%	Nassau	4	0.10%
DeSoto	14	0.36%	Okaloosa	17	0.44%
Dixie	3	0.08%	Okeechobee	7	0.18%
Duval	230	5.93%	Orange	187	4.82%
Escambia	47	1.21%	Osceola	53	1.37%
Flagler	25	0.64%	Palm Beach	107	2.76%
Franklin	5	0.13%	Pasco	78	2.01%
Gadsden	49	1.26%	Pinellas	319	8.22%
Gilchrist	1	0.03%	Polk	76	1.96%
Glades	2	0.05%	Putnam	3	0.08%
Gulf	1	0.03%	Santa Rosa	5	0.13%
Hamilton	3	0.08%	Sarasota	68	1.75%
Hardee	2	0.05%	Seminole	51	1.31%
Hendry	7	0.18%	St. Johns	12	0.31%
Hernando	37	0.95%	St. Lucie	63	1.62%
Highlands	13	0.34%	Sumter	5	0.13%
Hillsborough	475	12.25%	Suwannee	5	0.13%
Holmes	2	0.05%	Taylor	5	0.13%
Indian River	18	0.46%	Volusia	164	4.23%
Jackson	14	0.36%	Wakulla	9	0.23%
Jefferson	3	0.08%	Walton	5	0.13%
Lafayette	2	0.05%	Washington	7	0.18%
			Total	3,879	

A sample size for each county was calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. As shown in the figure below, the three counties with highest unmet quotas were:

- Broward
- Palm Beach
- Orange

Unmet Survey Quotas
(statewide total = 644 surveys still needed)

Number of Surveys Still Needed to Complete Quotas by County

1 455

County	Number of Surveys Still Needed
Alachua	2
Bay	1
Brevard	6
Collier	8
DeSoto	8
Duval	3
Franklin	5
Hardee	2
Hendry	43
Jefferson	5
Levy	1
Manatee	105
Polk	455

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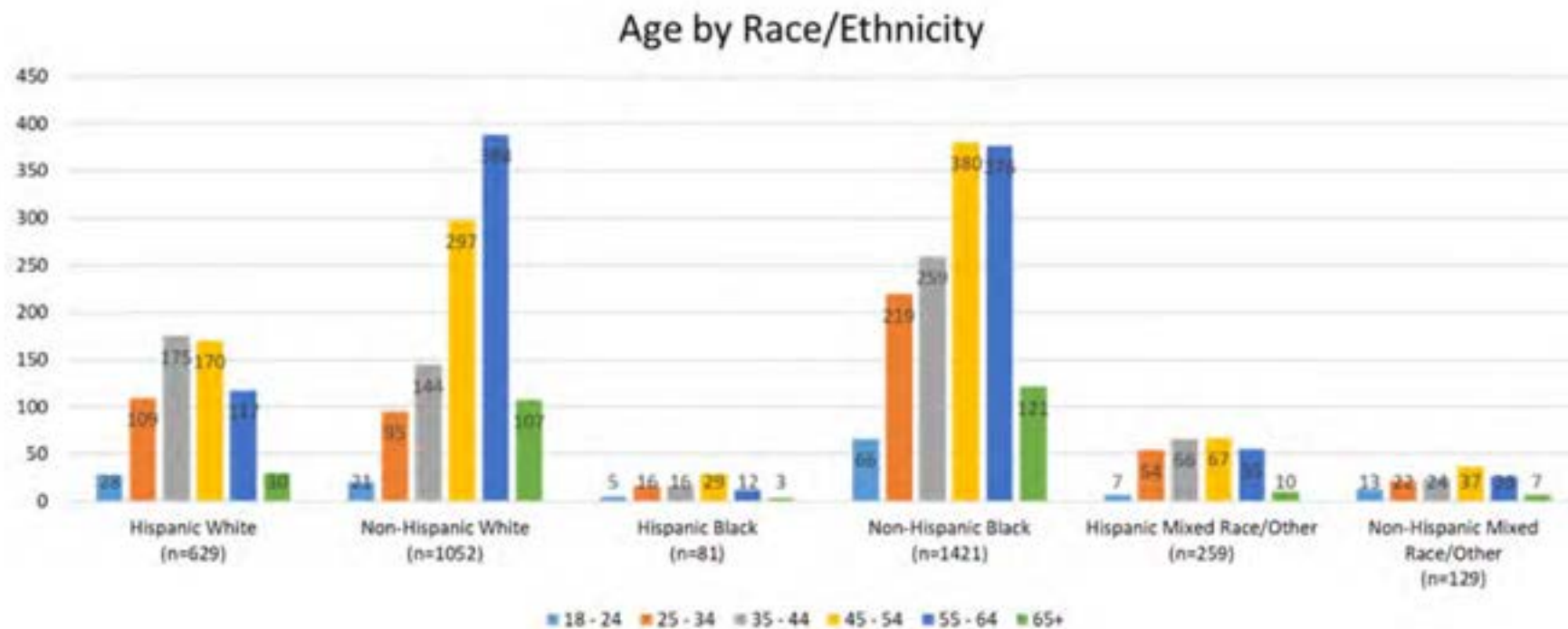
3.5.3 Priorities

The needs assessment process identified the following key priority areas: Demographics, HIV Medical Care, Patient Care Services, Jail and Prison Release Services, and Housing.

Demographics Summary

Appropriate sample sizes for each county were calculated based on the number of PWH. Each county was provided the minimum number of surveys to be sent to reach 25% of total PWH at a 10% response rate. The five counties with the most survey respondents were Miami-Dade, Hillsborough, Pinellas, Brevard, and Duval. Most counties met their quotas, but 13 did not. The three counties with highest unmet quotas were Broward, Palm Beach, and Orange.

Overall, most survey respondents fell into two age groups: 55 to 64 years old and 45 to 54 years old. Stratified by race/ethnicity (see Figure 15), this trend held true for those who identified as non-Hispanic White, non-Hispanic Black, and non-Hispanic multiracial/other. However, for those who identified as Hispanic White, Hispanic Black, and Hispanic multiracial/other, the trend showed that most fell into the 35 to 44 years old and 45 to 54 years old categories as seen in Figure 15.

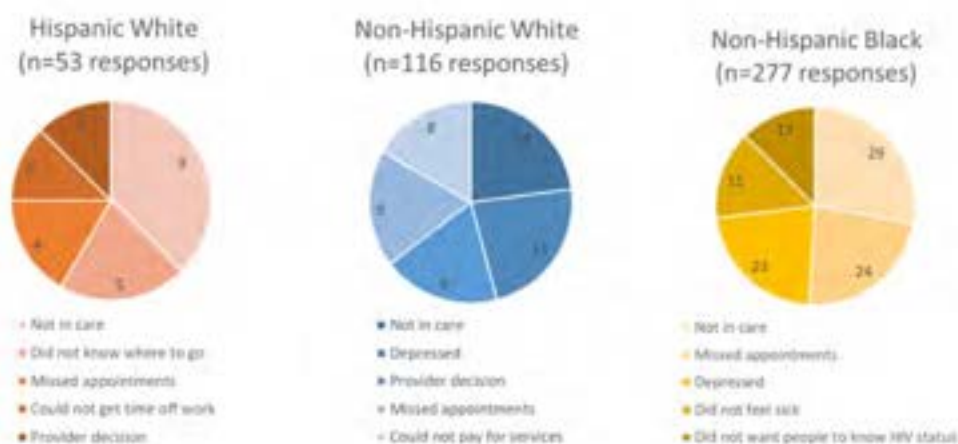
FIGURE 15: HIV CARE NEEDS SURVEY RESPONDENTS (PWH) BY AGE AND RACE/ETHNICITY

Most survey respondents reported working a full-time job for the past 12 months. The second largest group reported not being able to work due to disability. Approximately half of respondents reported that their 2018 household gross income (before taxes) was less than \$15,000 and roughly one-third reported incomes that were between \$15,000 and \$30,000. Stratified by race/ethnicity, most of those categorized as earning less than \$15,000 and those earning between \$15,000 and \$30,000 were non-Hispanic Black. Most of those categorized as earning between \$30,000 and \$50,000, between \$50,000 and \$100,000, and more than \$100,000 were non-Hispanic White.

HIV Medical Care Summary

Most survey respondents reported that they had seen a doctor about their HIV during the past 12 months. When asked about the frequency of HIV-related care, most reported receiving care two or three times during the past 12 months. For respondents who reported that they had not received HIV-related care or had received care fewer than two times in the past year, the most common reasons overall were that they were not in care, were depressed, or missed their appointments, as shown in Figure 16. When stratified by race/ethnicity, the most common reason given by Hispanic White, non-Hispanic White, and non-Hispanic Black persons remained that they were not in care. The second and third most common reasons given by Hispanic White persons were not knowing where to go and missing their appointments, respectively. For non-Hispanic White persons, the second and third most common reasons were that they were depressed and that this was their provider's decision, respectively. For non-Hispanic Black persons, the second and third most common reasons were that they missed their appointments and were depressed, respectively. The total numbers of responses from those who identify as Hispanic Black, Hispanic multiracial/other, and non-Hispanic multiracial/other about reasons for not receiving care were very low (8, 31, and 8, respectively).

FIGURE 16: TOP 5 REASONS RESPONDENTS HAD NOT BEEN IN CARE BY RACE/ETHNICITY



*Hispanic Black, Hispanic Multiracial/Other, and Non-Hispanic Mutliracial/Other not shown due to low number of responses.

The overwhelming majority of survey respondents received HIV-related medical care in the county where they live. For the small number of respondents who received care in a different county from where they live, the most common reasons given were that doctors or services were not available in their county of residence, preference and better doctors in a different county, continuity of care with an established provider, convenience and closer to home, and confidentiality.

Most survey respondents reported that they always take their HIV medications just as their doctor prescribed them. For those who reported that they did not always take their medications as prescribed, the reasons given included that the medication made them feel bad or sick, they could not afford the cost, they were on a medication break as directed by their physician, they did not know where to get medication, and forgetting.

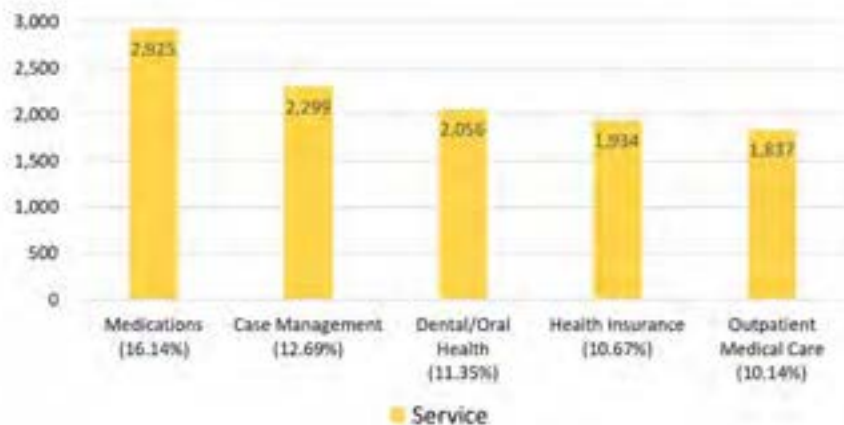
Patient Care Services Summary

Most survey respondents reported that they did get the patient care services they needed during the past 12 months. For those who did not get needed services, the five most common barriers listed were not knowing where to get services, being depressed, not having transportation, not being able to pay for services, and missing appointment(s). When stratified by race/ethnicity, the most common barrier listed for all race/ethnicity categories (except Hispanic Black persons) was not knowing where to get services. The top barrier to care for Hispanic Black persons was depression.

As shown in Figure 17, the top five patient care services deemed by respondents as most important for the state to provide for PWH were (in order of priority):

1. Medications
2. Case management
3. Dental and oral health
4. Health insurance
5. Outpatient medical care

FIGURE 17: TOP FIVE PATIENT CARE SERVICES MOST IMPORTANT TO SURVEY RESPONDENTS

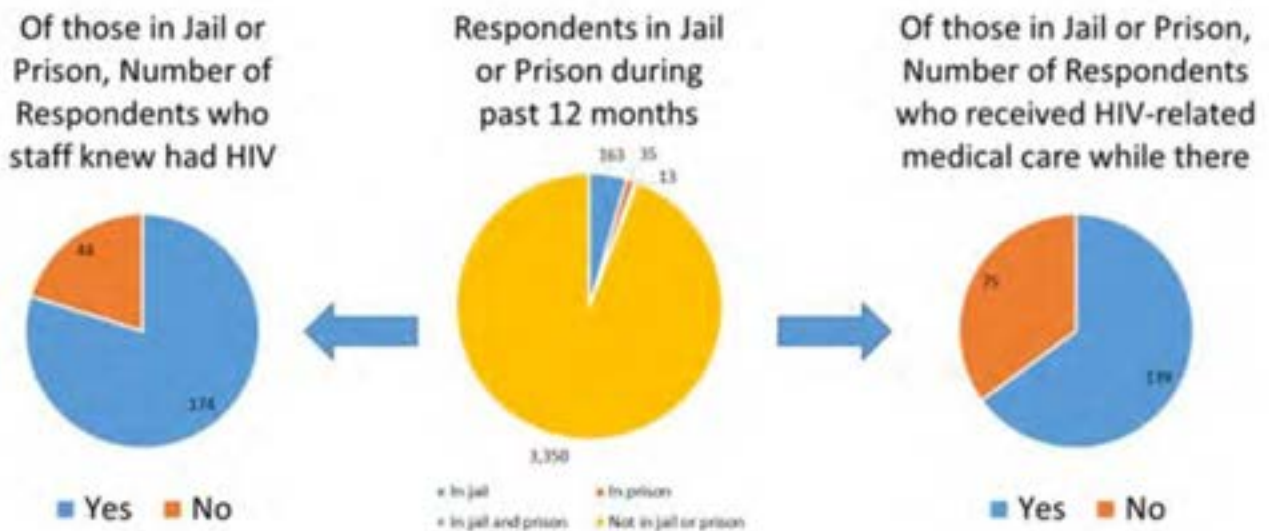


When stratified by race/ethnicity, the top two services reported by respondents as most important remained medications and case management across all race/ethnicity categories, but the priorities for dental and oral health, health insurance, and outpatient medical care were ranked differently (though they remained in the top five).

Jail and Prison Release Services Summary

The overwhelming majority of survey respondents reported that they had not been in jail or prison during the past 12 months as shown in Figure 18. Of the 211 who reported having been incarcerated (5.9% of all respondents), 82.5% reported that the jail or prison staff knew of their HIV status and most (65.9%) reported that they did receive HIV-related medical care. Upon release from jail/prison, 40.3% of respondents reported that they did not receive any HIV-related information or assistance. Of those who did receive care and assistance, 29.4% received a supply of HIV medication to take with them, 24.2% received referral to medical care, 22.3% received referral to case management, and 10.9% received information about finding housing.

FIGURE 18: SURVEY RESPONDENTS IN JAIL AND PRISON DURING THE PAST 12 MONTHS AND WHETHER SERVICES WERE RECEIVED WHILE INCARCERATED



Of the 240 respondents who answered the question about barriers to getting needed HIV services after release from jail or prison, most (59.6%) indicated that this question did not apply to them because they did get needed services. For those who experienced barriers to care, the most frequent barriers reported were:

- No insurance or financial reasons.
- No transportation to services.
- Did not know where to go for services.
- Could not get away from drugs.
- Had trouble finding trustworthy friends.

- Did not want others to know of their HIV status

Housing Summary

Overall, survey responses indicated that most respondents did not experience barriers to HIV-related care due to their current housing situation as shown in Table 8. Of those who did experience housing-related barriers, the top three barriers were not having money to pay rent, being afraid of others knowing their HIV status, and not having enough food to eat. When stratified by race/ethnicity, barriers varied in rank, but the top three barriers from the overall responses consistently remained in the top three across race/ethnicity categories.

TABLE 8: HIV HOUSING SERVICES RESPONDENTS NEEDED OR RECEIVED IN THE PAST 6 MONTHS

	Received Needed Services		Needed Service, But Could Not Get Service		Needed Service, But Did Not Know About Service		Did Not Need Service		Total Responses
	Count	Row %	Count	Row %	Count	Row %	Count	Row %	Count
Help finding an affordable place to live	357	11.26%	345	10.88%	303	9.56%	2,165	68.30%	3,170
Permanent, independent housing	258	8.62%	312	10.42%	266	8.88%	2,158	72.08%	2,994
Temporary short-term housing	141	4.91%	181	6.30%	152	5.29%	2,397	83.49%	2,871
Housing where my child(ren) can live with me	108	3.80%	69	2.43%	98	3.45%	2,567	90.32%	2,842
Nursing home	81	2.88%	48	1.71%	53	1.88%	2,633	93.53%	2,815
Money to pay utilities	281	9.49%	289	9.76%	319	10.78%	2,071	69.97%	2,960
Money to pay rent/mortgage	304	10.20%	319	10.70%	343	11.51%	2,015	67.59%	2,981
Housing for persons living with HIV	174	5.91%	249	8.46%	237	8.05%	2,285	77.59%	2,945
Assisted living facility	99	3.49%	82	2.89%	91	3.20%	2,568	90.42%	2,840
Column Totals	1,803		1,894		1,862		20,859		26,418

	Received Needed Services	Needed Service, But Could Not Get Service	Needed Service, But Did Not Know About Service	Did Not Need Service	Total Responses
% of Overall Total	6.82%	7.17%	7.05%	78.96%	100.00%

Overall, most survey responses indicated that respondents did not need any of the available housing services offered through Florida's HIV/AIDS Patient Care Program. For those who were in need, the services most frequently reported as being received, needed but unable to get, or needed but unaware of where to get (approximately 30% of all the survey responses given for each of the following services) were:

- Help finding an affordable place to live.
- Money to pay rent or mortgage.
- Money to pay utilities.
- Permanent, independent housing.

Between 65% and 70% of respondents in need of these services either could not get them or did not know about them. When stratified by race/ethnicity, non-Hispanic Black persons represented the largest number of responses across the board for all services respondents needed but could not get. This same trend held true for all services respondents needed but did not know about.

Overall, for those who needed services, most survey responses (approximately 60%) indicated that respondents did not experience barriers to getting needed housing services and were able to get them. But a sizeable proportion of responses (nearly 40%) indicated barriers to getting needed housing services. The top three barriers reported were that the respondent:

1. Did not know where to get services.
2. Did not qualify for services.
3. Was put on a waiting list.



Actions Taken

The following recommendations were developed to identify key activities to address needs and barriers of the key priority areas:

Demographics Recommendations

It is of concern that the three counties with the largest unmet survey quotas are also three of the counties that have high prevalence of PWH. Collectively, those counties were 603 surveys below quota. Given that this represents 20.6% of the total number of surveys needed to meet quota, it may present a significant deficit of information that is important to consider regarding allocation of resources for HIV

care and services. Going forward, planning for increased staffing and concentrated efforts ahead of survey implementation may help mitigate unmet quotas in counties with high prevalence of PWH.

If survey results are representative of PWH in Florida, they indicate that most are non-Hispanic Black males between the ages of 45 and 64 who have fulltime employment but are living below the poverty level. This highlights the continued disparities minorities face and the economic disadvantage of populations most affected by HIV. Giving priority to this priority population for outreach, staffing, and resources may be warranted to promote diverse community wellness.

With the development and release of the 2022 HIV Care Needs Survey and Needs Assessment Toolkit in October, Florida hopes to increase the number of surveys completed by PWH.

HIV Prevention

One of the priorities for the Department's HIV/AIDS Section is the development of a comprehensive HIV prevention needs assessment through surveys administered to and through HIP providers to address services provision (PrEP, HIV testing, Test & Treat, harm-reduction needs) for persons at risk for HIV. Other entities to be included in the needs assessment include CHDs and operational syringe services programs (SSPs). The Department hopes to accomplish this in 2023.

Policy Barriers

Currently, Florida laws do not present barriers to HIV prevention or patient care services. Minor limitations exist in state laws allowing for syringe exchange programs and include prohibitions on using state, county, or municipal funds to support the operation of the program and permitting a one-to-one exchange of syringes. Florida is also a Medicaid non-expansion state and this may have implications for HIV-related service coverage levels for persons who are eligible for Medicaid.

HIV Medical Care Recommendations

The top reasons given for not receiving care or receiving less frequent care were missed appointments and not in care. To ensure that all PWH in Florida receive the appropriate frequency of HIV-related care, it may be necessary to determine why they were not in care and why they missed appointments. Depression was another top reason given for not receiving care. This points to the importance of educating care providers to be aware of potential mental health and HIV comorbidities and the possible need to implement a protocol for mental health screening along with HIV care visits. To best address these needs and allocate resources appropriately, detailed attention to the top reasons for not receiving care in race/ethnicity categories may be helpful.

In counties where providers and services for HIV-related care are not available, the magnitude of those affected should be investigated and solutions to this problem should be explored. The desire for confidentiality was reported as a reason for seeking HIV-related care in a county other than the

respondent's county of residence. More efforts are needed to address HIV stigma and normalize HIV prevention and care seeking behaviors.

Because HIV medications, when taken as prescribed, are highly effective in attaining VLs that are undetectable and therefore not transmittable, it is imperative that all PWH receive appropriate medication and take it as directed by their physician. It is encouraging that most survey respondents reported that they always take their medications just as prescribed. However, even though the number of those who reported noncompliance with taking their medications is low (12.9%), other personal or biological issues may hinder persons from achieving sustained viral suppression. Reasons given by respondents for not taking medications as prescribed should be investigated further, and solutions or services should be found to overcome these barriers.

Patient Care Services Recommendations

Although most respondents received patient care services they needed, a large proportion (43.4%) did not. Barriers to care centered mostly around logistics, depression, and personal finances. To address logistics and personal finance barriers, allocating more resources for outreach and public information campaigns providing awareness of available HIV/AIDS services for those with low or no income may be helpful. Regarding depression, again we stress the importance of educating care providers to be aware of potential mental health and HIV comorbidities and the possible need to implement a protocol for mental health screening along with HIV care visits. Stigma may prevent persons with HIV from seeking mental health services. Additionally, partnering and finding more accessible mental health service providers is key.

As seen in Figure 19, of the four patient care services reported as most important to respondents, (1) dental and oral health, (2) medication, (3) case management, and (4) health insurance was also high on the list of needed services that respondents reported they could not get or did not know about. This is an area of concern; further investigation into this issue is warranted.

FIGURE 19: PATIENT CARE SERVICES



Jail and Prison Release Services Recommendations

Based on survey responses, the HIV status of 17.5% of those respondents who were incarcerated was not known to jail or prison staff. In addition, 34.1% of those incarcerated did not receive HIV-related medical care while in jail or prison, and 40.3% did not receive HIV-related information or assistance upon release. These numbers represent care intervention opportunities lost. Improvement for collaboration with jail and prison systems to improve continuity of HIV care and post-release accessibility is needed.

Housing Recommendations

Overall, survey results show that most respondents did not need housing services. This is likely a limitation of the persons who responded to the needs assessment. An opportunity could be to ensure that there is a separate avenue with HOPWA to address this in the future. Most who did need services did not experience barriers to getting these services, nor did they experience barriers to taking care of their HIV that were related to their current housing situation. But for those who needed housing services, most centered around needing help to find housing and help to pay for housing and utilities. Because needed housing services for a sizeable proportion of survey respondents were unmet, with the race/ethnicity category most represented in this proportion being non-Hispanic Black, further investigation focusing on this disparity is warranted.

Lastly, the most frequently reported barriers to getting needed housing services reveal distinctly different issues. The most common barrier was not knowing where to get services, which may indicate that public awareness campaigns for this may be needed. Florida does have a HOPWA campaign (Housing for Better Health-Assistance for Persons with HIV/AIDS in Florida); however, its effectiveness and reach may need to be evaluated. The second most common barrier was that respondents did not qualify for services. This may indicate a disconnect between actual need and the program criteria currently in place to determine need. The third most common barrier to getting housing services was that the respondent was put on the waiting list. Causes for this may include limited housing availability and resources and a need for more staffing to process housing services.

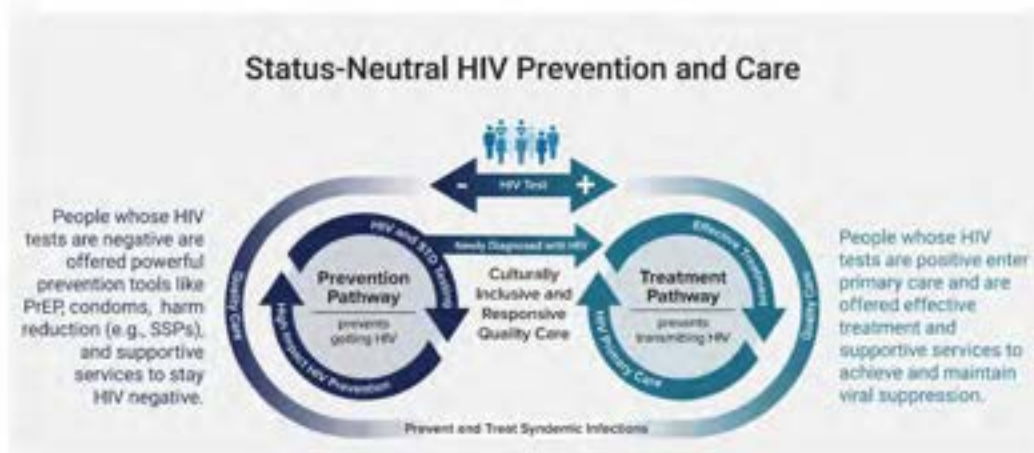
4 Situational Analysis

Florida is one of the most culturally diverse states in the nation with a vast array of residents from a wide variety of ethnic, racial, national, and religious backgrounds. The state has long attracted immigrants, particularly from Cuba, Haiti, Colombia, Venezuela, and Mexico. In fact, almost 21% of Florida's population are foreign-born persons (US Census Data - Quick Facts - Florida, 2021). With this diversity comes a higher incidence of disease burden from those in the emerging racial/ethnic minority populations from rural, socio-economically disadvantaged, and medically underserved backgrounds.

Florida continues to implement the best strategies to build a path to improve HIV prevention and care access, specifically among racial/ethnic minorities and other underserved groups. Specific demographics of racial and ethnic minorities and communities experience more barriers to accessing prevention and care services. For persons who are already diagnosed and living with HIV in Florida, activities centering around access to HIV care, including ART, retention in HIV care, and viral suppression, should be focused on such priority populations, including: Black heterosexual individuals (with added focus on Black WCBA), gay and bisexual males of all races/ethnicities, and transgender individuals of all races/ethnicities.

To further move the needle in reducing new HIV diagnoses in Florida, the Department's HIV/AIDS Section is proposing several high-impact initiatives based on the status-neutral approach to HIV prevention and care. The HIV status-neutral approach to reducing new HIV diagnoses involves initial HIV testing services as the entry point to HIV prevention and care services irrespective of a positive or negative test result. See Figure 20.

FIGURE 20: STATUS-NEUTRAL APPROACH TO HIV PREVENTION AND CARE



Source: <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>

The strategies proposed include:

1. Statewide expansion of routine HIV, HCV and syphilis screening in hospitals, emergency departments and other health care settings.
2. Increasing PrEP and PEP awareness and uptake.
3. Expansion and awareness of rapid antiretroviral therapy (ART) starts, i.e., Test and Treat.
4. Improving stigma, social determinants of health through awareness and education.
5. Improving health outcomes in aging populations with HIV.

To implement HIV prevention and care services based on the status-neutral approach, Florida will employ the initiatives and strategies which align with the EHE pillars below. The information below also highlights the strengths, challenges, and identified needs related to HIV prevention and care in Florida, the subsequent sections describe each of the following areas:

- DIAGNOSE all people with HIV as Early as Possible (Section 4.1)
- TREAT people with HIV rapidly and effectively to reach sustained viral suppression (Section 4.2)
- PREVENT new HIV transmissions by using proven interventions, including PrEP, and SSP (Section 4.3)
- RESPOND quickly to potential HIV outbreaks to get prevention and treatment services to people who need them (Section 4.4)
- Priority populations (Section 4.5)

4.1 DIAGNOSE People with HIV as Early as Possible

Routine HIV, STI, and HCV Testing in Health Care Settings

In July 2015, the Florida Legislature amended Florida’s HIV testing law to remove the need for separate informed consent prior to HIV testing in health care settings. In September 2016, Rule 64D-2.004, Florida Administrative Code (FAC), was adopted to implement the amended HIV testing law. The intent of this amendment was to simplify routine HIV testing in health care settings, improve the identification of new or existing HIV infections, and help to normalize HIV testing as a routine component of primary health care. There was no change in the law regarding non-health care settings. These changes align Florida more closely with the CDC’s HIV Screening Recommendations.⁴⁴

Since 2015, the Department, including CHDs, has developed a collaborative model for routine communicable disease screening with the Gilead Sciences’ Frontlines of Communities in The United States (FOCUS) initiative. The FOCUS program is a public health initiative that enables partners to develop and share best practices in routine blood-borne virus (HIV, HCV, HBV) screening, diagnosis, and linkage to care in accordance with screening guidelines promulgated by CDC, the U.S. Preventive Services Task Force (USPSTF), and state and local public health departments. FOCUS funding supports HIV, HCV, and HBV screening and linkage to the first appointment after diagnosis. FOCUS partners do not use FOCUS awards for activities beyond linkage to the first appointment.

Florida FOCUS partners include FQHCs and large hospital systems. The Department's public-private partnership with Gilead's FOCUS initiative began in 2016 with the establishment of the very first site—Homestead Hospital in Miami-Dade County. A Department DIS or Linkage to Care Coordinator works with each FOCUS emergency department partnership to assist with linkage to care and other services. The partnership with Homestead was expanded to include syphilis screening and the Department supports the cost of these screenings.

Currently, the Florida FOCUS program has 22 partners across the state (see map in Figure 21) and in 2021, institutions that have implemented the FOCUS program conducted 156,288 HIV tests (1.2% positivity), with 86% linked to care. Additionally, 74,910 HCV tests (4.6% HCV Ab positivity) were conducted and 75% linked to care. In 2022, Florida FOCUS projects plan to complete 187,000 HIV tests and 104,500 HCV tests and commits to onboard facilities to also conduct syphilis testing.

There is no monetary relationship between the Department and Gilead Sciences and as the partners age out of their relationship with Gilead, the Department has developed a cost-sharing model to continue to support testing and linkage to care at these sites by assisting with the costs of testing and reagents.

Current efforts to support expansion include the inclusion of this initiative as an objective in the State Health Improvement Plan where, by December 31, 2026, the Department and external partners aim to increase the number of emergency room or acute care hospitals that are conducting opt-out HIV screening, routine HCV screening, and syphilis testing with a smart screen algorithm from 1 (2021) to 15. Figure 21 visualizes 2022 partner reach for the state of Florida.

FIGURE 21: FLORIDA PARTNER REACH IN 2022



Gaps still exist in the implementation of routine HIV, STI, and HCV testing in hospital emergency departments (EDs) and primary health care settings. Accounts of individuals seeking medical care in hospital EDs for symptoms akin to acute HIV infection are frequent, and, oftentimes, persons visit the ED several times before being tested for HIV, diagnosed, and linked to care. Approximately 7 in 10 PWH saw

a health care provider in the 12 months prior to diagnosis and failed to be diagnosed.⁵⁹ Additionally, reimbursement by Medicaid for HIV testing in hospital EDs is a challenge as we move forward with routinizing testing in EDs; in some cases, testing may not be covered unless deemed medically necessary or clinicians may be less likely to bill when they frequently receive rejections.

From June 2019 to April 2020, the University of Miami AIDS Education and Training Center (UM-AETC) performed outreach to health care facilities in the highest HIV incidence areas throughout Miami-Dade and Broward counties to conduct assessments and academic detailing. Facilities included community health centers and primary care and internal medicine clinics. Assessments examined the status of health care facilities in implementing routine HIV testing and PrEP provision in accordance with CDC guidelines and in implementing or extending third-party billing for routine HIV screening. Less than a quarter (20%) of the health care provider practices reported offering routine HIV screening services to all patients ages 13 to 64, regardless of symptoms or demographics. Of the remaining clinics, 28.6% reported that they test patients based on symptoms and demographics and 30% reported testing only those who requested an HIV test. Among barriers to rapid HIV testing, most practices indicated that they never considered rapid HIV testing as a service (30%). Other barriers to providing rapid HIV testing were the perceived need to obtain consent, staff lacking training for administering and billing, the concern that testing would not be reimbursed by payors, and uncertainty about the implementation of in-office rapid testing.

To eliminate these barriers, the Department has done or will do the following:

- Conducted a Routine Screening Expansion Roundtable, which took place May 26, 2022. The purpose of this meeting, hosted by the Lieutenant Governor, was to bring together a wide variety of external stakeholders to discuss how to expand routine opt-out HIV, syphilis, and HCV screenings in EDs and acute care settings and move toward ending these syndemics in Florida.
- Update Chapter 64D-3, FAC, to include the mandatory reporting of all HIV test results. 64D-3 is titled “Control of Communicable Diseases and Conditions which may Significantly Affect Public Health”. Currently, providers and laboratories are required to report only positive HIV test results to the Department.
 1. Improve the reporting and surveillance of stage zero or acute diagnoses to understand the burden of recent transmission for intervention and prevention.
 2. Understand the scope and total HIV testing being conducted in Florida and calculate a state positivity rate that can be used to drive future interventions and prevention efforts.
- Conduct an assessment on current Florida FOCUS partners to understand who is aging out of the program, and when, and use current funding to support testing and linkage to care efforts.
- Work with directly funded RWHAP Part A programs in the six metropolitan areas of the state to collaborate on supporting routine screening efforts in those areas.
- Collaborate with AHCA to develop a Dear Colleague letter from Medicaid to clarify reimbursement support for routine HIV and HCV screening in hospital EDs.

- Explore leveraging Opioid Settlement Funds to help support the expansion of medication-assisted treatment pathways in hospitals.

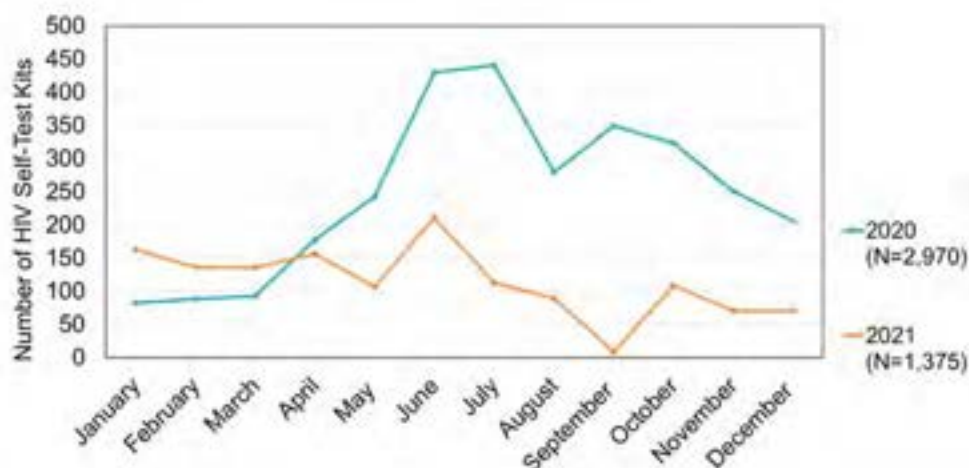
In addition to the FOCUS program, the HIV/AIDS Section also has a contract funded through federal grants with the University of Central Florida HealthARCH program that aims to assess the readiness of health systems in the seven metropolitan counties of high-HIV burden and onboard them to modify their electronic health records and offer routines screening for HIV.

Rapid HIV Testing through Non-Traditional Settings and Modalities

Considering Florida's percentage of PWH unaware of their status (14%), increased access to rapid HIV testing is required. Feedback received through community engagement indicated a need for expanded use of mobile testing units, HIV self-test kits, social and sexual network screening, and testing at non-traditional settings and hours. The Department currently supports more than 1,600 registered HIV testing sites around the state that conduct targeted HIV testing in non-health care settings in areas and communities with high HIV incidence. The Department supports these sites with rapid HIV test kits at no cost to the site. Sites must register with the Department and submit HIV testing data as criteria to receive rapid HIV test kits. In 2021, the Department conducted 73 rapid test trainings and certified 1,032 individuals to perform rapid HIV testing. The Department will continue to conduct rapid HIV testing trainings to certify individuals to perform rapid HIV testing in non-health care settings.

In June 2019, the Department began an HIV self-test kit distribution program to provide rapid HIV self-test kits to individuals, at no cost, and through an online request form (available at [KnowYourHIVStatus.com](https://www.knowyourhivstatus.com)). This program was particularly important as COVID-19 closures and restrictions fueled increases in the demand for alternative options for HIV testing. As shown in Figure 22, monthly requests for HIV self-test kits rose sharply beginning in April 2020 and continued through July 2020. Monthly requests tapered slightly from September through December 2020. In 2021, monthly requests for HIV self-test kits decreased but are still higher than pre-COVID levels. Since the program's inception, more than 4,600 rapid HIV self-test kits have been distributed. The HIV/AIDS Section continues to look for opportunities to collaborate, especially with internal Department partners such as the Bureau of Tobacco Free Florida to advertise the availability of free, in-home testing kits.

FIGURE 22: HIV SELF-TEST KITS DISTRIBUTED THROUGH KNOWYOURHIVSTATUS.COM, FLORIDA, 2020 vs. 2021



Additional funds will be needed to support and sustain the expansion of the in-home and point-of-care HIV testing program. Concerns around linkage to care for persons using HIV self-test kits exist and mechanisms will need to be developed to ensure appropriate follow up and timely linkage to care.

Partner Notification Services

Per section 384.26, F.S., the Department is the only entity authorized to perform HIV and STI partner services and notification, and these activities are carried out by trained DIS. While Florida maintains a mature and robust HIV/STI partner services program, opportunities to strengthen the DIS workforce and update partner notification mechanisms exist. Extensive training needs, high caseloads, and low staff retention not only contribute to high DIS turnover rates, averaging 40% annually over the past five years, but also impact the effectiveness of partner elicitation. Numbers of claimed partners have decreased as numbers of anonymous partners reported through mobile dating applications has increased, creating challenges for intervention. In 2017, the Department piloted the use of mobile dating applications as an added partner notification tool for persons exposed to HIV/STIs, with marginal success. Additional strategies are being explored to allow for HIV partner notification via text messaging or phone calls. Since summer 2022, the Bureau of Communicable Diseases has been working to secure approval to allow for text messaging by the DIS workforce as a tool to initiate confidential first contact with clients and enable DIS to conduct partner services for STI/HIV partner notification.

Florida is unique in that there are now four qualified staff to teach the week-long Passport to Partner Services training. In 2022, the STD Section will enter a contract with the University of South Florida to establish a learning academy and completely revamp the existing core training curriculum for DIS and STD program supervisors.

Billing and Reimbursement

In April 2013, the USPSTF gave routine HIV screening of all adolescents and adults, ages 15 to 65, an “A” rating, aligning the rating with the CDC’s HIV screening guidelines. The “A” rating has further implications given the ACA, which requires or incentivizes new private health plans, Medicare, and Medicaid to provide preventive services rated “A” or “B” at no cost to patients. Challenges exist with reimbursement by Medicaid for routine HIV screening in hospital EDs and some facilities report only being able to reimburse for those tests deemed medically necessary. As the state moves forward with expanding routine HIV screening in hospital EDs, more work is needed to ensure these facilities have the ability to bill and receive reimbursements from Medicaid for these screenings.

Billing third-party insurance was reported as a barrier to billing and reimbursement by almost one-third of providers assessed by UM-AETC and was the most prominent barrier encountered. Most clinics reported staff lack of knowledge regarding billing and coding and corporate decisions to be the greatest barriers to implementing routine HIV screening. Other notable barriers were lack of time and staffing capacity to perform billing, challenges in contracting with third-party payors, and difficulty managing multiple contracts with third-party payors.

Stigma

Stigma around HIV affects health care-seeking behavior. Stigma related to HIV/STI screening can occasionally lead individuals to state they do not possess insurance coverage for the service. Similar confidentiality concerns exist for young people who receive health insurance coverage through their parent or guardian (i.e., explanation of benefits). Fear of disclosure of confidential health information can deter youths and adults from seeking out HIV/STI screening and PrEP services. HIV testing locations that are associated with HIV/AIDS service organizations are also perceived as more stigmatizing, with clients citing additional disclosure concerns. There is a need for integration of HIV testing locations with other health care services and screenings to minimize stigma.

The MMP surveillance system also conducts a self-reported survey to understand the various types of stigmas PWH have experienced, including anticipated, enacted, and internalized HIV-related stigma using a 10-item scale ranging from 0 (no stigma) to 100 (high stigma) that measures four dimensions of HIV stigma: personalized stigma since HIV diagnosis, current disclosure concerns, current negative self-image, and current perceived public attitudes about people living with HIV. Analysis of the 2015–2020 Florida MMP data found that females (n=44) reported experiencing a higher level of stigma compared to males (n=32). Additionally, thirty-nine (n=39) transgender individuals reported experiencing stigma.

Thirty-seven (n=37) Black persons reported experiencing HIV-related stigma, compared to White (n=32) and/or Latino (n=32) survey respondents.

Thirty-eight (n=38) heterosexual people reported experiencing HIV-related stigma, compared to bisexual survey respondents (n=36).

Lastly, it was found that those ages 18–29 experienced a higher level of stigma (n=43) than ages 40–49 (n=36), and ages 30–39 (n=35). It was also found that ages 50 and higher experienced the lowest level of stigma (n=32).

Findings from a Department project with the University of Florida ⁴³ (a Bayesian spatial-temporal analysis of racial disparities in HIV clinical outcomes and a pilot stigma intervention protocol for people living with HIV in Florida) indicate that disparities in immune restoration and viral suppression vary by county. Identification of counties where these disparities are most severe provides useful information for the Department and other decision makers to reduce racial disparities in HIV clinical outcomes by implementing targeted interventions, with the ultimate objective of achieving HIV elimination goals in Florida. Stigma remains a key barrier to care engagement and ultimately achieving viral suppression and immune restoration. The preliminary work in this project outlines the development and validation of an updated measure of stigma, which could be implemented to better monitor stigma and its impacts, and an intervention to improve patient-provider communication about HIV-related stigma. The intervention was generally well received by participants and several potential routes of dissemination were identified.

4.2 TREAT People with HIV Rapidly and Effectively to Reach Sustained Viral Suppression

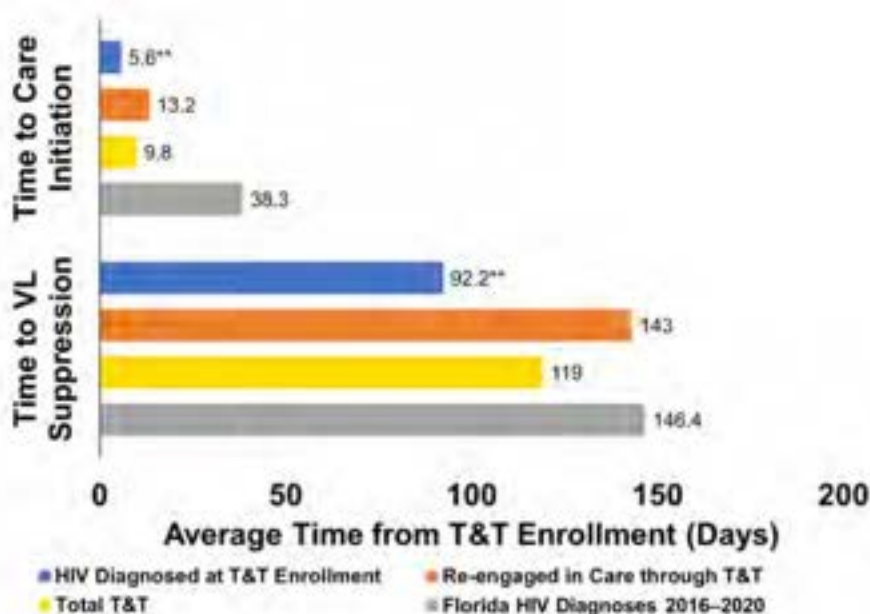
Access and adherence to HIV treatment is important to promote optimal health outcomes for PWH and harnessing the benefits of “treatment as prevention”—when someone takes their HIV medications as prescribed and the amount of HIV in the body is kept at such a low level, they reach viral suppression. Those virally suppressed essentially have no risk of sexually transmitting HIV to others. Treating PWH rapidly after diagnosis will help PWH to achieve and maintain viral suppression, which is part of the current HIV treatment guidelines and is a major pillar in EHE. According to the CDC, approximately 80% of new HIV transmissions occurring annually are from persons who are not receiving HIV-related care and medications. One issue is that the availability of treatments is not evenly accessible or distributed, compounding health disparities and the social determinants of health that fuel further transmission of HIV in the community. This represents a need for expanded access points, hours of operation (to include non-traditional hours and locations) and telehealth capabilities to reach persons with transport or other access issues. Other challenges exist around identifying and re-engaging PWH who are not in care to ensure medical adherence and viral suppression. All areas of the state have dedicated the Department’s linkage staff to not only link persons newly diagnosed with HIV but also identify PWH currently not in care and reengage them into HIV care and treatment.

Test and Treat Program and Rapid Access to ART

Since 2016, Florida has had a robust rapid access to ART program called Test and Treat (T&T). This program offers patients newly diagnosed with HIV, as well as those who have been lost to care and are returning to care, an opportunity to obtain expedited practitioner office visits, labs, and ART, combined with a support system of retention-in-care specialists, to reduce barriers to care engagement. In this

expedited “red-carpet” scenario, PWH have immediate access to a medical provider who can start them on ARV (antiretroviral) medications immediately. T&T has assisted in engaging individuals in care at a much faster rate than those not diagnosed through the program. Since the program’s inception, Florida’s T&T program has enrolled more than 7,374 clients statewide (comprising of 3,342 newly diagnosed individuals and 4,032 previously diagnosed individuals returning to care). Compared to persons diagnosed in Florida who are not enrolled in T&T (see Figure 23), it takes on average 38.3 days to initiate treatment compared to 5.6 days for those newly diagnosed through T&T. Furthermore, the average time to achieve viral suppression is much lower for those who initiate treatment rapidly through T&T—92.2 days compared to 146.4 days for those not engaged in T&T. Wider expansion and adoption of this strategy is needed to impact linkage, retention, and VL suppression rates. Almost all of Florida’s 67 counties have a HRSA-designated Health Professional Shortage Area (areas categorized as rural, partially rural, or non-rural), which represents a need to recruit and train more primary health care and dental service providers. Additionally, needs exist for expanded access points, hours of operation (to include non-traditional hours and locations), and expanded telehealth capabilities to reach persons in rural areas. There is also a need for increased access to treatment for persons diagnosed and living with co-occurring HCV/HIV.

FIGURE 23: TIME FROM T&T ENROLLMENT TO CARE INITIATION AND VL SUPPRESSION, MARCH 2016–DECEMBER 2020, FLORIDA



Below are activities that can help overcome the challenges related to T&T:

- Address gaps in the level of knowledge about the RWHAP system of care among non-RWHAP network health care providers. More education and training are needed for providers on the services available to clients (including ADAP), eligibility requirements, and access points in their service regions.

- Address the need for more training and resources for health care providers related to trauma-informed care (TIC) and intersectionality. Past and current traumatic experiences have an impact on whether a person acquires HIV, is diagnosed, is linked to care, is retained, and maintains viral suppression. Because HIV disproportionately impacts marginalized communities, it is important to consider intersectionality in concert with TIC.
- Intersectionality is a framework for conceptualizing a person, group of people, or social issue as affected by several discriminations and disadvantages; it considers people’s overlapping identities and experiences to better understand the complex prejudices they may face. Examples of social categorizations that inform identity include race/ethnicity, class, gender, sexual orientation, poverty and homelessness, and substance use.

Housing

Many Floridians experience homelessness or unstable housing, which presents a barrier to wellness for PWH as well as those at increased risk for HIV acquisition. Stable housing is closely linked with and is often one of the main determinants affecting HIV health outcomes. Florida’s Council on Homelessness annual report showed that prior to the emergence of the COVID-19 pandemic, homelessness in Florida has declined steadily from 57,551 identified as homeless in January 2010 to 28,328 in January 2020—a 50.8% reduction in homelessness over the last 10 years. In 2021, the Florida Housing Coalition reported Florida having the third-highest homeless population of any state in the nation, with 27,640 people living in homeless shelters and on the streets. It is important to consider the spectrum of housing instability for PWH—traditional definitions of homelessness or unstable housing—but also takes into account situations where individuals and families are residing in temporary residences (e.g., motels), staying with friends or family, or “couch-surfing.” While the federal Fair Housing Act makes it illegal to discriminate against PWH in the provision of housing, consumers frequently cite discrimination, fear of disclosure, and stigma as barriers to safe and affordable housing.³⁵

To meet the housing needs of low-income PWH and their families, the Department administers the HOPWA program. The HOPWA program is a federally-funded initiative through HUD that helps people with HIV/AIDS maintain stable housing and have access to treatment and support services—which can all lead to better health. In Florida, through the State HOPWA Program, 11 regional agencies and 6 cities deliver HOPWA-funded housing services. In addition to the state HOPWA Program, there are 6 non-state funded city HOPWA programs administered locally.

The Department oversees the state HOPWA program and contracts with local community organizations and CHDs as project sponsors to provide HOPWA services in 11 Ryan White Part B consortium geographical areas and six cities throughout the state. Six non-state funded cities redesignate their funds to the state for distribution and fund management by the state HOPWA program. However, the re-designated funds are to be spent in the Eligible Metropolitan Statistical Areas (EMSAs) on housing services in those areas, not the state at large. These cities (counties) include City of Palm Bay (Brevard), City of Cape Coral (Lee), City of Lakeland (Polk), City of Sarasota (Sarasota), City of Port Saint Lucie, (Saint Lucie), and City of Deltona (Volusia).

Additionally, six cities or EMSAs receive and retain management of HOPWA funds they receive directly from HUD; the Department does not manage the HOPWA programs for Jacksonville, Tampa, Orlando, West Palm Beach, Fort Lauderdale, and Miami-Dade. The Florida State HOPWA Program serves those areas of the state that do not directly qualify for HOPWA funding. Between 2020 and 2021, over 2,034 individuals received HOPWA services to ensure they could access and maintain a stable living environment for themselves and their immediate families. An assessment of the state's HOPWA program is needed to identify gaps and barriers in order to make changes to the program in 2023.

With EHE funding received directly through HRSA, RWHAP Part A programs are also exploring ways to leverage funds to assist with paying for housing and rental assistance for persons with HIV.

Patient and Peer Navigation

HIV health navigators (both patient and peers) have a positive impact on the health and well-being of people living with HIV. Patient navigation programs for persons newly diagnosed with HIV or those previously diagnosed and returning to care have consistently proven to be efficacious in ensuring individuals get linked to and are retained in treatment. The lived experiences of peers, “near-peers,” and community health workers are drivers for meeting the diverse needs of newly diagnosed individuals who may be overwhelmed by the thought of entering a health care system as complex as the HIV system of care. In addition, peer navigators act as a support line for persons newly entering or re-entering the care system, providing non-judgmental guidance. There is also a need for expanded patient or peer navigation among persons diagnosed with HCV. Expanded patient navigation is also needed for HIV-negative partners of PWH seeking services. Florida plans to establish and disseminate a statewide peer certification training program.

People with Co-Occurring HIV and Hepatitis C

The current opioid and crystal methamphetamine epidemics are fueling the number of co-infections. It is estimated that 60 to 90% of people who contracted HIV from intravenous drug use also have HCV.³⁶ People living with HCV often have difficulty accessing HCV treatment and related health care. In recent years, there have been improved HCV treatments that can cure HCV in as little as 8 to 12 weeks. ADAP clients living with HCV have access to assistance with HCV treatments. The ADAP formulary was updated in 2017 to include HCV treatments without the need for prior authorizations. Between 2020 and 2021, the ADAP assisted over 650 ADAP clients with access to HCV treatment supported by ADAP. There are opportunities for more uninsured HCV patients to be treated at some free clinics, FQHCs, private clinics, and a limited number of CHDs, but many patients are unaware of where to go when they are first diagnosed.

Expanded Pharmacy Benefits Manager (PBM) for Uninsured or Underinsured ADAP Clients

Clients enrolled in ADAP realize important health benefits. ADAP provides access to U.S. Food and Drug Administration (FDA)-approved medications to low-income individuals with HIV who have limited or no coverage from private insurance, Medicaid, Medicare, or the federally facilitated Marketplace®. About

53% of ADAP clients are uninsured or under-insured and receive medication assistance through the ADAP direct-dispense program. These clients receive assistance with approved ADAP formulary medications directly from the program's contracted pharmacy network. The remaining 47% of ADAP clients obtain access to ADAP formulary medications through supported health insurance plans. These clients are enrolled in the ADAP insurance program and receive assistance with insurance premiums as well as prescription co-pays and deductibles associated with ADAP formulary medications. The ADAP aims to achieve at least 95% of clients who achieve viral suppression regardless of their insurance status. For those in the ADAP insurance program, approximately 97% achieved viral suppression in 2021; however, for those enrolled in the ADAP direct-dispense program, there is a clear disparity with only 89% achieving viral suppression in 2021.

In October 2022, ADAP implemented a PBM network of pharmacies to its uninsured direct-dispense client population. With this initiative, ADAP will increase equity among insured and uninsured clients by providing expanded access to medications through a network of independent pharmacies and commercial chains. The PBM will provide the network of 340B pharmacies and manage the claims using a replenishment model in which direct-dispense clients can access ADAP medications statewide with the main goal of increasing access points and convenience for ADAP clients in Florida. The PBM pharmacy network will ensure access to ADAP formulary medications for enrolled clients served in the direct-dispense in 24 hours. ADAP eligibility files are shared with the contracted PBM entity multiple times throughout the day to ensure newly enrolled clients can access ADAP services during the same day they enroll in the program. The PBM entity will assist clients with their prescriptions by reviewing use data, addressing medication adherence issues, and collaborating with prescribers to resolve incorrect regimens and drug interactions. The PBM entity will also develop and provide training to case managers and health care providers, develop educational materials for providers and clients, and maintain a program information website for providers and clients.

Case Management

Case management plays a critical role in the care coordination of PWH as it assists patients in accessing services, identifying needs, and addressing gaps in services. Case managers also perform important functions such as ensuring rapid access to ART; providing medication samples, where appropriate and feasible; and determining eligibility and enrollment into services. Case manager caseloads are high and continue to increase, impacting the ability to effectively manage complex issues, such as providing medication adherence counseling, helping navigate the health care system, and staying informed and educating PWH on available health care coverage plans. There is a need for additional resources and training to support the case management workforce.

Injectable ART

In May 2021, Florida's ADAP added Cabenuva, the first long-acting injectable antiretroviral to the formulary. Uninsured and insured clients are able to access the medication with coordination between their practitioner's office and a specialty pharmacy. The program provided a series of technical

assistance presentations to providers, staff, and case managers to increase awareness and provide best practices for client adherence. Over 500 ADAP clients have accessed Cabenuva since its addition to the formulary in 2021.

Minority AIDS Initiative (MAI)

As shown in Figure 5 (Section 3.1), Florida continues to experience disparities in HIV diagnoses among adults, despite an annual decrease in the HIV diagnosis rate among Black persons in the past five years. MAI seeks to address the gaps in medical care capacity and increase the accessibility and availability of HIV medical care and related HIV services in minority communities through outreach and education. MAI funds are received from HRSA and are designed to improve linkage and reengagement to comprehensive care and ADAP for low-income racial and ethnic minorities who are living with HIV/AIDS. The Department receives the MAI funding allocation through the state's RWHAP Part B grant and these funds support six community-based providers in Florida counties with the highest HIV incidence. In FY 2021, Florida's funded MAI providers enrolled 1,033 clients, of which 64% were Black and 32% were Hispanic/Latino, a 28% increase from the previous fiscal year which saw 806 clients enrolled, of which 62% were Black and 31% were Hispanic/Latino. Many participants are individuals who had a previous HIV diagnosis but have fallen out of care and have not received care for more than six months. The Department's HIV/AIDS Section will continue to look for ways to strengthen the network of MAI providers with the development and release of the next funding solicitation.

Correctional Settings Initiatives

The Department continues to support treatment and prevention services for incarcerated individuals living with HIV. Persons with HIV in prisons and jails are disproportionately represented compared to the general population. The Department addresses this through the following corrections initiatives: the Pre-Release Planning Program (PRPP), the Peer Education Program (Peer-Ed), and Jail Linkage Programs (JLP). The Department maintains two interagency agreements with the Florida Department of Corrections (FDC) to provide PRPP and Peer-Ed.

JLP is concentrated in the higher populated metropolitan areas in Florida. Fourteen CHDs work to provide services to at-risk inmates and PWH inside the county jails. JLP functions include HIV testing and education in the facility, linkage to care following release from jail, linkage to support services, and follow up with individuals for up to three months following release to ensure medication and treatment adherence. In 2021, approximately 1,755 inmates were tested for HIV, of whom 31 had a positive result.

PRPP provides services to inmates with HIV who are preparing to return to their communities. In 2021, the PRPP provided linkage services to 644 inmates, of whom 305 were linked to care and 160 (52%) kept their appointments upon returning to their community. Recidivism, housing, and transportation are recurring barriers to recently released individuals accessing medical care. In addition, FDC conducts peer education train-the-trainer programs for select inmates at FDC's Central Florida Reception Center and Florida Women's Reception Center (the two largest reception centers in the state). In 2021, 53 inmates completed training to become inmate peer educators and conducted 146 peer-led HIV/STD prevention

and risk-reduction sessions to approximately 5,170 inmates. As a result of the peer education training session, 266 inmates requested an HIV test upon completion.

Expansion of Telehealth

The HIV/AIDS Section began offering telehealth (TH) services in January 2018. The TH program provides on-demand and scheduled PrEP, PEP, same-day or rapid ART and HIV and STD primary care evaluation and treatment visits. The HIV TH service is available to all 67 CHDs. As of May 2021, the Department is averaging over 100 services per month and has provided TH services to 1,604 CHD patients. In 2020, the Department launched a TelePrEP program where patients can access PrEP services through the CHD system via a dedicated telehealth practitioner team. Further credentialing of the HIV TH team of three providers in other CHDs is occurring to allow for these services to be provided by the team. Florida plans to expand and promote the use of telehealth and other new technologies to help alleviate barriers and improve access to HIV prevention and care services.

Insurance Coverage and Affordable Health Care

Florida remains a non-Medicaid expansion state and from 2015 to 2020, an average of 12.7% of people in Florida did not have health insurance coverage (compared to 8.7% for the U.S.).³⁸ The ACA has enabled more individuals to enroll in health insurance but some, particularly those who live just above the federal poverty level (i.e., the working poor), are still unable to afford the cost of coverage. Individuals who fall into this category and need health care are often forced to make difficult choices based on competing life priorities.

As a Part B grant recipient through the RWHAP HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87), the Department administers the ADAP program. Florida ADAP provides FDA-approved medications to low-income PWH between 0 and 100% FPL who have limited or no health coverage from private insurance, Medicaid, or Medicare. ADAP assists with some premiums and with out-of-pocket costs for drugs on the program formulary. Out-of-pocket costs can be deductibles, co-pays, coinsurance, or similar costs for Medicare Part C or D. Health insurance assistance funded through ADAP is part of ADAP, not a separate program. ADAP provides premium assistance for ACA Marketplace® plans for people with HIV whose income is between 75 and 400% of the FPL. The strategy of enrolling these clients in the direct-dispense program is more cost-effective than enrolling them in the insurance program. Clients in the direct-dispense program have access to the RWHAP system of care, which includes access to outpatient ambulatory health services, case management, and other allowable services. ADAP clients enrolled in the direct-dispense program achieved a VL suppression rate of 89%.

In addition, approximately 93% of ADAP clients enrolled in the program for at least six months have undetectable HIV VL, indicating their HIV disease is under control and unlikely to be spread sexually. The ADAP program aims to achieve at least 95% of clients enrolled in the program at least 6 months who achieve viral suppression regardless of their insurance status. For those in the insured program, approximately 98% achieved viral suppression in 2021, however, for those not insured, there is a clear disparity with only 89% achieving viral suppression in 2021. The approach that Florida ADAP takes

constitutes a close working relationship between the ADAP state health office team, Florida’s 67 CHDs, and 3 contracted statewide service providers: CVS Caremark for PBM services for ADAP insured clients, Magellan Rx for PBM services for ADAP uninsured and underinsured clients and Broward Regional Health Planning Council for Insurance Benefits Management (IBM) services for clients seeking enrollment and premium assistance with health insurance coverage. The Department’s ADAP is operationalized at the CHDs, where ADAP staff assist clients with enrollment by ensuring eligibility determinations and re-certifications. ADAP staff at CHDs use the ADAP database, called Provide, to upload client eligibility documentation. Eligibility files are shared with the contracted PBM and IBM providers multiple times throughout the day to ensure newly enrolled clients can access ADAP services during the same day they enroll in the program. Provide also helps ADAP staff keep track of their client caseload; the system helps identify clients who should be enrolled in the direct-dispense or insurance program based on the information presented during their enrollment. CHD ADAP staff also work closely with the provider community and RWHAP case managers to coordinate efforts with clients to promote medication adherence and retention in care.¹⁶

Additional Unmet Needs of Persons with HIV

Further work is needed to address the unmet needs of PWH identified through various mechanisms—including needs assessment surveys and Florida’s MMP project. The MMP is a surveillance system designed to understand the met and unmet needs of PWH. Among those surveyed in Florida from 2015 to 2020, the most common unmet need was access to dental services (24%), followed by shelter or housing services (14%), SNAP or WIC (12%), and meal or food services (9%). Other unmet needs included mental health services (8%) transportation assistance (8%), HIV case management services (8%), HIV peer group support (6%), medicine through ADAP (4%), and patient navigation services (5%).

4.3 PREVENT New HIV Transmissions by Using Proven Interventions, Including PrEP and Syringe Services Programs (SSPs)

Access to PrEP and PEP

The use of ARV medications to prevent HIV transmission in persons at risk for acquiring HIV is an effective prevention tool. Part of CDC’s HIP approach includes PrEP; in 2014, CDC issued clinical PrEP guidelines for health care providers. CDC recommends PrEP as a prevention tool for persons at increased risk for HIV: persons in sero-different relationships, gay and bisexual men who have sexual partners of unknown HIV status, and PWID. As of December 2018, the Department’s CHDs in each of Florida’s 67 counties are providing PrEP services (counseling, medications, follow-up testing) with support from state funding. CHDs provide PrEP primarily through the STI and family planning clinics and medication is provided at no cost to the client (repeatedly) through the state’s supply of medication. Since the launch of the Department’s PrEP drug assistance program in 2018 over 11,319 CHD clients have received PrEP medications. Current challenges to PrEP delivery through the CHDs include clinician

and staffing shortages and limited capacity for clinicians in smaller CHDs (e.g., fewer clinicians performing multiple duties in the clinic).

The Department’s publicly funded PrEP drug assistance program only accounts for a small portion of all PrEP services statewide. Numerous private-sector partners—including private physicians, FQHCs, community health centers, sexual health clinics, community-based organizations, HIP providers—are screening, prescribing, and maintaining people on PrEP throughout Florida. Also, over the past two years, HRSA has funded approximately 22 FQHCs through their EHE Primary Care HIV Prevention funding opportunity for health centers to expand access to medication to prevent HIV (including PrEP and related services), connect people to care, and ensure care services are well coordinated. According to the latest data available on AIDSVu, Florida has seen an increase in the rate of PrEP users per 100,000 population since 2016; as of 2021, the rate was 226 per 100,000. Florida now ranks third among states and jurisdictions with the highest rate of PrEP users, behind Washington D.C. and New York. PrEP data from AIDSVu reflect the number of people prescribed PrEP in a calendar year. AIDSVu uses data from a database that contains anonymized individual-level prescription records collected electronically from U.S. retail pharmacies, traditional pharmacies, specialty mail-order pharmacies, long-term care facilities, and other pharmacies (e.g., in-hospital pharmacies, HMO pharmacies).⁴⁹

Disparities in the uptake of PrEP and PEP still exist among key priority populations (e.g., Black, and Hispanic males and females, and transgender individuals). Taking a sexual history and discussing sexual health with patients should be a routine practice for primary health care providers; however, limited time for office visits and the reluctance of some providers to discuss sex with their patients presents barriers to routinization. There is a need for increased access to PrEP services in non-traditional settings and through innovative practices. PrEP delivery via telehealth (or “TelePrEP”) was recommended by community groups, clients, and providers as a mechanism by which people facing transportation and employment barriers could access PrEP and increase adherence to follow-up testing. Partnerships with retail pharmacies and clinics and through mobile applications may assist in bridging gaps in PrEP and PEP access. In 2020, by leveraging the existing state telehealth practitioner team, the Department launched a TelePrEP program where patients can access PrEP services through the CHD system.

Currently, federal funding requires the implementation of PrEP and PEP services but does not allow states to allocate funding for medications and limitations for covering associated clinical costs exist. While there are patient assistance programs available to offset the cost of medications, medical visits, and lab testing costs still pose a significant barrier to already disproportionately impacted populations. Clients receiving PrEP have reported that returning every three months for follow-up testing is a barrier to remaining adherent; and in rural and semi-rural areas of the state, transportation to follow-up medical appointments can present further challenges. Clients also cited the cost of medical visits and lab tests and not being able to get time off from work for appointments as barriers to PrEP initiation and maintenance. As a result, more clinics and pharmacies have started to offer non-traditional and after-hours services to increase access to PrEP and PEP. In late December 2021, Apretude (cabotegravir extended-release injectable suspension) received FDA approval for HIV PrEP. Injectable PrEP provides a new option to prevent HIV that does not involve taking a daily pill—which for some people presents

challenges. In summer 2022, the Department initiated a pilot project to test the feasibility of delivering Apretude through CHD clinics. Three CHD clinics (Alachua, Hillsborough, and Miami-Dade) were chosen to participate in the pilot project and represent geographic areas with varying HIV incidence.

In 2019, the USPSTF issued a Grade A recommendation for offering PrEP with effective antiretroviral therapy to persons at increased risk of HIV acquisition. Under the ACA, most private insurance plans must cover preventive services with an “A” or “B” recommendation from the USPSTF without copays or deductibles. This means that at least one PrEP option should be available at no cost to qualifying individuals on these plans.

Increased public and private partnerships are needed to fill gaps in access to PEP services. Many CHD clinics have traditional hours, making them ill-suited as delivery points. Access to PEP is needed quickly after exposure to HIV (in 72 hours) to prevent seroconversion. Clients requesting PEP tend to do so more often during evening hours and weekends. Partnerships with retail pharmacies, rape crisis centers, and sexual assault nursing teams in hospital EDs are needed to expand access points to PEP.

Substance Use Disorders, Syringe Service Programs, and Health Care Access

The past-year prevalence of substance use disorders among adults in Florida was 14.8% in 2019–2020, and the prevalence of needing but not receiving treatment for substance use was 7.5%. According to the Florida Association of Managing Entities, 5,117 adults were added to a waitlist for substance use services in FY 2020–2021.⁵⁰

The most recently published prevalence rates for various substances and substance use disorder among young adults (ages 18–25) and adults in Florida are presented in Table 9 below:

TABLE 9: PREVALENCE OF SUBSTANCE USE AND SUBSTANCE USE DISORDER IN THE PAST YEAR, IN FLORIDA BY ADULT AGE GROUP (2019–2020)

	18 and Older	18–25	26 and Older
Marijuana Use	16.6%	32.9%	14.5%
Cocaine Use	1.7%	4.4%	1.4%
Methamphetamine Use	0.6%	0.6%	0.6%
Heroin Use	0.2%	0.1%	0.2%
Prescription Pain Reliever Misuse	3.6%	4.8%	3.4%
Alcohol Use Disorder	9.5%	13.6%	9.0%

According to FDCF, 2020 Florida Youth Substance Abuse Survey State (FYSAS) report, substance use among students in Florida continues to decline. Among middle and high school students in Florida, between 2010 and 2020, the prevalence of lifetime alcohol use decreased from approximately 52% to 35% and the past-30-day prevalence of alcohol use decreased from 29% to 15%. Regarding marijuana use, the prevalence of lifetime and past-30-day marijuana use among middle and high school students also decreased between 2010 and 2020. Lifetime prevalence decreased from approximately 24% to 20% and past 30-day prevalence decreased from 13% to 11%. According to estimates from the 2022 FYSAS, among high schoolers the lifetime prevalence is 2.8% for opioid misuse, 4.1% for stimulant misuse, and 5.7% for opioid and stimulant misuse.⁴⁵

Section 381.0038(4), F.S., or the Infectious Disease Elimination Act (IDEA), was passed by the Florida Legislature in 2016 and in 2019, the Governor signed a bill amending IDEA to allow county commissions to authorize syringe exchange programs in their county by way of county ordinance. The IDEA legislation mandates that SSPs operate a one-to-one exchange; provide or make referrals for HIV and HCV testing; provide access to substance use prevention, education, and treatment; and provide emergency opioid antagonist kits (naloxone kits). A CDC Determination of Need for Florida for SSPs was approved on February 1, 2020. The CDC Determination of Need supports federal funding applications for SSPs and other organizations. In Florida, there are five approved and currently operational SSPs: IDEA Exchange Miami (located in Miami-Dade County) operated by the University of Miami Miller School of Medicine, the SPOT (in Broward County) operated by Care Resource, the Rebel Recovery SSP (in Palm Beach County) implemented by Rebel Recovery FL, IDEA Exchange Tampa (in Hillsborough County) implemented by Tampa General Hospital and the University of South Florida, and IDEA Orlando (in Orange County) implemented by Hope and Help. An SSP in Pinellas County will be opening their doors in 2022.

Apart from federal funds, grants and donations are the only authorized funding sources for SSP operations in Florida. The five currently operating SSPs receive funding for harm-reduction supplies and services from private grants, donations, and foundations. FDCF donates naloxone nasal spray kits to the SSPs. All sites report that the biggest barrier to effective implementation and operation of their program is funding for harm-reduction supplies. Current funding is inadequate to support the foundational operation of the exchanges, with one site reporting continuous supply shortages that have led to the SSP closing on certain days of the week at a time when the program was experiencing rapid growth.

Since the inception of FDCF's Overdose Prevention Program, the five operational SSPs have distributed over 30,000 naloxone kits and reported 5,602 reversals or rescues. About 29% of all reversals reported to FDCF are through the SSPs. Supplying SSPs with naloxone kits therefore remains a top priority. As other harm-reduction organizations, recovery community organizations, and peer networks, expand and evolve in ways that engage and maintain relationships with the hardest to reach, most at risk individuals in their communities, they should also receive priority support for naloxone distribution. Additionally, in March 2022, the Florida Harm Reduction Collective (FLHRC) established a mail-based naloxone distribution program. The FLHRC comprises of recovery community organizations, overdose prevention programs, SSPs, CBOs, and other stakeholders working to decrease the harms of drug use and eliminate

the stigma associated with harm-reduction. Since March 2022, FLHRC has distributed 1,482 naloxone kits and received 104 reports of overdose reversals through their mail-based naloxone distribution efforts.

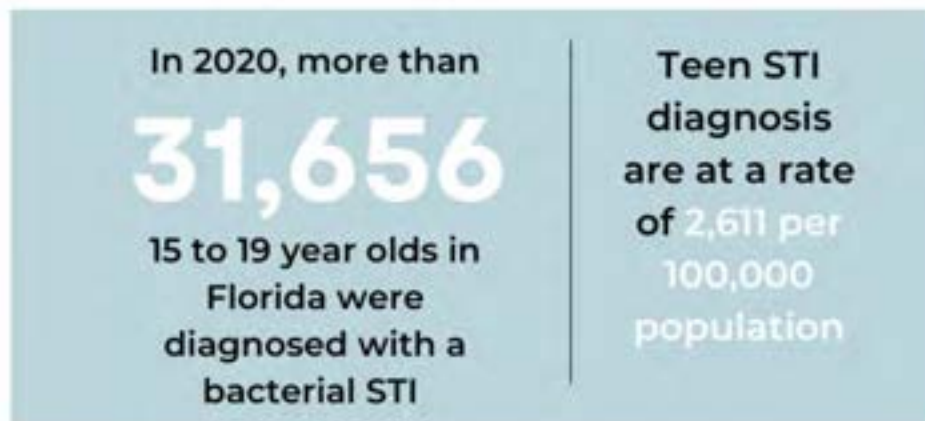
Florida's overdose epidemic continues to pose a considerable challenge that the Department addresses through surveillance, prevention, education, and policy efforts. The Florida Overdose Data to Action (OD2A) program has a direct connection to the State Health Improvement Plan and the Department's Strategic Plan. The Department also recently launched an initiative to make naloxone kits available at all 67 CHDs. In 2021, as part of the nationwide opioid litigation undertaken by more than a dozen states, Florida was able to secure more than \$1 billion in settlement funds which will be used to support prevention, treatment, and recovery related services.

The Department supports the IDEA Exchange Miami to provide training and technical assistance to new SSPs, as well as education to local communities on the evidence behind SSPs in the prevention of HIV, HCV, and overdose. Another project, supported by the congenital syphilis grant routinely screens women who inject drugs for HIV and syphilis to reduce the likelihood of babies born with congenital syphilis and link women to treatment and care. Lastly, we will create tangible and measurable steps in addressing viral hepatitis statewide by developing a robust hepatitis elimination plan. We will focus on priority populations disproportionately affected by hepatitis A, B, and C through improving access to prevention, diagnosis, and treatment and increasing vaccination among those priority populations. Also, we will increase access to medication-assisted therapies and linkage to HCV treatment among PWID.

During FY 2021–2022, FDCF deployed HIV Early Intervention Services set-aside funding from the SAMHSA Substance Abuse Prevention and Treatment Block Grant to conduct 18,313 HIV tests across 47 treatment provider sites. A total of 163 tests were positive for HIV.

Comprehensive Health Education and Interventions for Youth

In 2020, more than 31,656 persons between 15 and 19 years of age in Florida were diagnosed with a bacterial STI (syphilis, chlamydia, gonorrhea), for a rate of 2,611 per 100,000 population as shown in Figure 24. These numbers are down slightly from previous years due to the lack of testing and access to testing during the COVID-19 crisis. The presence of an STI increases a person's risk of acquiring HIV. The teen birth rate in Florida has decreased by 59.7%, from 37.2 per 1,000 population in 2009 to 15.0 per 1,000 population in 2020. Of the 4,708 HIV diagnoses in Florida in 2021, 13% (634) were among 13 to 24-year-olds, of whom 53% were Black, 33% were Hispanic/Latino, 12% were White, and 2% were multiracial/other. Most youth diagnoses were attributed to sexual contact, with only 2% attributed to other risks. Of the 2,678 young PWH in Florida in 2021, 67% had a suppressed viral load (versus 69% for all PWH in Florida).

FIGURE 24: TEEN STI RATES

Section 1003.42(2)(n), F.S., requires comprehensive health education that incorporates disease prevention and includes language on the benefits of sexual abstinence and the consequences of teenage pregnancy. Additionally, section 1003.46, F.S., allows school boards to include additional instruction regarding HIV/AIDS. Such instruction may include information about “means used to control the spread of [AIDS].” As outlined in section 1003.42, F.S., parents may submit a written request to the school principal to exempt their child from “the teaching of reproductive health or any disease, including HIV/AIDS, its symptoms, development, and treatment.” Specific content in any subject matter is determined by local school district policy, which gives districts the latitude to determine the type of education program that is implemented. Florida plans to look for alternative settings in which to provide HIV education to youth such as recreation centers, after-school programs, faith-based programs, youth coalitions, and juvenile justice facilities.

Perinatal HIV Prevention Efforts

Perinatal transmission of HIV is when HIV is passed from a woman with HIV to her child during pregnancy, childbirth, or breastfeeding. The use of HIV medicines and other strategies have helped to lower the rate of perinatal transmission of HIV to 1% or less in the US and Europe.³⁷ In Florida, the Department is actively managing the following perinatal HIV initiatives:

- Targeted Outreach for Pregnant Women Act (TOPWA)** – Section 381.0045, F.S., also known as the “Targeted Outreach for Pregnant Women Act of 1998” provides a state funding appropriation for programs to provide outreach and linkage services to pregnant women who may not seek proper prenatal care, who suffer from substance-use disorders, or who are living with HIV or are at increased risk for HIV acquisition. TOPWA providers serve pregnant women who are HIV negative and those living with HIV to ensure they are linked to and receive adequate prenatal care and adhere to medical treatment to prevent perinatal transmission. There are seven funded TOPWA programs in Florida and they provided services to 1,772 clients in 2021. Black females represented 45% of enrollees, Hispanic females represented 44%, and White females represented 7%. Females living with HIV made up just under 8% of TOPWA enrollments.

- **Fetal Infant Mortality Review (FIMR)/HIV Prevention Methodology** – The Department is developing a FIMR/HIV Prevention Methodology in conjunction with a Community Action Team. These efforts are part of a larger effort the Department is undertaking to reduce communicable diseases in WCBA to include congenital syphilis, HBV, and HCV.
- **Baby Rxxpress** – The Department’s Baby Rxxpress program provides a six-week course of ARV medication to newborns with HIV exposure, lowering the risk of mother-to-child HIV transmission to less than 1%. In 2020, Baby Rxxpress filled 344 prescriptions for ARV medications for 256 newborns with HIV exposure at a cost of \$13,556.00, or just under \$53 per baby. Baby Rxxpress maintains over 85 participating pharmacies across the state. Participating partners include Empath Health Pharmacy, Health Matters Pharmacy, Walgreens Co., Jackson Pharmacy (three specialty locations), Scripts Pharmacy, and Jackson Drugs.

HIV High-Impact Prevention (HIP) Provider Network

In early 2019, the Department made awards for HIP Request for Applications (RFA) 18-001. HIP RFA 18-001 was released in fall 2018 and provided non-profit organizations an opportunity to apply for funding provided by the Department through the state’s integrated HIV prevention and surveillance grant. A total of \$10 million from this grant was allocated and 44 awards were made to organizations throughout the state that serve Florida’s priority populations. Three-year contracts were executed beginning January 1, 2019, and ending on December 31, 2021, with the option for up to three, one-year renewals. These awards have the ability to be continued through December 31, 2024.

Funded HIP providers deliver a wide array of services, depending on the category of funding and includes, but are not limited to, routine and prioritized testing; integrated STI screening, linkage and reengagement to prevention and care services; interventions for PWH and persons at increased risk of acquiring HIV; PrEP and PEP services; condom distribution; outreach, education, and community engagement; social media and marketing; and essential support services.

In 2021, a total of 12,281 PWH received risk-reduction interventions through contracted HIP providers. Of the PWH receiving risk-reduction interventions, 39.5% identified as MSM, 29% identified as heterosexual males, 28.7% identified as heterosexual females, and 2.8% identified as transgender. Interventions for PWH include Partnership for Health, CLEAR, ARTAS, Healthy Relationships, Connect, Peer Support, and personalized risk-reduction counseling.

Forty-one of the 44 funded HIP providers deliver PrEP screening and referrals and 16 of the providers are able to prescribe for PrEP onsite. In 2021, approximately 42,138 clients of HIP providers were found to be eligible for PrEP services, and, of those, 24,562 were referred for PrEP services and 1,211 were prescribed PrEP.

Risk-reduction interventions for HIV-negative persons at increased risk for acquiring HIV are also delivered by contracted HIP providers. In 2021, a total of 16,235 HIV-negative persons received risk reduction interventions through contracted HIP providers and of those, 43% identified as heterosexual

females, 38% identified as heterosexual males, 18% identified as MSM, and 1% identified as transgender. Interventions for persons with a negative or unknown HIV status include VOICES, CLEAR, Social Network Strategy, Mpowerment, Popular Opinion Leader, Personalized Cognitive Counseling, RESPECT, Community PROMISE, HIV and STD educational sessions, and personalized risk reduction counseling services.

HIP providers are also required to screen clients and refer them to essential support services to assist with housing, transportation, mental health, substance use disorder, and other barriers to care. In 2021, HIP providers screened 51,306 clients for essential support services; 21,224 were referred to services and 2,032 were linked to essential support services.

HIV Minority Media Campaign

In 1999, the Department established a statewide minority media campaign for HIV prevention, as required by section 381.046, F.S. This campaign was most recently rebranded in 2017 with the theme “Protect Yourself.” In 2020, the campaign evolved to include the stories and testimonials of real individuals from Florida impacted by HIV. Figure 25 provides an example of how the Protect Yourself campaign images were used.

FIGURE 25: PROTECT YOURSELF CAMPAIGN IMAGE



The Protect Yourself campaign is implemented across all industry standard platforms including broadcast radio and television, digital and mobile advertising, out-of-home advertising (billboards, bus stops), a dedicated website, social media, and public outreach events. The Department works with local areas to supplement media buys as applicable. The Department updates the campaign annually with input from local and statewide advisory and work groups. During COVID-19, the HIV media campaign was instrumental in getting out social media messaging and website content to populations at risk for or living with HIV. More recently, the HIV media campaign was used to quickly disseminate information and messaging for HIV priority populations related to hepatitis A, meningococcal disease, and Mpox virus. Moving forward, the Department plans to broaden the scope of the campaign to address syndemics (STIs, viral hepatitis).

As previously discussed in Section 2.5, the Department announced its endorsement of the Prevention Access Campaign’s U=U in June 2020. In becoming a U=U partner, the Department joined nearly 1,000 organizations around the world supporting the science-backed message that PWH who use antiretroviral

therapy and have an undetectable viral load in their blood have effectively no risk of sexually transmitting HIV.

4.4 RESPOND Quickly to Potential HIV Outbreaks to Get Needed Prevention and Treatment Services to People Who Need Them

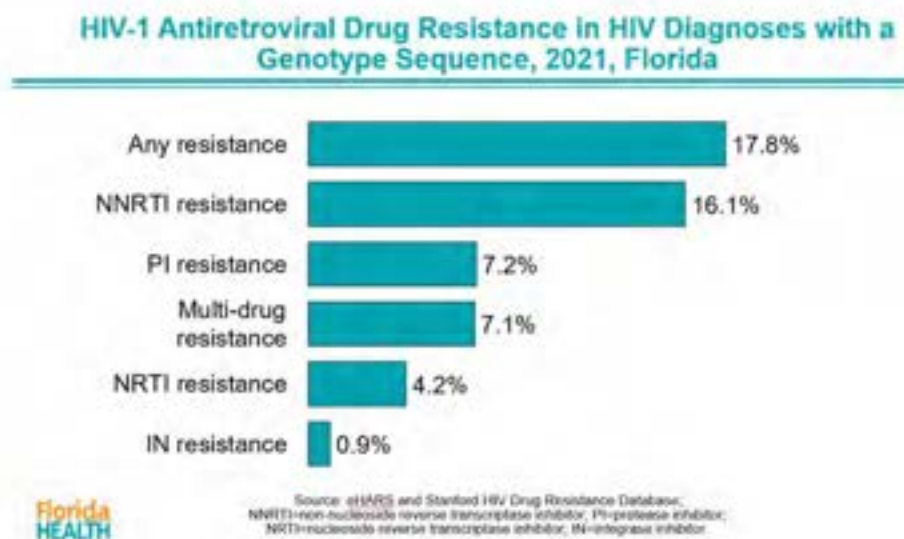
Cluster Detection and Response Plan

The Department is actively conducting surveillance and investigation for HIV clusters. The Department routinely conducts monthly analysis to detect rapidly growing molecular clusters and time-space clusters of public health significance. Additionally, a state level cluster review committee is convened monthly to review cluster data, discuss challenges, and brainstorm strategies to improve the statewide response. Since fall 2021, the state health office has established routine communication with CHDs experiencing clusters to coordinate and guide local responses to investigate and respond to clusters. Florida's updated HIV Cluster Detection and Response plans were submitted to CDC in fall of 2021 and will be updated in 2023. The Department's Bureau of Communicable Diseases plans to engage community stakeholders in further development of the cluster detection and response plan and will accomplish this through the FCPN and associated workgroups, RWHAP partners, and other stakeholders.

Increase Receipt of Genotype Test Results

As the number of analyzable HIV-1 genotype sequences reported to the state has decreased and the number of physicians ordering those tests has also decreased, the Department will enhance physician capacity to order genotype testing for those newly diagnosed or those not on ART returning to care. Figure 26 breaks out resistance type with a genotype sequence.

FIGURE 26: HIV-1 ANTIRETROVIRAL DRUG RESISTANCE IN HIV DIAGNOSES WITH A GENOTYPE SEQUENCE 2021, FLORIDA



The Department is engaging laboratories to improve the completeness and timeliness of electronic laboratory reporting of all reportable HIV lab results including genotype consensus sequences used in transmission network analyses. To increase the receipt of genotypes test results, the Department and its partners are:

- Developing a protocol with the Department’s Bureau of Public Health Laboratories to facilitate access to HIV genotype testing.
- Engaging and educating providers on current HRSA recommendations to order baseline genotypes for newly diagnosed and those returning to care and increase understanding of clinical and epidemiological importance of these tests.
- Educating providers and laboratories on statutory reporting requirements for HIV.
- Educating provider population on response and genotype testing.
- Creating a health care provider letter demonstrating the importance of genotype testing.
- Collaborating with the University of Florida to conduct focus groups on molecular surveillance.
- Conducting laboratory survey on current types and volume of HIV testing in Florida.
- Conducting provider survey on current test ordering strategies.
- Creating of a laboratory report card for laboratories and providers to facilitate improvements.

Data to Care (D2C)

HIV is a reportable disease where routinely collected surveillance data are used as a strategic tool to trigger HIP activities. The D2C initiative is a HIP activity that relies on the use of surveillance data to generate lists of persons living with HIV not in care in Florida. Linkage services are offered to those not receiving treatment by connecting them with HIV care. Florida is a high-morbidity state that has implemented a statewide D2C program since 2015, with the goal of reaching individuals who were not linked to HIV care in one month of diagnosis or if not virally suppressed and part of an HIV transmission cluster and network. In partnership with the six RWHAP Part A programs located in the seven EHE counties and through funding received by Georgetown University, the Department is embarking on a data sharing effort to improve linkage to HIV care for persons out of care in those jurisdictions. Enhancing and expanding on the prioritization of D2C activities by focusing on priority populations that need linkage to care, for example, homeless persons, non-White minorities, non-U.S. born, and persons who inject drugs are populations with the highest rate (>21%) of being out of care (no care in the past 12 months) in 2021, compared to the state (20%). Furthermore, males with IDU, Black men, and persons aged 13 to 39 are populations with the lowest percentage of viral suppression rates (<68%) in 2021, compared to the state (69%). The Department is also increasing linkage-to-care staff training to promote diverse community wellness.

Education and Outreach

As part of the ongoing efforts to respond to HIV transmission clusters and outbreaks, the Department collaborates to provide education, outreach, and community engagement with Floridians at risk for HIV or currently living with HIV, informing them of available HIV prevention and treatment options and

other resources in their area. The Department will complete the following activities to improve awareness of HIV-related services and cluster detection and response actions:

- Generate an annual surveillance summary detailing the community-level response to transmission networks in areas of high HIV burden.
- Create and develop education materials to improve awareness and reduce anxiety surrounding HIV transmission network response activities citing standard public health practice.

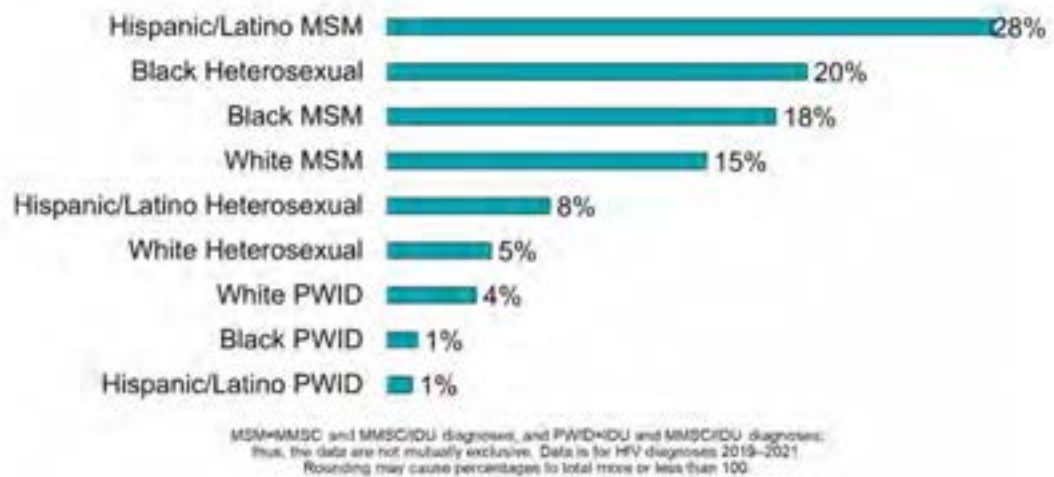
Additionally, several of the RWHAP Part A jurisdictions receiving EHE funding from HRSA have purchased mobile medical units to improve their ability to take services and education to populations and communities.

HIV Criminalization

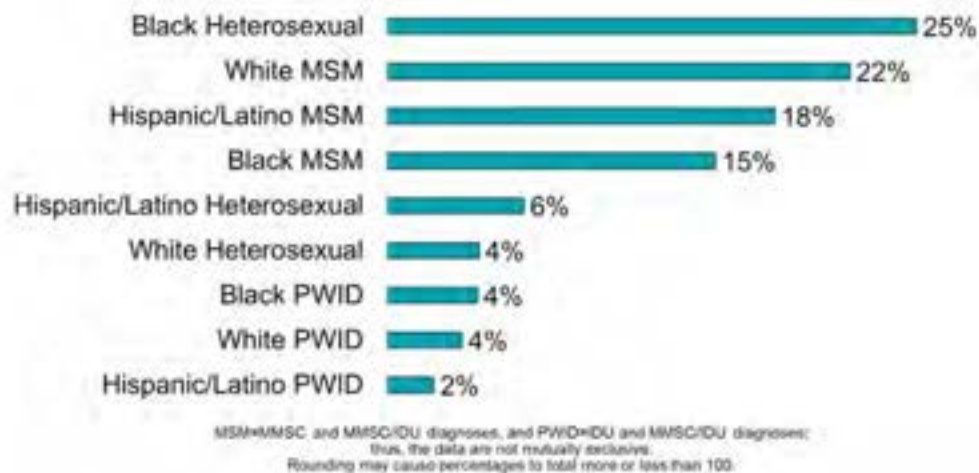
While molecular HIV surveillance (MHS) cannot determine the directionality of disease transmission, it remains a public and community concern that MHS data could be used in criminal transmission prosecutions. An often-required aspect of criminal prosecutions is the “intent to transmit” disease, which cannot be presumed through molecular surveillance or epidemiologic data. However, the ability to use these data in a criminal prosecution poses a threat to community buy-in of routine public health surveillance practices and the use of these data for improving HIV detection and prevention efforts.⁵⁴ In October 2022, the President’s Advisory Council on HIV/AIDS convened and developed recommendations related to MHS such as: local adaptations of MHS must be responsive to the needs in a given jurisdiction based on reviews of state and local HIV criminalization laws; establishment of community advisory boards focused on MHS and cluster detection and response; and plain language notifications be available to PWH about the types of surveillance being conducted and safeguards in place to protect access to and usage of those data. Education to the community at-large is needed on the recent advancements in biomedical interventions, since PWH on medication and virally suppressed (i.e., U=U) have effectively no risk of transmitting the virus to others through sex.

4.5 Priority Populations

Priority populations for primary HIV prevention are derived from the average proportion of each of the race and mode of exposure groups diagnosed with HIV in the last three years (2019–2021). This information is used to address those at the highest risk of acquiring HIV and with the greatest need for primary prevention services (i.e., services directed toward people who have a negative or unknown HIV status). As shown in Figure 27, the top five priority populations are Hispanic/Latino MSM (28% of new diagnoses over the past three years), Black heterosexuals (20%), Black MSM (18%), White MSM (15%), and Hispanic/Latino heterosexuals (8%).

FIGURE 27: PRIORITY POPULATIONS FOR PRIMARY HIV PREVENTION, FLORIDA, 2021

Priority populations for secondary prevention for PWH represent the proportion of each of the race and mode of exposure groups to the total PWH. Secondary HIV prevention activities are directed toward people with HIV, with the intention of preventing transmission to those who are HIV negative. This information is used to prevent HIV transmission through services provided to PWH in these affected demographic groups. As shown in Figure 28, for 2021, the top priority groups include Black heterosexuals (25%), White MSM (22%), Hispanic/Latino MSM (18%), Black MSM (15%), and Hispanic/Latino heterosexuals (6%). Efforts to reduce the transmission of HIV include improving viral suppression among Black males and females and among WCBA (aged 15 to 44).

FIGURE 28: PRIORITY POPULATIONS FOR SECONDARY HIV PREVENTION FOR PWH, FLORIDA, 2021

There were 120,502 persons with an HIV diagnosis living in Florida through 2021 which is estimated to represent only 86% of persons with HIV—the remainder of whom are unaware of their status (approximately 14%, based on the current CDC methodology used to calculate percentage unaware). Persons living with HIV but unaware of their status also need to be prioritized and underscore the

importance of implementing a status-neutral approach to HIV prevention and care. Routine screening is needed to diagnose persons with HIV who are unaware of their status and rapidly link them to care and treatment to achieve viral suppression.

The full Epidemiological Profile for HIV in Florida, 2021, will be provided as a separate attachment. It was developed in accordance with the Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2022–2026 issued by the CDC and HRSA in June 2021. This document provides a comprehensive data overview of HIV, STDs, and HCV in Florida. The full Epidemiological Profile for HIV in Florida, 2021, will also be used to address CDC-PS18-1802 grant requirements.

5 2022–2026 Goals and Objectives

In January 2021, HHS released the HIV National Strategic Plan: A Roadmap to End the Epidemic 2021–2025 which creates a collective vision for HIV service delivery across the nation. IPC Plans created for every jurisdiction address four goals:

- Prevent new HIV infections.
- Improve HIV-related health outcomes for people with HIV.
- Reduce HIV-related disparities.
- Achieve integrated, coordinated efforts that address the HIV Epidemic among all partners and stakeholders.

Objectives have been identified for each of the four goals, and the details of such are outlined in the subsequent section.

Table 10 outlines the goals and objectives for how Florida will address the strategies to diagnose, treat, prevent, and respond to HIV; the goals and objectives align with the NHAS. Actionable activities have been identified to address each of the goals and objectives, along with other pertinent information to inform a plan of action. Those additional details are described in Appendix 9.1 Strategy and Activity Table.

TABLE 10: GOALS AND OBJECTIVES

Goal	Objective
Goal 1: Prevent New HIV Infections	Objective 1.1. Increase awareness of HIV.
	Objective 1.2. Increase knowledge of HIV status.
	Objective 1.3: Expand and improve implementation of effective prevention Interventions.
	Objective 1.4 Increase capacity of health care delivery systems, public health, and health workforce to prevent and diagnose HIV.
Goal 2: Improve HIV-Related Health Outcome of PWH	Objective 2.1. Link people to care rapidly after diagnosis and provide low-barrier access to HIV treatment.
	Objective 2.2: Identify, engage, or reengage people with HIV who are not in care or not virally suppressed.
	Objective 2.3: Increase retention and adherence to treatment to achieve and maintain long-term viral suppression.

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Goal	Objective
	Objective 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV.
	Objective 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors.
	Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure.
Goal 3: Reduce HIV-related Disparities	Objective 3.1. Reduce HIV-related stigma and discrimination.
	Objective 3.2. Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum.
	Objective 3.3. Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV.
	Objective 3.4: Address social determinants of health and co-occurring conditions that exacerbate HIV-related disparities.
	Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations.
	Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust.
Goal 4: Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic Among All Partners and Interested Parties	Objective 4.1. Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and institutional factors including stigma, discrimination, and violence.
	Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and CBOs, the private sector, academic partners, and the community.
	Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data.
	Objective 4.4: Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.

6 2022–2026 Integrated Planning Implementation, Monitoring, and Jurisdictional Follow Up

To break down the approach for Integrated Planning Implementation, Monitoring and Jurisdictional follow up, the subsequent sections will detail how best to ensure the success of IPC Plan goals and objectives through the following five key phases:

- Implementation (Section 6.1)
- Monitoring (Section 6.2)
- Evaluation (Section 6.3)
- Improvement (Section 6.4)
- Reporting and Dissemination (Section 6.5)

6.1 Implementation

The Department will continue to coordinate and collaborate with internal and external partners and stakeholders to meet the objectives of the IPC Plan. The Department's RWHAP Part B; RWHAP Part A, C, D, and F programs; PWH; and other members of the FCPN-associated committees, workgroups, and advisory groups (e.g., FL Gay Men's HIV Workgroup, Community HIV Advisory Group, Florida Black Leaders Group, CQM Committee); EHE-funded jurisdictions and directly-funded providers; HIV prevention and care providers; state and local agency administrators; and persons at increased risk for HIV will be included in each step of the IPC Plan implementation, monitoring and evaluation. Through this coordinated implementation approach, the Department and partners can explore opportunities to better leverage funding streams supporting Florida's HIV prevention, care, and treatment services (e.g., CDC and HRSA funding to state and local entities). Implementation progress of the IPC Plan will also be used to identify where more resources (e.g., funding, staffing) may be needed to ensure IPC Plan objectives are met.

6.2 Monitoring

The goal of the monitoring and evaluation plan is to assess successful implementation of the unified IPC Plan as measured by:

- Completion of stated strategies and activities.
- Annual progress toward the target measurements of stated goals, objectives, and benchmarks.

Data are used to direct efforts to ensure the program achieves the intended results and to help identify additional operational and process improvement opportunities.

Through biannual meetings and monthly committee calls, the Department's HIV/AIDS Section and the FCPN will actively participate in regular monitoring of strategies and activities set forth in the unified IPC

Plan. The Department, in collaboration with the FCPN Coordination of Efforts Committee, will establish mechanisms and time frames the state will use to monitor, evaluate, and update the IPC Plan, as necessary. This committee leads efforts to ensure data indicators for plan activities are being tracked and that progress is communicated with appropriate programs and partners to meet plan objectives. Data on performance indicators will be collected and disseminated through a status report to statewide partners. Local planning body feedback will also be collected and shared by FCPN representatives for each respective area. The Department currently uses an electronic dashboard tool to collect EHE-related activity information and consideration is being given to using this tool to collect activity-related information for the IPC Plan. Regular FCPN meetings are the principal mechanism for updating planning bodies and stakeholders on the progress of plan implementation as well as soliciting and using feedback from stakeholders for ongoing plan improvements. A standing agenda item to review IPC activity progress will be added to the state's FCPN meetings. After each FCPN meeting, a summary report is provided to all attendees and shared with community partners; this mechanism will be used to share information on the IPC Plan's progress toward completing activities and achieving objectives.

The IPC Plan will receive a detailed annual review by the Department HIV/AIDS Section leadership. As part of the annual review, the section will use surveillance and program data to assess health outcomes along the HIV Care Continuum that impact the quality of the HIV service delivery system. This will allow for adjustments to be made in response to changing conditions, and information from the review will be provided to FCPN for feedback.

The Department's HIV/AIDS Section, with the engagement of stakeholders, will review the strategic plan using identified measures and indicators to analyze, assess, and evaluate outcomes and determine whether modifications to the IPC Plan are necessary. The diverse range of perspectives—knowledge, values, needs, and abilities—of stakeholders will be applied through a participatory planning and evaluation process. The collaborative approach, structured and arranged to interweave state and local community partnerships with shared discretion and responsibilities, will help to achieve the IPC Plan objectives more effectively than each program could on its own. This approach will align with, support, and advance the goals of the IPC initiative, the NHAS, and the Department, as well as meet CDC and HRSA requirements. As the state of Florida moves forward in ending the epidemic, regularly scheduled events to inform all stakeholders and researchers of relevant data and evidence for improving or, more precisely, monitoring and evaluating the implementation and impact of the IPC Plan is essential. These opportunities will ensure that plan implementers are working with the best available evidence to work toward ending the epidemic.

6.3 Evaluation

Meaningful measures and indicators will be used to monitor both operational performance and progress on objectives, strategies, and activities in the strategic plan. Data are used to make program decisions and direct efforts to ensure the state achieves the intended results and also to help identify additional operational and process improvement opportunities.

The IPC Plan will receive a detailed annual review by HIV/AIDS Section leadership subsequent to Florida's legislative session and the Department's budget planning process. As part of the annual review, the section will use surveillance and program data to assess health outcomes along the HIV Care Continuum which impact the quality of the HIV service delivery system. This will allow for adjustments to be made in response to changing conditions and information from the review will be provided for input and feedback to the FCPN.

Strategic planning, the process generating the statewide IPC Plan, helps focus resources on vital objectives chosen to move the Patient Care and Prevention programs toward fulfillment of the NHAS goals. The IPC Plan identifies key objectives that Florida will pursue in the next five years, along with strategies and activities that will guide and facilitate the necessary actions required to achieve the desired outcomes. Plan objectives each have a corresponding measure for ongoing monitoring. Using meaningful measures and data indicators will ensure Department HIV/AIDS Section leadership, RWHAP Part A partners and the FCPN planning body members are able to manage and track efforts toward the intended results, while identifying improvement opportunities over the course of the five-year period.

Evaluation ensures the strategies and activities are making changes that positively affect outcomes of the IPC Plan objectives. Evaluation that focuses on project outputs, provides accountability for public resources relating to specific actions. It establishes the empirical basis needed for the ongoing cycle of collaborative planning and the actions that need to be accomplished. The evaluation component is an extension of the integrated Plan, Do, Study, Act cycle which is a continuous process. The IPC Plan must be flexible to allow for adjustments as there are changes to external or internal conditions; yet a meaningful evaluation must be integrated in the planning process and include a review and analysis of the intended outcome. The HIV/AIDS Section, with the engagement of stakeholders, will review the strategic plan using meaningful performance measures and indicators to analyze, assess and evaluate outcomes and determine whether modifications to the IPC Plan are necessary. Through participatory evaluation and diverse range of perspectives, knowledge, values, needs, and abilities of stakeholders will be applied to the planning and evaluation process.

6.4 Improvement

Through routine (biannual) monitoring and communication of progress in achieving the goals and objectives outlined in the IPC Plan, the state will identify areas in need of improvement and make necessary adjustments to the IPC Plan. Revisions will be made on an annual basis and items for proposed revision will be reviewed with RWHAP Part A jurisdictions, members of the FCPN and associated workgroups and advisory bodies, and other key stakeholders, voted on, and implemented. The collaborative approach—structured and arranged to interweave state and community partnerships with shared discretion and responsibilities—will help to achieve the IPC Plan objectives more effectively than each program could on its own. This approach will align, support, and advance the goals of the NHAS, the Department, as well as meet CDC and HRSA requirements, to ensure improvement in the access to and quality of HIV prevention and care services throughout Florida.

6.5 Reporting and Dissemination

Summarized annual data are uploaded to the Department's HIV/AIDS Section web page (<http://floridaaids.org/>) and are also available on an internal SharePoint site for internal use at the state and CHD level. Annual data releases include a comprehensive epidemiological profile for the state and for each partnership area, a state slide set presented annually to FCPN and RWHAP partners, and other annual data products. The epidemiological (epi) profiles are an expanded Excel workbook with multiple tabs containing 5-year trend analyses of HIV (demographics, diagnosis, AIDS, deaths, and continuum of care), STIs, HBV, HCV, and TB.

Various factsheets are generated to portray epidemiology and disease highlights for a demographic population. These fact sheets highlight summary data for priority population groups and are updated annually, shared with community stakeholders, and uploaded to the Department's external web and internal SharePoint sites. Integrated slide sets and epidemiological profile tables are generated to support stakeholder engagement and planning. The Department's HIV/AIDS Section has generated compressive slides sets and epi profiles specifically for each of the 14 partnership areas each year since the 1990s. These slide sets and epi profiles are shared with the RWHAP Part A entities, community stakeholders, field surveillance staff, and others who may request these data. These data are frequently used as tools for program planning and evaluation.

Data Sharing and Use

De-identified HIV, viral hepatitis, STD, and TB data are routinely shared via ad-hoc requests to surveillance programs with outside entities including, but not limited to, academic institutions, community partners, RWHAP Parts, internal agency partners and collaborators, and the public.

Each of these programs provide annual data which are uploaded into FLHealth CHARTS (<https://www.flhealthcharts.gov/charts/CommunicableDiseases/default.aspx>). In addition, FL Health CHARTS is updating the FLHealth CHARTS website (a web-based platform that provides easy access to health indicator data at the community and statewide level for the state of Florida from a multitude of sources) with a new dashboard (at the county level) that will incorporate a multitude of HIV/AIDS indicators including, but not limited to, demographic and socio-economic indicators, partner services data, testing and treatment facilities, PrEP, and other data not previously included on FL Health CHARTS. By ensuring all these data and information are made readily accessible and user friendly, the new dashboard will help local and state planning bodies develop more effective and efficient programs and corresponding activities and monitor progress of IPC strategies and activities.

Along with HIV data, the Department also summarizes data from MMP and NHBS surveillance along with the Department's PrEP, Test and Treat, and HIV counseling and testing data. Data from the needs assessments are also shared in reports sent out to FCPN membership.

7 Letter of Concurrence

For the purpose of this plan, the FCPN membership served as the designated entity to certify concurrence with the content, strategies and activities included in the IPC Plan. The FCPN membership held the concurrence session on October 19, 2022, to officially adopt Florida’s Statewide Integrated HIV Prevention and Care Plan, 2022–2026. Moving forward, all updates to concurrence will be completed through the state’s integrated HIV planning process and with the FCPN.

The concurrence process included:

- Several virtual IPC Planning sessions that reflected the progression of the statewide IPC Plan to ensure that members of the planning body and other community stakeholders had an opportunity to provide input into the development of goals, objectives, strategies, and activities proposed in the IPC Plan.
- Opportunities for FCPN members and community stakeholders to submit their feedback to the state health office representatives with a response to their inquiries and recommendations.
- An opportunity for the FCPN to vote to accept the IPC Plan for submission to HRSA and CDC.

FIGURE 29: LETTER OF CONCURRENCE

F C P N

Florida Comprehensive Planning Network

Dear Colleague:

The Statewide Florida Comprehensive Planning Network (FCPN) concurs with the following submission by the Florida Department of Health in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV/AIDS Prevention (DHAP) and HRSA's HMAIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SC5N) for calendar year (CY) 2022–2026.

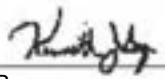
Members of FCPN include PWH and representatives across the state representing patient care and prevention groups, local planning bodies, CEOs, academic institutions, local and regional clinics, city, and county governments, RWHA Program recipients, the transgender community, advocacy groups, substance use and social service providers and behavioral science groups.

After a year of collaboration with our planning body members, federal/state/local partners, and community stakeholders, this plan reflects Florida's commitment to eliminating new HIV transmissions and reducing HIV related deaths in our state. FCPN members and guests helped to develop and prioritize the proposed strategies and activities for inclusion into the plan during the Summer 2022 meeting. FCPN members and guests reviewed and made suggestions to the first draft of the plan during the Fall 2022 in-person/virtual meeting. Comments and suggestions from FCPN members were then incorporated into the final draft of the plan.

The FCPN has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected populations and geographical areas with high rates of HIV.

The planning body concurs that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance.

Asttie Co-Chairs of the FCPN, the signatures below confirm the concurrence of the planning body with the Integrated HIV Prevention and Care Plan 2022-2026.

 _____ Ken Bargar FCPN Community Co-Chair	1/5/23 _____ Date
 _____ Daniel Wall FCPN Community Co-Chair	1/5/23 _____ Date

Florida Comprehensive Planning Network
c/o The AIDS Institute
17 Davis Blvd., Ste. 403
Tampa, FL 33606

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9 Appendix

9.1 Strategy and Activity Table

The table below provides details on the activities suggested to address each strategy. Strategies are categorized by the goal and objective that they fall in.

9.1.1 Goal 1: Prevent New HIV Infections

9.1.1.1 Objective 1.1. Increase awareness of HIV

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TABLE 11: STRATEGIES AND ACTIVITIES

Strategy 1.1.1		Develop and implement campaigns and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.			
Data Indicators		• Number of campaigns developed • Number of publicly funded HIV tests • Number of areas engaging with law enforcement • Stigma measure to be developed • Additional specific, quantifiable measures for each activity (TBD)			
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth			
Timeframe		Critical Partners		Activities	
By 12/31/2026		• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Case managers • Health educators • Peer workers • Community health workers • Linkage Coordinators • Faith-based Organizations		• Develop stigma toolkit and campaign and localized stigma task forces. • Engage with law enforcement around HIV awareness and stigma, and HIV information in their curriculum for youth intervention programs. • Increase culturally competent sexual health education outside of schools. • Increase the use of digital media resources to include messaging on dating apps (e.g., Grindr) and social media apps (e.g., TikTok). • Solicit and execute agreement with new media vendor to deliver HIV media services statewide and to add campaign material to increase awareness of HIV testing, PrEP, treatment, prevention, and stigma awareness among priority groups.	
Planning Areas					
Statewide					

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Strategy 1.1.2		Increase awareness of HIV among people, communities, and the health workforce in geographically disproportionately affected areas.	
Data Indicators	Priority Populations	• Number of publicly funded HIV tests • Number of BRTA/FRTA partnerships • Number of outreach and education efforts to specific priority populations • Additional specific, quantifiable measures for each activity (TBD)	
		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth; sex workers and human trafficking victims	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Case managers • Health educators • Peer workers	• Increase targeted outreach and education efforts specific to specialized groups, (e.g., FQHCs, local gang taskforces, and other geographically disproportionate communities). • Increase the number of BRTA and FRTA initiatives and partners statewide to increase HIV awareness and reach in communities. • Offer in-person learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators (as a result of increased HIV 101 train the trainer opportunities). • Provide HIV education and information to school district stakeholders to encourage buy-in and adoption of culturally competent sexual health education curriculum. • Develop education materials that are both age appropriate and language appropriate.	
Planning Areas			
Statewide			

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Strategy 1.1.3	Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders.	
Data Indicators	• Number of campaigns with integrated messaging addressing syndemics • Number of new or non-traditional partnerships established to deliver education around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth; individuals with dual diagnoses	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance use treatment settings • Mobile units • STD clinics • SSPs • Drug treatment programs • Case managers • Health educators • Peer workers • Community health workers	• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV messaging in messaging related to other communicable disease areas. • Increase awareness and collaboration with existing SSP to incorporate viral hepatitis, STIs, mental health and substance use disorder messaging in campaigns. • Collaborate with non-traditional and new partners to deliver HIV, STI, viral hepatitis, substance use disorder and mental health messaging across multiple platforms (e.g., radio, print, digital, social media, out-of-home, venue/event-based). Ensure all messaging is culturally and linguistically appropriate. • Identify and engage with other organizations and coalitions that have existing campaigns for STIs, viral hepatitis, substance use, mental health, behavioral health, etc. to encourage these groups to include HIV prevention and care messages in their efforts. • Partner with SAMHSA funding recipients update or create messaging related to the nexus between HIV/STIs and HCV, substance use, and/or mental health. • Collaborate with other local EMAs, RWHAP providers (e.g., Part C clinics), and FQHCs to incorporate additional HIV messaging into existing activities and/or campaigns.
Planning Areas		
Statewide		

9.1.1.2 Objective 1.2. Increase knowledge of HIV Status

Strategy 1.2.1		Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.	
Data Indicators		• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Develop messaging that normalizes routine HIV testing and reduces stigma surrounding HIV testing. Utilize peers and popular opinion leaders to increase testing in communities. • Ensure providers are kept up to date through education and communication. • Implement routine HIV and STIs screening in health care settings and priority testing in non-health care settings. Expand routine HIV testing to include additional medical settings (e.g., EDs, urgent care facilities, OB/GYN, and primary care providers). • Increase opportunities for HIV testing and address barriers to testing in traditional and non-traditional settings. • Increase testing accessibility through increased partnerships with outside-the-box providers, such as non-traditional medical settings, civic groups, local papers, event planners, FBOs, population-based care providers, and others. Ensure testing is where people are.	
Planning Areas			
Statewide			

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Strategy 1.2.2	Develop new and expand implementation of effective, evidence-based or evidence informed models for HIV testing that improve convenience and access.	
Data Indicators	• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs	• Assess current HIV testing laws for opportunities to consider increasing testing requirements in additional circumstances. • Decrease barriers to testing by increasing testing beyond traditional venues and work hours and normalizing knowing your status. • Identify barriers to testing and care from people with lived experience and develop improvements to delivery. • Provide easy access to home test kits, including through self-serve vending machines and as add-ons to other self-tests (such as COVID, pregnancy); improve reporting structures to increase self-test linkage. • Routinize HIV testing as part of the standard of care during an annual physical as well as during other health or wellness visit appointments or opportunities.
Planning Areas		
Statewide		

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Strategy 1.2.3		Incorporate a status neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.	
Data Indicators		• Number of new HIV diagnoses • Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Develop and provide status-neutral resources around testing, treatment, prevention, and other services. • Educate private providers about status neutral HIV prevention and care services. • Ensure strong linkage to PrEP and PEP infrastructure that exists. • Increase the use of combined testing and vaccination efforts as a means of destigmatizing HIV prevention and testing services. • Support and expand the use of a “no wrong door” approach for HIV prevention and care services in a variety of organizations.	
Planning Areas			
Statewide			

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Strategy 1.2.4		Provide partner services to people diagnosed with HIV or other STIs and sexual or needle sharing partners.	
Data Indicators		• Number of people receiving HIV partner services interviews • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs	• Increase collaboration with needle exchange/harm-reduction programs. • Increase partner services capacity, whether by increasing funding for DIS positions, allowing additional Department staff to provide partner services, or allowing non-Department organizations to provide partner services. • Provide partner services during non-traditional hours and via telehealth to reduce barriers. • Reduce barriers around partner disclosure and referral. • Use partner services to provide negative partners access to PrEP, educational materials, and other preventative resources and services.	
Planning Areas			
Statewide			

9.1.1.3 Objective 1.3: Expand and Improve Implementation of Effective Prevention Interventions

Strategy 1.3.1		Engage people at risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.	
Data Indicators		• Number of publicly funded HIV tests • Number of HIV self-test kits distributed • Number of people receiving prescriptions for PrEP • Number of primary care visits (AHCA report) • Number of FQHC visits for priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs • AHCA (Medicaid/Medicare)	• Create local Prevention Interventions Taskforces to work collaboratively to raise awareness (e.g., utilizing non-health care events), share resources, and provide referrals. • Incorporate additional public health professionals in care settings • Increase academic detailing in Primary Care, Urgent Care, and Emergency Department settings to raise awareness for prevention interventions. • Increase the number of community mobilization initiatives and partnerships in communities, (e.g., FRTA and BRTA). • Partner with additional social service organizations, (e.g., domestic violence care providers, human trafficking organizations, United Way, YMCA, Boys and Girls club, and others) to expand HIV testing, prevention, and care services.	
Planning Areas			
Statewide			

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Strategy 1.3.2	Scale-up treatment as prevention/U=U by diagnosing all people with HIV, as early as possible and engaging them in care and treatment to achieve and maintain viral suppression.		
Data Indicators	• Number of publicly funded HIV tests • Number of people receiving prescriptions for PrEP • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Use existing planning bodies to work collaboratively to expand and increase rapid ART access programs. • Increase viral suppression rates by increasing the use of peers in programs and using messaging that focuses on living a healthy life. • Review programs with low VL suppression to identify areas for technical assistance and increase the number of trained evidence-based Intervention (EBI) providers in those programs to assist in navigation services and other interventions to reduce community VL. • Scale up of injectable ARV programs (i.e., PrEP and HIV treatment).	
Planning Areas			
Statewide			

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Strategy 1.3.3		Make HIV prevention, including condoms, PrEP, PEP, SSPs easier to access and support continued use.	
Data Indicators		• Number of condoms distributed statewide • Number of people receiving prescriptions for PrEP • Number of people receiving PEP • Number of operational SSPs • Additional specific, quantifiable measures for each activity (TBD)	
		Priority Populations PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Use existing planning bodies to work collaboratively to raise awareness and share resources on PrEP, PEP, condoms, and SSP, in order to provide referrals and increase accessibility of services. • Increase the number of PrEP providers through academic detailing and education. • Encourage that SSPs (including clean-needle distribution and exchange) are placed in proximity of known overdose events or deaths. • Increase awareness and promote the use of the Provider PrEP hotline.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.3.4		Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.	
Data Indicators		• Number of cultural humility trainings performed • Number of engagement activities with local and state civic, community and spiritual leaders • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Correctional health settings • SSPs	• Embrace the adoption of assessing quality of life instead of limiting approach to focusing on health outcomes only. • Engage with local and state civic, political, community, and spiritual leaders to increase awareness of HIV and populations living with and affected by HIV. • Increase cultural humility trainings and other linguistically appropriate trainings for delivering HIV prevention services. • Partner with the Florida Department of Education (FDOE) to open conversations on how to evaluate outcomes of current health education programs for success. • Provide HIV messaging in English, Spanish, and Haitian-Creole.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 1.3.5	Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.	
Data Indicators	• Number of partnerships with HIV-related research entities • Number of HIV research sharing events and opportunities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Academia • SSPs	• Expand frameworks for evaluation of EBIs through collaborative efforts and partnerships. • Expand the use of economic modeling to optimize public health strategies and interventions (e.g., PrEP 2-1-1) in additional jurisdictions. • Strengthen partnerships with HIV-related research entities (e.g., Florida Consortium for HIV Research [FCHAR]) to increase knowledge sharing and build expertise. Encourage attendance at Florida HIV Community, Providers & Researchers Conference.
Planning Areas		
Statewide		

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Strategy 1.3.6	Expand implementation research to successfully adapt EBIs to local environments to maximize potential for uptake and sustainability.	
Data Indicators	• Number of partnerships with HIV-related research entities • Number of HIV research sharing events/opportunities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Academia • SSPs	• Adapt interventions frameworks to be more inclusive of all communities. • Conduct listening sessions with those currently implementing interventions and those participating in interventions to uncover best practices and lessons learned. • Increase collaboration with state and national entities, subject matter experts (SMEs) and CBA and TA providers to share information and findings that may lead to innovation and strategies.
Planning Areas		
Statewide		

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9.1.1.4 Objective 1.4 Increase capacity of health care delivery systems, public health, and health workforce to prevent and diagnose HIV

Strategy 1.4.1	Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.		
Data Indicators	• Number of cultural humility trainings performed • Number of public health workforce trainings on PrEP and PEP, mental health, and substance use and misuse • Number of partnerships with rural health networks • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Community-based organizations, health care delivery systems, public health, and health workforce		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Drug treatment programs • Correctional health settings • SSPs • Case managers • Health educators • Peer workers • Linkage coordinators	• Collaborate with local, state, and national training partners to increase and expand training cultural humility trainings. • Collaborate with local, state, and national training partners to provide additional training for the public health workforce and front-line staff on PrEP and PEP prescribing, mental health, and substance use and misuse. • Expand awareness and use of the Collaborative Pharmacy Practice Agreement which gives pharmacists authority to provide specific patient care services, including PrEP. • Expand partnerships with rural health networks. • Explore opportunities to incentivize the expansion of the health care workforce and health care facilities. • Identify language barriers and use stigma-free language for vulnerable populations.	
Planning Areas			
Statewide			

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Strategy 1.4.2		Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.	
Data Indicators		• Number of cultural humility trainings performed • Number of HIV testing providers in rural areas • Number of partnerships with rural health networks • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Community-based organizations, health care delivery systems, public health, and health workforce	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Drug treatment programs • SSPs • Case managers • Health educators • Peer workers • Linkage coordinators	• Determine areas that lack providers and find ways to incentivize organizations to serve as HIV CBOs. • Encourage HIV testing as a workplace activity. • Engage community hubs and community leaders to broaden their social services by provided HIV testing. • Use all available training resources (local and national) to create a diverse testing force across the state in both traditional and non-traditional settings.	
Planning Areas			
Statewide			

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Strategy 1.4.3	Increase inclusion of paraprofessionals and SMEs on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.	
Data Indicators	• Number of partnerships with private entities • Assessment of ART barriers conducted • Number of peer navigators or near-peers • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Case managers • Health educators • Linkage coordinators • Peer and near-peer workers • CHWs	• Assess barriers to antiretroviral therapy (HIV treatment or PrEP) in communities • Develop a community-based workforce that is able to provide more services in a single visit • Find creative ways to combat critical workforce attrition • Increase the number of peer navigators providing services. • Leverage partnerships with private entities to increase access to prevention services. • Develop pathways which promote career growth for paraprofessionals.
Planning Areas		
Statewide		

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Strategy 1.4.4	Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV.	
Data Indicators	• Number of academic institutions receiving education and outreach • Number of local providers, peer navigators and near-peers that reflect priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Case managers • Health educators • Linkage coordinators • Peer workers, Near Peers • CHWs	• Increase the number of local care providers, peer navigators, and SMEs of color in order to reflect the burden of the epidemic in a county. • Increase the number of inclusive sexual health services being offered by providing training on sexual orientation and gender identity. • Provide education and outreach to academic institutions (e.g., public health programs, nursing, other paramedical programs) to encourage integration of testing and prevention training into curriculum to increase the number of certified testers. • Require HIV education and training of school personnel. • Require HIV education in clinical licensure. • Establish best practices for responsible parties to hire and retain employees that reflect the epidemic.
Planning Areas		
Statewide		

Goal 2: Improve HIV-Related Health Outcomes of Persons with HIV (PWH)**9.1.2.1 Objective 2.1. Link people to care rapidly after diagnosis and provide low-barrier access to HIV treatment**

Strategy 2.1.1		Increase linkage to HIV medical care in 30-days of diagnosis, as early as the same day.	
Data Indicators		• Number of new HIV diagnoses • Number of PWH engaged in care through T&T • Number of PWH engaged in care through telehealth • Number of PWH linked to same-day treatment (rapid ART) • Percent of newly diagnosed PWH linked to HIV medical care in 30 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Persons living with diagnosed HIV	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners		• Facilitate the ability of peers, medical providers, and eligibility staff to link clients to care and access rapid ART medications. • Collaborate with local partners and providers across multiple platforms to incorporate more T&T facilities that will offer rapid access to ART and PrEP and PEP medications. • Increase awareness with local providers to incorporate messaging on T&T and rapid ART protocols. • Support the use of incentives such as food and transportation vouchers and phones to assist with linkage to care activities.
Planning Areas			
Statewide			

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Strategy 2.1.2	Provide same-day initiation or rapid start (within 7 days) of ART for those who are able to take it.	
Data Indicators	• Number of new HIV diagnoses • Number of PWH engaged in care through T&T • Number of PWH engaged in care through telehealth • Number of PWH linked to same-day treatment (rapid ART) • Percent of newly diagnosed PWH linked to HIV medical care in 7 days of diagnosis • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local Part A and EHE programs	• Establish youth ambassadors and advocates; collaborate with academic institutions (e.g., Scale It Up Florida). • Expand routine HIV and STI testing to include additional medical settings (e.g., pediatricians, primary care, and student health centers). • Increase targeted outreach and education efforts specific to specialized youth and teen groups. • Increase the number of culturally competent sexual health education in educational, recreational, and faith-based organizations, facilities, and groups.
Planning Areas		
Statewide		

9.1.2.2 Objective 2.2: Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

Strategy 2.2.1	Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.	
Data Indicators	• Number of new HIV diagnoses • Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners	• Collaborate with local partners and providers across more platforms to incorporate more T&T facilities that will offer rapid ART and PrEP and PEP medications. • Develop a single-point eligibility data system that will support all RWHAP partners to assist with linkage and retention services. • Execute cooperative agreements and data sharing agreements with local providers, jails, and prisons to link and refer clients to care who are soon to be released from an institution. • Support data sharing efforts and educate peers, DIS, medical providers, pharmacists, and eligibility and outreach staff on how to assist in linking clients to care and accessing rapid ART medications.
Planning Areas		
Statewide		

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Strategy 2.2.2		Identify and address barriers for people who have never engaged in care or who have fallen out of care.	
Data Indicators		• Number of new HIV diagnoses • Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local RWHAP Part A and EHE partners		• Expand opportunities to increase awareness and education of local providers on how to incorporate messaging and services for mental health, substance use, homelessness, and other wrap-around services. • Expand routine HIV/STI testing, and substance use counseling to additional settings such as homeless shelters, urgent care centers, substance use treatment centers. • Expand RWHAP drug formularies to include more treatment drugs for comorbidities. • Expand the use of mobile units to assist with linkage and reengagement efforts. • Support the use of peers to assist with linkage, reengagement, and retention efforts.
Planning Areas			
Statewide			

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9.1.2.3 Objective 2.3: Increase retention and adherence to treatment to achieve and maintain long-term viral suppression.

Strategy 2.3.1		Support the transition of health care systems, organizations, and clients to become more health literate in the provision of HIV prevention, care, and treatment services.	
Data Indicators		• Number of in-person and virtual learning opportunities for staff providing prevention, care, and treatment services • Number of plain language processes and materials developed to assist clients who are newly diagnosed or returning to care • Number of peers and near-peers providing linkage, reengagement, or retention efforts • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Persons living with diagnosed HIV, health care systems, community-based organizations	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Local Part A and EHE programs	• Develop plain language processes and materials to assist clients who are newly diagnosed or returning to care. • Offer in person and virtual learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators and clients (as a result of increased HIV 101 train the trainer opportunities). • Support the use of peers and near-peers to assist with linkage, reengagement, and retention efforts.	
Planning Areas			
Statewide			

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Strategy 2.3.2		Develop and implement effective, evidence based or evidence-informed interventions and supportive services that improve retention in care.	
Data Indicators		• Number of peers, near-peers, and/or CHWs providing retention support • Number of peer programs implemented • Number of provider educational opportunities around syndemics • PWH reengaged through D2C • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Peers and near-peers • CHWs • Linkage coordinators • Local RWHAP Part A and EHE partners		• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) into primary care practice. • Expand the use of peers, linkage coordinators and CHWs to implement the ARTAS intervention strategies and adherence measures. • Identify and integrate best practices for peer programs from similar states and jurisdictions. • Review EBIs for effectiveness by using validated tools to predict engagement. Ensure EBIs include target audience. Establish rapid response protocols. • Streamline clinical protocols to eliminate client burden by reducing the frequency of CD4/VL labs, providing 3–6 months of medications at one time, and offering telehealth clinical and case management services.
Planning Areas			
Statewide			

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Strategy 2.3.3	Develop and implement effective, evidence-based, or evidence-informed interventions such as HIV telemedicine, accessible pharmacy services, CHWs and peer navigators, and others, that improve convenience and access, facilitate adherence, and increase achievement and maintenance of viral suppression.	
Data Indicators	• Number of PWH linked to same-day treatment (rapid ART) • Number of PWH reengaged through D2C • Number of PWH engaged in care through telehealth • Number of peers, near-peers, and CHWs providing linkage and retention support • PWH reengaged through D2C • Percent of PWH retained in care • Percent of PWH who are virally suppressed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, health care systems, academic institutions, community-based organizations	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Pharmacies • Peers and near-peers • Case managers • CHWs • Linkage coordinators • SSPs • Local RWHAP Part A and EHE partners	• Allow 3–6 months of ART medications to be dispensed at one time. • Create funding opportunities for community-based providers to support recruitment and retention of staff. • Develop a single-point eligibility data system integrated with multi-data systems that will support all RWHAP parts. Implement a centralized eligibility determination system for all RWHAP Parts. • Expand access to health insurance coverage to eligible clients. • Provide training to health workers and peers that will support or increase adherence measures.
Planning Areas		
Statewide		

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Strategy 2.3.4	Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence and durable viral suppression.	
Data Indicators	• Number of collaborations with academic institutions engaged in HIV research • Number of updates to providers on ongoing or recruiting efforts on clinical trials • Number of FQHCs and other community health settings engaged in research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, health care systems, academic institutions, community-based organizations	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Encourage persons living with HIV to participate in the research by making research findings easier to understand. • Engage and collaborate with local colleges and universities to increase research opportunities at the local level. • Engage local organizations such as FQHCs to assist with research and interventions. • Provide paid incentives to encourage persons living with HIV, students, or researchers to get involved in the research. • Provide updates to providers on ongoing or recruiting efforts on clinical trials.
Planning Areas		
Statewide		

9.1.2.4 Objective 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

Strategy 2.4.1	Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.	
Data Indicators	• Number of cultural humility trainings performed • Number of public health workforce trainings on PrEP and PEP, mental health, and substance use or misuse • Number of PWH engaged in care through telehealth • Number of peers, near-peers, and CHWs providing linkage and retention support • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, community health centers, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Pharmacies • Peers and near-peers • Case managers • Linkage coordinators • CHWs • SSPs • Local RWHAP Part A and EHE partners	• Collaborate with the AETC to assist with training efforts. • Establish a statewide conference for medical providers. • Expand telehealth to increase capacity for services and use mobile units to increase outreach efforts. • Increase culturally competent HIV trainings to local providers. • Increase targeted outreach and education efforts specific to specialized providers.
Planning Areas		
Statewide		

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Strategy 2.4.2		Increase the diversity of the workforce of providers who deliver HIV and supporting services.	
Data Indicators	Priority Populations	• Number of public health workforce trainings on basic HIV education • Number of peers, near-peers, and/or community health workers providing linkage and retention support • Number of provider educational opportunities around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
		Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, and health workforce	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Peers and near-peers • Case managers • CHWs • SSPs • Local RWHAP Part A and EHE partners		• Facilitate the ability of peers, medical providers, and eligibility staff to link clients to care and access rapid ART medications. • Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) into primary care practice. • Increase providers of color in communities. • Offer in-person and virtual learning opportunities for basic HIV 101 education and increase the number of trained HIV 101 educators (as a result of increased HIV 101 train the trainer opportunities). • Modify contractual language in HIV contracts to encourage staffing reflects the local demographics of the HIV population.
Planning Areas			
Statewide			

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Strategy 2.4.3	Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.	
Data Indicators	• Number of peer navigators or near-peers • Number of public health workforce trainings on basic HIV education • Number of peers, near-peers, and CHWs providing screening and adherence support • Number of provider educational opportunities around syndemics • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, community-based organizations, health care delivery systems, public health, paraprofessional, and health workforce	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • Peers and near-peers • Case managers • CHWs • SSPs • Certified addiction professionals and counselors • Local RWHAP Part A and EHE partners	• Collaborate with social service organizations on screening and management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions. • Identify support staff who can be trained to provide support services in a range of industries (i.e., medical COE). • Develop and implement a statewide peer certification program. • Increase training and inclusion opportunities for CHWs. • Collaborate with other social service providers to increase screening and management of HIV, STI, viral hepatitis, and mental and substance abuse. • Expand collaborations with school health services to provide support to the younger population. • Identify and promote trainings for paraprofessionals regarding social determinants of health and the syndemics facing Florida.
Planning Areas		
Statewide		

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9.1.2.5 Objective 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

Strategy 2.5.1	Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.		
Data Indicators	• Number of partnerships with organizations that serve PWH aged 50+ • Assessment of barriers to care for PWH aged 50+ • Number of educational opportunities for PWH aged 50+ • Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Broaden the scope of partnerships to include established entities who serve PWH over the age of 50 providing primary, specialty and pharmacy services. • Utilize statewide advisory groups to identify barriers in models of care for PWH who are aging. • Collaborate with existing service providers (e.g., Eldersource, Department of Elder Affairs, Visiting Angels) that work with the elderly to integrate in HIV prevention, care, and support services. • Increase HIV and aging education in senior centers, assisted living facilities, retirement communities, and others. • Collaborate with geriatric care providers to educate on risk of aging PWH. Also educate them on risk for older patients who may be at risk of acquiring HIV, e.g., how to talk to and engage older adults in sexual health conversations.	
Planning Areas			
Statewide			

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Strategy 2.5.2	Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.		
Data Indicators	• Number of partnerships with organizations which address psychosocial and behavioral health for PWH aged 50+ and long-term survivors. • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Local RWHAP Part A and EHE partners	• Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) and behavioral health into primary care practice. • Increase provider knowledge on the aging HIV population and the effects on dementia. • Expand partner networks to include organizations already addressing psychosocial and behavioral health for persons with HIV aged 50+ and long-term survivors. • Engage national aging institutions to advise on establishing the most effective program design to address psycho-social and behavioral needs of the aging population including substance use and mental health treatment. • Review existing research and evidence-based practices from mainstream non-HIV oriented care providers and integrate into HIV-oriented care. • Establish Long Term Survivor Empowerment Teams which can foster individual virtual or in-person mental health sessions assessing the needs of patients and ensuring their needs are met accordingly. • Reach out to existing elder services providers to learn more about what they offer and what's working and ask how HIV prevention and support could be added into their efforts.	
Planning Areas			
Statewide			

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Strategy 2.5.3	Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.		
Data Indicators	• Number of partnerships with organizations which address psychosocial and behavioral health for PWH aged 50+ and long-term survivors. • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities in settings where persons aged 50+ may reside or congregate (senior centers, retirement communities) • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	Persons over the age of 50 living with diagnosed HIV		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Local RWHAP Part A and EHE partners	• Collaborate with local Area Agencies on Aging. • Collaborate with local partners to educate providers across more platforms on syndemics and work to incorporate HIV (including aging HIV population) and behavioral health into primary care practice. • Establish a long-term survivor peer empowerment team (statewide).	
Planning Areas			
Statewide			

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Strategy 2.5.4	Promote research, cross-agency collaborations, and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.	
Data Indicators	• Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities provided by HIV long-term survivor groups • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Academy of HIV Medicine • Area Agencies on Aging • Association of Nurses in AIDS Care • Local RWHAP Part A and EHE partners	• Create housing opportunities for the aging HIV population. • Expand funding to allow medical and support care for comorbidities. • Integrate cross-agency collaborations to include access to all client-level data to all RWHAP parts. • Provide education around HIV and aging to local partners and service organizations • Provide HIV education to the Florida Insurance Commission's office to promote less insurance burdens on HIV care. • Collaborate with HIV long-term survivor's groups to provide education to various stakeholder groups.
Planning Areas		
Statewide		

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Strategy 2.5.5	Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.	
Data Indicators	• Number RWHAP programs offering geriatric case management services • Number of collaborations with service providers that specialize in services for the aging population • Number of educational opportunities on substance use and mental health for PWH aged 50+ • Number of educational opportunities provided by HIV long-term survivor groups • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • FDEA • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Mobile units • STD clinics • Drug treatment programs • SSPs • Academia • Area Agencies on Aging • Assisted living and skilled nursing facilities • Local RWHAP Part A and EHE partners	• Expand RWHAP services to offer geriatric case management and offer partner prevention services. • Explore opportunities to educate local and state legislators on the important role medical marijuana plays in the management of HIV disease. • Increase awareness with local providers to incorporate messaging on T&T and rapid ART protocols, HIV stigma and care, and aging HIV population. • Increase provider knowledge on aging HIV population, including persons with perinatally-acquired HIV • Revise service delivery models to address healthy aging and address comorbidities.
Planning Areas		
Statewide		

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9.1.2.6 Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure.

Strategy 2.6.1		Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.	
Data Indicators		• Number RWHAP programs offering geriatric case management services • Number of collaborations with service providers that specialize in services for the aging population • Number of collaborations with academic institutions focusing on HIV therapies and HIV cure research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners		• Collaborate with academic institutions to explore opportunities for research around HIV therapies and an HIV cure. • Explore ways to leverage RWHAP Part A funding to support services for aging PWH. • Provide HIV education to the Florida Insurance Commission's office to promote less insurance burdens on HIV care.
Planning Areas			
Statewide			

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Strategy 2.6.2	Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ARV-free remission, reduce, and eliminate viral reservoirs, and achieve HIV cure.	
Data Indicators	• Percent of ADAP clients using injectable ART • Number of collaborations with academic institutions focusing on HIV therapies and HIV cure research • Number of collaborations with academic institutions engaged in clinical research and ART clinical trials • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Persons living with diagnosed HIV, academic institutions, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Local RWHAP Part A and EHE partners	• Engage with medical providers and insurance companies to on ways to reduce the burden of medication interruption. • Collaborate with academic partners and institutions on clinical research and ART clinical trials. • Collaborate with academic partners and institutions to explore opportunities for research around HIV therapies and an HIV cure. • Increase access to ART injection medications through ADAP and other payer sources.
Planning Areas		
Statewide		

**Goal 3: Reduce HIV-related Disparities and Health Inequities****9.1.3.1 Objective 3.1. Reduce HIV-related stigma and discrimination**

Strategy 3.1.1	Strengthen enforcement of civil rights laws (including language access services and disability rights), reform state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, and sexism.	
Data Indicators	• Number of educational and skills building opportunities for PWH • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Advocates • Local and state law enforcement • First responders • Department of Justice and U.S. Immigration and Customs Enforcement satellite offices • Correctional facilities • HIV Justice Coalitions • RWHAP partners	• Educate local and state law enforcement agencies on culturally competent HIV basics, civil rights, and trauma informed care. • Educate local and state legislators, political and civic. Leaders and organizations, and policy makers on basic HIV transmission, prevention, and care; include HIV data specific to local areas. • Support education and skill building opportunities for PWH to promote understanding of civil rights and engagement in policy making.
Planning Areas		
Statewide		

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Strategy 3.1.2	Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or at risk for HIV.	
Data Indicators	• Number of continuing education opportunities and trainings for health care professionals and front-line staff • Number of HIV stigma materials developed and/or disseminated • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	Health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • State and local law enforcement • First responders • RWHAP partners	• Develop and/or identify and disseminate HIV stigma materials and resources for health care professionals and front-line staff. • Identify and disseminate continuing education opportunities and training for health care professionals and front-line staff on HIV stigma; include working with the AETC and Area Health Education Centers. • Work with professional organizations to encourage the adoption of HIV stigma training as part of professional standards for health care professionals and front-line staff.
Planning Areas		
Statewide		

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Strategy 3.1.3	Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.	
Data Indicators	• Number of outreach and education opportunities to recruit peers • Number of community and faith-based leaders engaged in trainings that address HIV stigma and misconceptions • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Conduct outreach and education campaigns to train and employ peers to provide education, navigation, and support services. • Create opportunities and invite marginalized individuals to speak and join virtually (and anonymously) to present their perspectives, educate, and stay protected. • Engage community- and faith-based leaders at local and state levels to develop and host culturally tailored trainings that address stigma and HIV misconceptions. • Support local areas to develop general education and social media campaigns and materials to de-stigmatize HIV and those living with or affected by HIV.
Planning Areas		
Statewide		

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Strategy 3.1.4	Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.	
Data Indicators	• Number of new diagnoses in communities and priority populations at increased risk for HIV • Number of mobile medical units providing services to priority populations • Number of ongoing and new initiatives for priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Identify or develop information to educate potential funders and philanthropic organizations to increase awareness of HIV-impacted populations and communities. • Support ongoing and new initiatives and programs specifically focused on priority populations. • Use HIV data to target HIV and STI education and outreach to high-priority populations and ZIP codes which reflect the residents and effectively represent the community. • Use mobile medical units and street outreach to bring services and resources to communities and populations where the need is greatest.
Planning Areas		
Statewide		

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Strategy 3.1.5		Create funding opportunities that specifically address social determinants of health (SDOH) as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.	
Data Indicators	Priority Populations	- Number of funding opportunities which support programs that address SDOH in Black, Hispanic and other racial/ethnic communities - Number of educational opportunities which address SDOH - Additional specific, quantifiable measures for each activity (TBD)	
		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	- The Department - Community- and faith-based organizations - Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites - Behavioral health care and substance abuse settings - Drug treatment programs - SSPs - Academia - Tribal organizations - RWHAP partners		- Approach private corporations and other entities for sponsorship and educational opportunities to address SDOH. - Develop mini grants and create other opportunities to support programs that address SDOH in Black, Hispanic/Latino, and other racial/ethnic communities. - Explore opportunities to expand the use of MAI funding and assess outcomes.
Planning Areas			
Statewide			

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9.1.3.2 Objective 3.2. Reduce disparities in new HIV diagnoses, in knowledge of status, and along the HIV care continuum

Strategy 3.2.1		Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.	
Data Indicators		• Number of materials developed and disseminated which highlight HIV-related disparities • Number of HIV data dashboards available • Number of educational opportunities and listening sessions for impacted communities • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP partners	• Develop and expand the use of easy-to-read materials (e.g., infographics, one pagers) to help audiences of varying types (general public, clients, providers) to highlight HIV-related disparities. • Expand the use of data dashboards and provide education to relevant groups on how to access and use the information to increase awareness of HIV-related disparities. • Focus efforts to educate and gather information from populations and communities impacted by disparities. Include client perspectives and needs in addition to quantitative data.	
Planning Areas			
Statewide			

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Strategy 3.2.2	Develop new and scale up effective, evidence-based, or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.	
Data Indicators	• Number of collaborations with academic institutions and other partners (outside of HIV) • Number of funding opportunities which focus on improving health outcomes in priority populations • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community-HIV Advisory Group • RWHAP partners	• Collaborate with academic institutions and other partners (outside of HIV) to develop EBIs focused on priority populations and geographic areas impacted by disparities; other partners include mental health, substance use, SAMHSA providers, local homeless coalitions, and others.). • Develop funding mechanisms to support the development or scale up of interventions to improve health outcomes (e.g., mini-grants, RFAs, purchase orders). • Support opportunities at local and state levels to develop or scale up EBIs, including developing internship programs to engage young professionals. • Use local economic modeling to determine those interventions for scale up (e.g., interventions that have the greatest potential to reduce HIV in communities and populations experiencing disparities).
Planning Areas		
Statewide		

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9.1.3.3 Objective 3.3. Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

Strategy 3.3.1		Create and promote public leadership opportunities for people with or at risk for HIV.	
Data Indicators		• Number of people with or at risk for HIV on planning bodies and other advisory groups • Establishment of peer navigator certification program • Number of training and mentorship opportunities for PWH to build leadership and advocacy skills • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • Community-HIV Advisory Group • SSPs • Academia • RWHAP partners	• Develop and support opportunities for people living with or affected by HIV to serve in leadership roles at state and local levels (e.g., HIV Speaker's Bureau). • Establish a statewide peer navigator and educator certification program. • Increase and expand education, training, and mentorship opportunities for PWH to build skills for engaging in a variety of leadership and advocacy roles (social, political, civic, spiritual). • Create an inventory of chairs and co-chairs for local area advisory and planning groups	
Planning Areas			
Statewide			

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Strategy 3.3.2	Work with communities to reframe HIV services and HIV-related messaging so they do not stigmatize people or behaviors.	
Data Indicators	• Number of HIV-related materials reviewed by the state’s educational material review panel • Number of engagement activities conducted with priority populations and local leaders to develop HIV-related messaging • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community-HIV Advisory Group • Educational material review panel • RWHAP partners	• Engage with priority populations and local leaders/influencers to develop HIV-related messaging that does not stigmatize. • Ensure the intentional use of people-first and inclusive language in HIV service delivery, educational materials, and informational campaigns (review existing and incorporate into new products). • Expand the use the state’s health education review panel (i.e., Carlos Alvarez Educational Material Review Panel) to ensure HIV-related messaging and materials are culturally and linguistically appropriate and use people-first language.
Planning Areas		
Statewide		

9.1.3.4 Objective 3.4: Address social determinants of health and co-occurring conditions that exacerbate HIV-related disparities

Strategy 3.4.1		Develop whole-person systems of care that address co-occurring conditions for people with HIV or at risk for HIV.	
Data Indicators		• Number of syphilis diagnoses in communities and priority populations at risk for STIs • Number of HCV diagnoses in communities and priority populations at increased risk for HCV, including PWID • STI, HCV, and TB co-infection rates among persons diagnosed with HIV • Number of new diagnoses in communities and priority populations at increased risk for HIV • Viral suppression percentages in communities and priority populations at increased risk for HIV • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP (all parts) and EHE partners		• Expand local partnerships and collaborate with local providers to address and alleviate barriers to accessing care. • Identify opportunities to centralize eligibility, enrollment services, and health care services for PWH (e.g., HOPWA, RW, ADAP). • Incorporate other health screenings and services into HIV care. • Pilot health care models and interventions for people at risk for or living with HIV who have co-occurring conditions e.g., SUD and mental health conditions.
Planning Areas			
Statewide			

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Strategy 3.4.2	Adopt policies that reduce cost, payment, and coverage barriers to improve the delivery and receipt of services for people with or at risk for HIV.	
Data Indicators	• Number of HIV service providers offering after hours and weekend services for HIV clients • Number of training and cross-training opportunities for medical case managers, RWHAP Part B, HOPWA, and CBOs • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • RWHAP Part A and EHE partners • RWHAP Part B • Health care and related policy and advocacy orgs. • Insurance providers • Pharmaceutical industry partners	• Centralize eligibility processes and cross-train medical case managers, RWHAP Part B, HOPWA and CBOs. • Streamline clinical practices, reduce annual number of visits, CDH, PVC tests. Three or 6-month ART prescriptions. • Explore cost-effective programs that reduce cost, payment, and coverage barriers to improve the delivery and receipt of services for people with or at risk for HIV and use their findings for adopting related policies. • Create consistencies in the RWHAP system of care (Part A, Part B) to eliminate barriers to HIV care (e.g., longer time in between recertification, reciprocal eligibility). • Explore the incorporation of afterhours and weekend services for HIV clients to assist with retention in and adherence to care. • Engage in discussions with Florida Office of Insurance Regulation, Medicaid/Medicare (ACHA), and other entities to identify policies that create barriers for delivery of HIV services for people with or at risk for HIV.
Planning Areas		
Statewide		

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Strategy 3.4.3		Improve screening and linkage to services for people with or at risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.	
Data Indicators		• Number of educational opportunities for providers specializing in co-occurring conditions • Number of partnerships with agencies implementing routine screening and linkage services • Number of mobile units offering HIV/STI screening, treatment, and prevention services during non-traditional hours • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • STD clinics • Mobile units • Drug treatment programs • SSPs • Academia • RWHAP and EHE partners	• Educate providers specializing in co-occurring conditions. • Expand collaboration with FQHCs (and FQHC look-alikes) at state level to improve screening. • Expand partnerships with agencies to expand routine screening and linkage to care services for persons newly diagnosed with HIV or for persons previously diagnosed who are returning to care. • Address challenges and barriers to screening and linkage to services for people with or at risk for HIV who are diagnosed with and are receiving services for co-occurring conditions. • For those at risk, educate non-HIV providers to conduct sexual health and substance use risk assessments routinely. Work with medical certification boards to ensure ongoing education and compliance. • Increase the use of mobile units offering HIV and STI screening, treatment, and prevention services beyond traditional testing hours. • Explore opportunities to modify electronic medical records to increase routine screening and facilitate information sharing	
Planning Areas			
Statewide			

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Strategy 3.4.4	Develop and implement effective, evidence-based- or evidence-informed interventions that address social determinants of health among people with or at risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.	
Data Indicators	• Number of mobile units providing outreach services to priority populations • Number of educational materials identified and disseminated on client rights and health literacy • Stigma indicator to be developed • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Peers and near-peers • CHWs • RWHAP (all parts) and EHE partners • Local and state law enforcement • Housing coalitions • Health care and related policy and advocacy orgs. • Transportation agencies	• Expand the use of mobile outreach units and telehealth technology to address SDOH and provide linkage referrals. • Explore opportunities to use peers and CHWs as mentors outside of the health care system. • Identify and disseminate information and trainings for clients on their rights, grievance policies, customer feedback, and health literacy.
Planning Areas		
Statewide		

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Strategy 3.4.5	Develop new and scale up effective, evidence-based/informed interventions to improve health outcomes and QOL for people across lifespan including youth and people over 50 w/ or at risk for HIV, and long-term survivors.	
Data Indicators	- Establishment of telehealth provider network - Number of cultural humility trainings for providers - Number of non-traditional HIV/STI testing and treatment sites - Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons aged 50+; youth; long-term survivors	
Timeframe	Critical Partners	Activities
By 12/31/2026	- The Department - FDEA - Community- and faith-based organizations - Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites - Behavioral health care and substance abuse settings - Drug treatment programs - SSPs - Academia - Area Agencies on Aging - Elder services agencies	- Develop a telehealth provider network. - Expand access to HIV/STI testing and treatment outside of public health; include public-private partnerships. - Identify and disseminate trainings that include cultural humility trainings for providers. - Identify best practices for consortia to find and identify EBIs. - Promote long-term survivor groups and the Florida Gay Men's HIV Workgroup.
Planning Areas		
Statewide		

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Strategy 3.4.6	Develop new and scale up effective, evidence-based/informed interventions that address intersecting factors of HIV, trauma and violence, and gender especially among cis- and transgender women and gay and bisexual men.	
Data Indicators	• Number of trainings identified and disseminated on TIC • Number of training opportunities for evidence-based interventions addressing mental health • Number of training opportunities to educate the HIV, STD, hepatitis/substance use, and mental health workforce on intersecting issues • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; persons in high-seroprevalent areas; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Correctional settings • RWHAP and EHE partners • Correctional settings • Advocacy groups	• Create opportunities to support providers and agencies implementing EBIs that address trauma and violence. • Identify and disseminate provider trainings on trauma informed care (TIC). • Identify and develop training-of-trainers for TIC to ensure all RWHAP are using a TIC approach. • Provide training opportunities for existing EBIs in the mental health practice. • Identify existing effective, EBIs that address intersecting factors of HIV, trauma and violence, and gender. • Recruit staff with lived experience that reflect the PWH they are trying to serve. • Educate the HIV, STD, hepatitis, substance use, and mental health workforce on the intersecting issues. Ensure diverse organizations are involved in the development of new cross-sectional interventions. Seek out or directly provide funds to support collaborative efforts.
Planning Areas		
Statewide		

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- 9.1.3.5 Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations.

Strategy 3.5.1		Promote the expansion of existing programs and initiatives designed to increase the numbers of racial/ethnic minority research and health professionals.	
Data Indicators		• Number of trainings for HBCUs around HIV prevention, care, and treatment • Number of partnerships established with HBCUs • Development of inventory of SPNS projects and opportunities for replication • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		Racial/ethnic minority research and health professionals	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations		• Create a state-funded program to fill federal gaps. • Cross-train CHWs. • Increase promotion of the HIV field in academic institutions (e.g., MPH programs, Schools of Medicine, Pharmacy, Nursing, and Social Work) through career fairs and supporting certifications and training programs. • Provide training and opportunities for partnership with HBCUs around HIV prevention, care, and treatment. • Develop an inventory of SPNS and support funding opportunities to replicate effective programs.
Planning Areas			
Statewide			

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Strategy 3.5.2	Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.	
Data Indicators	• Number of organizations identified that have mentorship programs • Number of training opportunities identified for PWH to build leadership and advocacy skills • Number of professional groups and associations engaged • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations	• Identify and support the use of mentorship programs for individuals from diverse backgrounds • Elevate voices of people living with HIV through increased advocacy and training. Encourage their participation through support groups. Ensure people who represent the population are in positions to assist with peer support services. • Support implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals. • Identify organizations that have existing mentoring programs and disseminate the information with other agencies to coordinate efforts. • Reach out to professional groups that emphasize memberships of color like the National Association for Black Social Workers, HBCUs, sororities and fraternities, civic organizations, and others.
Planning Areas		
Statewide		

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Strategy 3.5.3		Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.	
Data Indicators		• Number of opportunities to collaborate with the Florida Center for HIV/AIDS Research • Number of research study opportunities shared with community partners and planning bodies • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWI and persons who use drugs	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Health care providers • Health care professional organizations	• Develop professional articles for publication. • Identify opportunities to collaborate with the FCHAR. • Provide information on and encourage community participation in legitimate research studies and grants. • Recruit youth and young adults to participate in local and state HIV planning bodies and advisory workgroups. • Support the use of community opinion leaders and social networking strategies. • Amplify and encourage efforts to share research output with participants.	
Planning Areas			
Statewide			

9.1.3.6 Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust.

Strategy 3.6.1			Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
Data Indicators	• Number of educational and community sharing opportunities to share information and address misinformation • Number of anti-stigma campaigns and materials developed to dispel HIV myths • Assessment of common myths and misconceptions held in and among priority populations • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth		
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Peers and near-peers • CHWs • Academia • Media partners • Digital content providers • RWHAP and EHE partners		• Assess common myths and misconceptions in and among priority populations and identify strategies to combat misinformation. • Promote the use of community sharing experiences and educational opportunities (e.g., community forums, celebrations, observance days). • Ensure messaging is succinct, culturally appropriate, consistent with HIV treatment guidelines, and delivered by persons credible to diverse populations across the state. • Develop and disseminate anti-stigma campaigns which focus on dispelling myths and misconceptions about HIV. • Expand the use of community gatekeepers and social network strategies to deliver HIV information through culturally appropriate methods. • Use existing workgroups to assist with developing and testing strategies to promote accurate creation, dissemination, and uptake of information and to counter misinformation.
Planning Areas			
Statewide			

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Strategy 3.6.2		Increase diversity and cultural competence in health communication research, training, and policy.	
Data Indicators		• Number of collaborations with HBCU medical colleges and other schools of health • Number and type of training opportunities for cultural humility in health communication research • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • HBCUs • Professional and policy organizations and associations	• Create opportunities for advancement among diverse candidates. • Identify ways to create more targeted messaging for specific populations of PWH and consistently use language that is both people-first and inclusive. • Work with HBCU medical colleges such as Pharmacy, Social Work, Nursing, Medical Schools, and others. • Provide training opportunities for diversity and cultural competence in health communication research, training, and policy (e.g., conferences, webinars, lunch-and-learns). • Train and hire PWH who are qualified for roles in HIV leadership, research, training, peer support, and others. • Work with statewide advisory groups and SMEs to identify ways in which diversity and cultural humility can be incorporated into health communication trainings.	
Planning Areas			
Statewide			

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Strategy 3.6.3		Expand community engagement in health communication initiatives and research.	
Data Indicators	Priority Populations	• Number and type of engagements with CBOs, social service agencies and community resource centers • Assessment of populations that may not be receiving accurate health information • Number of collaborations with academic institutions to solicit feedback on health communication initiatives and research • Additional specific, quantifiable measures for each activity (TBD)	
		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Community gatekeepers • RWHAP and EHE partners	• Identify ways to engage priority populations and communities in HIV media and messaging initiatives and research. • Increase engagement with CBOs, community resource centers, and social service agencies to help develop new health communication initiatives; activities could include townhall meetings, focus groups, health fairs, community celebrations, cultural events, and others. • Assess populations that may not be receiving accurate health communications, recruit leaders from those populations and train them to disseminate communications (through staffing agreement). • Engage with academic institutions (e.g., HBCUs) to solicit feedback on health communication initiatives and research. • Amplify and encourage efforts to share research output with participants.	
Statewide			

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Strategy 3.6.4	Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.	
Data Indicators	• Number and type of needs assessments conducted • Number of educational opportunities for providers, peers, and staff on health literacy identified and disseminated • Number and type of health literacy resources identified and developed for clients • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • AETC • Community gatekeepers • CHWs • Peers and near-peers	• Explore ways in which to incorporate critical analysis and health communication skills into HIV programs and services to increase client skills needed for health literacy and advocacy. • Ensure that needs assessments are conducted regularly, including questions related to provider communication skills and HIV-related messaging, in order to better respond to community needs and identify areas for improvement. • Identify and disseminate educational opportunities for providers, peers, and staff on health literacy, and encourage providers to screen clients for health literacy in order to be able to ensure the successful transfer of health information and health communication. • Identify and develop health literacy resources for clients that are new to care in order to help orient them to ways they can become more knowledgeable about their health and actively participate in their plan of care. • Increase provider and staff knowledge for strategies to identify and address misinformation and for strategies that increase the sharing of accurate health information.
Planning Areas		
Statewide		

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Strategy 3.6.5			Expand effective communication strategies between providers and clients to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.
Data Indicators			• Number of local leaders, influencers, and gatekeepers recruited to assist with communication initiatives • Number of CHWs and peers • Number of education and training opportunities on leading with empathy, active listening, patient experience, and on TIC • Additional specific, quantifiable measures for each activity (TBD)
Priority Populations			HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • AETC • Community gatekeepers • CHWs • Peers and near-peers	• Identify best practices for effective communication strategies between providers and clients to address medical mistrust. • Recruit local leaders, influencers, and gatekeepers to assist with communication initiatives designed to build trust. • Use CHWs and peers help to bridge communication gaps between clients and providers. • Offer education and training on leading with empathy, active listening, patient experience, and TIC to promote understanding amongst clients and providers to build trust in the client to provider relationship. • Research best practices in effective communication and explore the creation of a health communication resource compendium. • Increase the reach of messaging and media by engaging with community leaders and expanding partnerships to include organizations and agencies of all size. • Offer third-party encryption messaging to strengthen consumer trust.	
Planning Areas			
Statewide			



Goal 4: Achieve Integrated, Coordinated Efforts that Address the HIV Epidemic Among All Partners and Interested Parties

9.1.4.1 Objective 4.1. Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and/or institutional factors including stigma, discrimination, and violence

Strategy 4.1.1	Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness/housing instability, STIs, viral hepatitis, and substance abuse/mental health disorders.	
Data Indicators	• Development of community of practice to share expertise and collaborate on focus areas • Number of trainings identified and disseminated related to human trafficking, domestic violence, and sexual assault • Number of partnerships with mobile providers • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • Housing coalitions • HOPWA providers • State and local law enforcement	• Develop a Community of Practice program (HUD, Homeless Coalition, FDOE, FDC) to learn, share expertise, and collaborate on focus areas. • Expand marketing and advertising campaigns of internal and external partners to promote and increase awareness of resources and services. • Identify and disseminate trainings and technical assistance on human trafficking, domestic and intimate partner violence and sexual assault for health care staff. • Increase partnerships with mobile service providers. • Leverage social media and outreach to disseminate program results and lesson learned.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.1.2	Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.	
Data Indicators	• Number of reciprocal agreements established with local community partners • Number of HIV service providers using a no-wrong-door approach to screening and linkage services • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Health care providers • RWHAP and EHE partners	• Adopt a no-wrong-door approach focused on streamlining referral processes and linkage to care. A no-wrong-door approach provides individuals with or links them to appropriate services regardless of where they enter the system of care. This principle commits all service agencies to respond to the individual's stated and assessed needs with appropriate treatment or supportive linkage with programs capable of meeting the client's needs. • Establish local referral networking system to increase access to care through assignment of health care navigators. • Establish reciprocal agreements with local community partners.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.1.3	Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.	
Data Indicators	• Number of local information sessions conducted with stakeholders to identify barriers to service delivery • Analysis of data from the state’s HIV/AIDS hotline • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health and human rights advocates • HIV/AIDS policy experts • Health care providers • STD clinics • RWHAP and EHE partners • Local planning bodies	• Analyze and explore ways to use data from the state HIV/AIDS hotline to assess barriers. • Access statewide resources to identify gaps in service and funding opportunities to combat programmatic barriers. • Conduct local information sessions/workshops with stakeholders to analyze data and identify problematic areas as it relates to the delivery of service. • Create incident reporting system to identify individuals in need of assistance (e.g., assault, discrimination, housing). • Engage with local and state legislators to educate and inform on workforce capacity and impacts of staffing shortages.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.1.4		Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, and local partners.	
Data Indicators	Priority Populations	• Development of collaborative forum to share and learn about OD2A programs • Number of local health care facilities participating in local community health needs assessments • Additional specific, quantifiable measures for each activity (TBD)	
		HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • FDCF • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings and providers • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners • Local planning bodies		• Ensure the Community Health Improvement Plan and Community Health Assessment is inclusive of internal and external partners. • Create a collaborative forum to share and learn about (OD2A programs across multi-agencies (e.g., faith-based organizations, CBOs, providers, the Department, FDCF). • Ensure the State Health Improvement Plan process and planning is inclusive of external groups and partners. • Establish a role or function in existing local planning bodies to conduct research into opioid initiatives and networks. • Invite local health care facilities to participate in local community health needs assessments.
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.1.5	Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.	
Data Indicators	• Number of opportunities to education state and local legislators on harm-reduction practices • Number of local planning bodies supporting or participating in opioid initiatives • Number and type of naloxone access points • Number of naloxone training courses identified and disseminated • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • State and local law enforcement • Local planning bodies • RWHAP and EHE partners	• Educate local and state legislators on the use of fentanyl test strips and alignment with harm-reduction practices. • Establish a role or function in existing local planning bodies across multiple agencies (CHD, community, state, FCPN, OD2A project opioid providers) to support and/participate in opioid initiatives or the development of an opioid initiative. • Implement Naloxone Training Course and Training Program (CDC) • Increase the number of access points for naloxone (statewide). • Integrate OD2A into RWHAP service delivery system at local levels.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

9.1.4.2 Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and CBOs, the private sector, academic partners, and the community

Strategy 4.2.1		Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.	
Data Indicators		• Development of interactive locator for mobile service providers • Number of public-private partnerships established at local levels • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHP and EHE partners • Digital resource providers (e.g., AIDSVu)		• Develop a mapping tool/interactive map locator/pin map of mobile units. • Develop regular partnership meetings with internal and external service providers at the local level. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Identify best practices and interventions from other jurisdictions that address similar priority populations. • Increase the use of outreach and education to reach priority populations and geographies.
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.2.2	Enhance collaboration among local, state, tribal, territorial, national, and federal partners, and the community to address policy barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.	
Data Indicators	• Development of centralized information platform to collect integrated HIV planning information • Number of and type of materials developed and disseminated in three languages (i.e., English, Spanish and Haitian-Creole) • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health and human rights advocates • HIV/AIDS policy experts • Health care providers • PWH engaged in services • Tribal organizations • Minority leadership programs • RWHAP and EHE partners	• Appoint community liaisons among local, state, tribal, territorial, national, and federal partners to assess and address barriers and social determinants via policy change and enhanced communication. • Create a centralized information platform to house local, county, state, consortium planning body meeting information, and proposed activities, and projects. • Create opportunities to bring a wide variety of partners and stakeholders together to increase cross-collaboration. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Incorporate three-language formula in marketing and advertising materials to overcome social barriers in disproportionate communities.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.2.3		Coordinate across partners to quickly detect and respond to HIV outbreaks.	
Data Indicators		• Number and geographic location of HIV transmission clusters identified • Number of intersectional teams developed at local levels for outbreak response • Number of mobile units using HIV transmission cluster data to direct positioning • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations		PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners	• Create a centralized system for outbreak detection, reporting, and notification (e.g., meningitis, Mpox, HIV, STD, viral hepatitis). • Develop intersectional teams and protocols that include Department DIS, RWHAP programs, funded EHE providers, case managers, local medical and support services providers to share information and rapidly identify and link individuals diagnosed with HIV to care and treatment. • Establish response planning teams across multi-agencies and multi-sectors of the community (e.g., faith-based organizations, CBOs, providers, the Department) to track HIV outbreaks and provide rapid access to HIV treatment and care. • Use HIV transmission cluster data to direct the positioning of mobile units to respond to clusters of active transmission.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.2.4	Support collaborations between CBOs, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.	
Data Indicators	• Inventory of multi-agency collaborations at local levels • Number of partnerships with non-traditional sites to provide HIV awareness, prevention, or linkage services • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; gay, bisexual, and other MSM of all races/ethnicities; Black and Hispanic heterosexuals; transgender individuals; PWID and persons who use drugs; youth; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Educational institutions • Health care providers • Housing providers • RWHAP and EHE partners	• Advocate for the revision of MOAs and contracts to include specific standards, wrap-around services (e.g., housing, mental health services, and participation in planning). • Assess and review state and national collaborative frameworks to identify and adopt approaches that enhance current and future public-private partnerships that help scale up best practices and advances in HIV prevention and treatment. • Educate local and state legislators on the state's priority populations and geographies. • Form partnerships with non-traditional sites (e.g., gas stations, sporting events, public restrooms, rest stops) for the extension of providing HIV prevention and treatment services or awareness. • Identify best practices for increasing collaborations among CBOs, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.
Planning Areas		
Statewide		

9.1.4.3 Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

Strategy 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.		
Data Indicators	- Development of centralized dashboard to share aggregate HIV-related data - Number of data sharing agreements developed with RWHAP partners - Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	- The Department - Community- and faith-based organizations - Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites - Behavioral health care and substance abuse settings - Drug treatment programs - SSPs - Academia - Health care providers - RWHAP and EHE partners - AHCA - Correctional settings - Community HIV Advisory Group	- Create centralized system or dashboard to share aggregate HIV-related data (e.g., testing, treatment, surveillance) internally and externally that can be readily used to understand local area disease burden, obtain information for grant requirements and using data for action and response. - Design a data system and process for improving data sharing amongst all RWHAP Parts, Florida ADAP, and service providers to improve client-level data sharing and HRSA RSR reporting requirements. - Develop a process to improve and simplify the sharing of HIV-related data both internally and externally to the Department to improve service provision. - Develop a process to increase working with external partners such as VA, private providers, Medicare, and others to improve data sharing at state and local levels. - Ensure that forms and policies around release of information and methods for release (e.g., text, email, phone) are continuously updated and shared with providers.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.3.2	Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator’s Health IT Certification Program, and health information exchange networks, to improve HIV prevention efforts and care outcomes.	
Data Indicators	• Evaluation of digital resources and clinical decision support tools • Development of reciprocal client-informed consent and release of information • Number of local areas with electronic referral systems • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • RWHAP and EHE partners • Community HIV Advisory Group • AHCA • Correctional settings	• Assess the ability to create a Health Information Exchange (HIE) and master client index among HIV service providers and link the current Florida HIE to data in the HIV/AIDS Section to improve linkage to care efforts. • Create a reciprocal (e.g., across agencies and all RWHAP parts) client-informed consent and release of information to acknowledge that data may be shared to improve service provision and linkage to care needs. • Develop a process and system to initiate and track electronic referrals to HIV-related prevention, treatment services and other ancillary services. Consult with the AIMS workgroup to review current resources. • Evaluate and promote the use of digital resources and clinical decision support tools. • Identify ways to improve data collection efforts for HIV prevention efforts (e.g., HIV self-test kit information).
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.3.3			Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy supportive manner.
Data Indicators	• Development of client-centered training module around public health data collection and uses of patient information for public health • Development of reciprocal client-informed consent and release of information • Number and type of information shared around use of patient portals to facilitate client access to medical information • Assessment of information sharing methods best suited for rural communities and other areas with limited internet access • Additional specific, quantifiable measures for each activity (TBD)		
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers		
Timeframe	Critical Partners	Activities	
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Create a client-centered training module around public health data collection and uses of patient information for public health purposes to assist with alleviating fears about misuse and privacy concerns. • Provide guidance and supportive information to encourage the use of patient portals from providers and laboratories to ensure that clients have direct access to their medical information. • Ensure health communication and messaging from provider to client is private, secure, and accessible, and occurs through a HIPAA-compliant platform or channel. • Explore the incorporation of a centralized patient portal or health information application. • Encourage providers currently using patient portals to offer additional client-centered education on patient portal functionality and utilization. • Explore the increase of in-app or in-portal patient health education opportunities. • Assess methods to increase information sharing and patient health education opportunities for people living in rural communities or other areas with limited internet access.	
Planning Areas			
Statewide			

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

9.1.4.4 Objective 4.4: Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.

Strategy 4.4.1	Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, CBOs, allied health professionals, people with HIV and their advocates, the private sector, and other partners.	
Data Indicators	• Number and type of public-private partnerships established and maintained • Development of statewide conference on HIV • Number of non-traditional partners participating in local HIV awareness events • Number of HIV prevention and treatment sites using ARV starter packs • Additional specific, quantifiable measures for each activity (TBD)	
Priority Populations	PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners	Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group	• Review and assess state and national collaborative frameworks to identify and adopt approaches that enhance current and future public-private partnerships that help scale up best practices and advances in HIV prevention and treatment. • Conduct an annual statewide conference on HIV and invite a wide range of traditional and non-traditional partners to participate and attend and share best practices. • Foster strong public-private partnerships to accelerate advances in HIV by inviting stakeholders outside of typical HIV partnerships to attend awareness days and generate new approaches to addressing the HIV epidemic. • Identify public-private partnership EBIs to scale up the use of ARV starter packs.
Planning Areas		
Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.4.2		Expand opportunities and mechanisms for information sharing and peer technical assistance in and across jurisdictions to move effective interventions into practice more swiftly.	
Data Indicators	Priority Populations	• Development of centralized information repository on best practices programs and interventions for addressing the HIV epidemic • Number and type of information sharing mechanisms used in local areas • Number of multi-agency collaboratives supporting data and information sharing • Additional specific, quantifiable measures for each activity (TBD)	
		PWH; HIV research and health care professionals and front-line staff, community-based organizations, health care delivery systems, and public health systems; HIV prevention and treatment providers	
Timeframe	Critical Partners		Activities
By 12/31/2026	• The Department • Community- and faith-based organizations • Health care settings including hospitals, FQHCs, private physician practices, and reproductive health sites • Behavioral health care and substance abuse settings • Drug treatment programs • SSPs • Academia • Health care providers • PWH engaged in services • RWHAP and EHE partners • AHCA • Correctional settings • Community HIV Advisory Group		• Create a centralized information repository to house and disseminate information on best practices, meeting information, and other information that will assist with addressing the HIV epidemic. • Develop local e-newsletters or other mechanisms to disseminate information quarterly on available resources and EBIs being used in the state. • Identify and establish local area collaborative coalitions across multi-agencies and multi-sectors of the community (e.g., faith-based organizations, CBOs, providers, the Department and others) to support data and information sharing and identify best practices that address the HIV epidemic. • Identify state and local subject matter experts and create a state specific technical assistance network.
Planning Areas	Statewide		

State of Florida Integrated HIV Prevention and Care Plan, 2022–2026

Strategy 4.4.3			Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing persons of all ages living with HIV.
Data Indicators	• Development of centralized information repository on best practices programs and interventions for addressing the HIV epidemic • Number and type of information sharing mechanisms used in local areas • Number of multi-agency collaboratives supporting data and information sharing • Additional specific, quantifiable measures for each activity (TBD)		
	Priority Populations		
Timeframe			Critical Partners
By 12/31/2026			Activities
Planning Areas			
Statewide			

9.2 Partnership Area Interview Questionnaires



9.3 Partnership Area Resource Inventories



9.4 Epidemiologic Profile

The full Epidemiologic Profile of HIV in Florida, 2017–2021 will be made available separately.

9.5 Other Supporting Documentation



9.6 Glossary

Acquired Immunodeficiency Syndrome (AIDS): A condition that exists when a person has tested positive for HIV and has one or more of 26 listed opportunistic illnesses/infections and/or a T-cell count of 200 or less per micro-liter of blood.

Business Responds to AIDS (BRTA): Modeled after the CDC initiative by the same name, developed initially in 1992, BRTA programs support targeted HIV prevention efforts through partnerships with local businesses. BRTA programs mobilize businesses and labor organizations to respond to HIV/AIDS in the workplace and the community with subtle, noninvasive approaches to raise awareness, promote services, and break down stigma. BRTA activities involve the use of promotional and incentive items that businesses can use to generate conversations around HIV/AIDS with their customers.

Community-Based Organization: A non-profit organization with a 501(c)(3) designation.

Community Engagement: The process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address affecting the well-being of those people.

Community Health Worker: Trusted, knowledgeable frontline health personnel who typically come from the communities they serve. CHWs bridge cultural and linguistic barriers, expand access to coverage and care, and improve health outcomes.

Counseling, Testing and Linkage: Provision of counseling, testing and direct assistance in getting a client enrolled into the health and social service system.

Culturally Appropriate: Conforming to a culture's acceptable expressions and standards of behavior and thought. Interventions and educational materials are more likely to be culturally appropriate when representatives of the intended target audience are involved in planning, developing, and pilot testing them.

Epidemic: The occurrence of cases of an illness, specific health-related behavior, or other health-related events in a community or region in excess of normal expectancy.

Ethnicity: The cultural characteristics that connect a particular group or groups of people to each other, such as people of Hispanic or Latino origin.

Faith-Based Organization: A non-governmental agency owned by religiously affiliated entities such as (1) individual churches, mosques, synagogues, temples, or other places of worship or (2) a network or coalition of churches, mosques, synagogues, temples, or other places of worship.

Faith Responds to AIDS (FRTA): Built on the same framework as BRTA, FRTA is a Florida adaptation of the BRTA initiative but for faith-based organizations. FRTA programs are faith-based initiatives that mobilize churches and other faith-based institutions to raise awareness and reduce stigma around HIV/AIDS. FRTA programs are particularly effective at reaching minority communities. FRTA activities involve the use of promotional and incentive items that faith-based organizations can use to generate conversations around HIV/AIDS with their members.

Females: Individuals of the sex that produces large and generally immobile gametes (ova or eggs).

High-Impact Prevention (HIP): Using combinations of scientifically proven, cost-effective and scalable interventions targeted towards the highest risk populations in the right geographic areas to reduce new HIV infections.

HIV Mode of Exposure: Specific behaviors or actions that expose people to HIV and can potentially lead to HIV acquisition. Examples include unprotected anal or vaginal sex with a person living with HIV, injecting drugs with non-sterile, shared drug injection equipment, and male-to-male sexual contact.

Human Immunodeficiency Virus (HIV): The retrovirus virus can lead to AIDS, if not treated. The virus occurs in two types—HIV-1 and HIV-2. Both types are transmitted through direct contact (e.g., through sexual intercourse or sharing injection drug equipment) with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-positive mother to her child during pregnancy, birth, or breastfeeding.

Incidence: The occurrence of new cases of disease or injury in a population over a specified period of time.

Integrated Prevention and Care Plan: A plan based on the Integrated HIV Prevention and Care Plan Guidance that requires a collaborative process between CDC and HRSA to identify and address: statewide goals for HIV prevention and care; emphasize the populations and communities most affected by the epidemic; highlight areas of need, service gaps, and barriers; identify health disparities and social determinants of HIV-related health; outline activities for implementing goals; and, identify factors for measuring success in achieving goals.

Intervention: A specific activity (or set of related activities) intended to reduce the risk of HIV transmission or acquisition. Interventions may be either biomedical or behavioral and have distinct process and outcome objectives and protocols outlining the steps for implementation.

Linkage: Actively assisting clients with accessing needed services through a time-limited professional relationship. The active assistance typically lasts a few days to a few weeks and includes a follow-up component to assess whether linkage has occurred. Linkage services can include assessment, supportive counseling, education, advocacy, and accompanying clients to initial appointments.

Males: Individuals of the sex that produces small, mobile gametes (sperm).

Men who have Sex with Men (MSM): Men who report sexual contact with other men and men who report sexual contact with both men and women (i.e., bisexual contact), whether or not they identify as gay.

National HIV/AIDS Strategy for the United States: A comprehensive plan focused on reducing HIV incidence, increasing access to care and optimizing health outcomes, and reducing HIV-related health disparities.

Navigation Services: Patient navigation assistance is the process of helping a person obtain timely and appropriate medical or social services, taking into account provider preferences,

insurance status, scheduling issues, and other factors that may complicate access or utilization of services.

Navigator: Patient navigators are peers, volunteers, and/or staff members of clinics, health departments, and community-based organizations. Patient navigators may be lay persons, paraprofessionals, or medical professionals (e.g., RNs, LPNs).

Partner Services: A systematic approach to notifying sex and needle-sharing partners of PWH of their possible exposure to HIV so they can be offered HIV testing and learn their status or, if already diagnosed, prevent transmission to others. Partner Services helps partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

Peers (or Near-Peers): Specially trained individuals from the community who may or may not be living with HIV/AIDS, but ultimately have lived experience.

Perinatal: Occurring during the period around birth (5 months before and 1 month after)

Post-Exposure Prophylaxis (PEP): The provision of antiretroviral medications to prevent transmission of HIV following an occupational or non-occupational exposure. Non-occupational post-exposure prophylaxis is referred to as nPEP.

Pre-Exposure Prophylaxis (PrEP): Antiretroviral medication taken to prevention acquiring HIV.

Prevalence: The number of people with a specific disease or condition in a given population at a specific time.

Race: A person's self-reported classification of the biological heritage with which they most closely identify.

Rapid HIV Test: A point-of-care HIV screening test used in both clinical and non-clinical settings, usually with blood from a finger stick or with oral fluid.

Ryan White Treatment Modernization Act: The name given to the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act when it was reauthorized in 2006. This is the primary federal legislation that addresses the needs of persons in the United States living with HIV/AIDS and their families. The original CARE Act was enacted in 1990.

Seroprevalence: The overall occurrence of a disease or condition within a defined population at one time, as measured by blood tests.

Sex: Either of the two main biological categories (male and female) into which humans and most other living things are divided on the basis of their reproductive functions.

Social Determinants: The economic and social conditions that influence the health of persons, communities, and jurisdictions and include conditions for early childhood development; education, employment, and work; food security; health services; housing; income; and social exclusion.

Surveillance: The ongoing and systematic collection, analysis, and interpretation of data about occurrences of a disease or health condition.

Syndemic: The aggregation of two or more concurrent or sequential epidemics or disease clusters in a population with biological interactions, which exacerbate the prognosis and burden of disease.

Transgender: A person who does not identify with their sex at birth and may undergo gender transitionary care including hormone therapy and/or surgical procedures. This is also recognized as gender dysphoria.



2022-2026

STATE OF FLORIDA

Integrated HIV Prevention and Care Plan

EXHIBIT L

**US Department of Health and Human Services
Centers for Disease Control and Prevention
Health Resources and Services Administration**



**Virtual Meeting of the
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment**

April 26-28, 2022

Record of the Proceedings

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Executive Summary

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

CDC and HRSA Welcome and Updates

The meeting began with detailed updates from CDC and HRSA. The CDC update highlighted a number of important areas of interest from the NCHHSTP HIV, STD, viral hepatitis, and school/adolescent health programs including: a brief update on the continuing impact of COVID-19; NCHHSTP's equity initiative and strategic plan; harm reduction and Syringe Services Programs; discussion of mental health concerns in youth; Ending the HIV Epidemic (EHE) update; discussion on updated hepatitis B vaccination and screening and testing recommendations; and integrating STI and HIV services to address the syndemic. Highlights from the HRSA/HAB presentation included the introduction of a new Administrator, launch of a new Ryan White website, release of the National HIV/AIDS Strategy (2022–2025) in December 2021, and policy and data updates. CHAC members discussed recent policy changes and their potential impacts on LGBTQ (lesbian, gay, bisexual, transgender, and questioning) youth's access to information, resources, and equitable care.

Strategizing an Approach to Providing Comprehensive STI Services

During this panel, CHAC heard from programs in Mississippi, New York, and Minnesota that highlighted innovative strategies they are employing to increase access to testing and comprehensive STI services. These strategies included using the school space to increase access to health services for young people, leveraging technology, and the effort to align that with the COVID-19 pandemic response to: 1) innovate and modernize the public health infrastructure, which can serve as a good model moving forward in jurisdictions; and 2) determine how to secure and sustain funding to support these efforts moving forward in a post-COVID world.

Leveraging Policy to Advance HIV, VH, and STI Priorities

This panel focused on utilizing policy as a public health intervention as an approach to solving expansive issues in public health. The National Viral Hepatitis Roundtable presented on the state of Medicaid access with respect to Hepatitis C. The California Department of Public Health (CDPH) Office of AIDS provided an update on Senate Bill (SB) 159 pertaining to HIV pre-exposure and post-exposure prophylaxis (PrEP & PEP) for California pharmacists and the STD Control Branch presented on leveraging policy changes for STI and VH prevention, testing, and treatment. The Louisiana Office of Public Health STD/HIV/Hepatitis Program described Louisiana's *Hepatitis C Elimination Plan: 2019-2024*. The Transitions Clinic Network described issues pertaining to the Medicaid Inmate Exclusion Policy (MIEP) which reduces barriers to care for post-incarceration, reintegrating individuals.

Turning the Tide on Self-Testing and Sample Collection

This special presentation focused on self-testing and sample collection, highlighting the pipeline and approval process for self-collection kits. CHAC heard data on how impactful self-collection kits could be on communities that historically have not utilized traditional brick-and-mortar structures. The availability of self-collection kits has been demonstrated to increase testing practices in a number of communities. Discussion focused on how the Food and Drug

Administration (FDA) views HIV versus HCV and manufacturers' willingness to produce self-testing kits and seek FDA approval. Additionally, CHAC members discussed the differences in the criteria used for regulatory authorization of collection kits/methods domestically versus internationally and the potential for the review and revision of FDA process to increase access to and use of self-test kits.

Applied Syndemic Approach to HIV, VH, and STIs: Focusing on People

This panel focused on implementation of programmatic syndemic approaches, which underscored the need to take a "whole person" approach in terms of the issues that influence an individual's ability to access the resources that are being put forward, utilize them effectively, and achieve successful health outcomes. The New Mexico Department of Health (NMDOH) described its comprehensive harm reduction program focused on meeting people where they are to support HCV treatment and syphilis services. The North Dakota State Correctional Health Authority emphasized that corrections health is an important part of public health and represents a vulnerable and underserved population and can be an ideal setting for delivering comprehensive services. The San Francisco Unified School District (SFUSD) described policies and mandates, community partnerships, resources, training, and initiatives that help support comprehensive sexual health services to SFUSD youth. Finally, CDC's Division of HIV Prevention (DHP) provided an update focused on advancing syndemic approaches through cluster detection and response, emphasizing that cluster detection and response can guide tailored implementation of proven treatment and prevention strategies for HIV and other syndemic conditions where transmission is occurring most rapidly.

Telehealth/Telemedicine Working Group (WG)

The Telehealth/Telemedicine WG put forth several recommendations focused on enhancing routine screening through virtual services for all populations, health equity's relationship to telehealth service provision, and deployment of the Tele-PrEP initiative for Federally Qualified Health Centers (FHQCs).

Presidential Advisory Council on HIV/AIDS (PACHA)

CHAC was provided an update on PACHA's 73rd full council meeting that was convened virtually on March 14-15, 2022. This presentation emphasized the importance of hearing the voices of the community that will help guide PACHA in moving forward in terms of making recommendations to support EHE and in implementing the National HIV/AIDS Strategy (NHAS).

Business Session

The Business Session focused on CHAC actions and proposed future agenda topics. The next CHAC meeting is scheduled for November 1-3, 2022.

Future Agenda Topics Proposed

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

CHAC Actions

During this meeting, CHAC members voted unanimously to:

- Adopt the November 2021 CHAC meeting minutes, with no edits proposed.
 - Send the letter of recommendations presented by the Telehealth WG to the HHS Secretary, with a minor revision of repositioning the health equity recommendation as the first bullet.
 - Develop and send a letter to the HHS Secretary regarding LGBTQ youth.
 - Create a Self-Collection Self-Testing WG to consider issues related to self-testing, potentially including: 1) Differences in FDA risk classification of HCV and HIV; 2) Criteria required and data available for the FDA approval process; and 3) Downregulation to class II diagnostics. In addition, this WG will draft a letter to be presented to CHAC for a potential vote during the November 2022 meeting.
 - Establish a Workforce WG to liaise with PACHA on their efforts, to discuss the main issues CHAC is to consider on workforce including exploring the role of other professionals and community health workers (CHWs) in this space, and to discuss topics to potentially inform a panel for the November 2022 CHAC meeting.
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**US DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
April 26-28, 2022**

Minutes of the Meeting

The United States (US) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 26-28, 2022.

The CHAC is a committee chartered under the Federal Advisory Committee Act (FACA) to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies, and priorities for HIV, viral hepatitis, and STD prevention and treatment efforts for the nation. Information for the public to attend the CHAC meeting virtually was published in the *Federal Register*, in accordance with FACA rules and regulations. All sessions of the meeting were open to the public. Please see Appendix A for Membership Attendance.

Day 1: Opening of the Meeting and Roll Call

Marah E. Condit, MS

Public Health Analyst, Advisory Committee Management Lead
Office of Policy, Planning, and Partnerships
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Ms. Condit welcomed participants to the CHAC meeting, called the proceedings to order at 11:00 AM Eastern Time (ET), reviewed ground rules, and provided instructions for discussion periods. She indicated that members of the public would have an opportunity to provide oral comments at 3:30 PM ET during the second day, and that public comments would not be accepted at any other point during the meeting.

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

On behalf of CDC and HRSA, Dr. Mermin welcomed those present and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. Members should be mindful of potential conflicts of interest (COIs) identified by the Committee Management Office (CMO) and recuse themselves from voting or participating in any discussions for which they could be conflicted. He then conducted a roll call to determine the CHAC voting and *Ex-Officio* members who were in attendance and establish quorum. Quorum was maintained during all 3 days of the meeting.

Conflict of Interest Disclosures

CHAC Voting Member Institution/Organization	Disclosure of Conflicts
Jean R. Anderson, MD Johns Hopkins Medical Institutions	Stocks: Apple, Amazon, Cisco, Alphabet, Splunk Research Funding: Merck, Gilead
Wendy Armstrong, MD Emory University School of Medicine	Research Funding: HRSA/Ryan White Parts A, B, D that supports part of her salary as well
Jodie Dionne-Odom, MD, MSPH University of Alabama, Birmingham	Research Funding: NIH
Shannon Brown Dowler, MD North Carolina Medicaid	None
Daniel Driffin, MPH D3 Consulting	None
Travis Gayles, MD, PhD Hazel Health	Self-recusal for Telehealth related topics
Meredith Greene, MD University of California, San Francisco	Research Funding: Gilead, NIH Works in a Ryan White-funded clinic
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN Duke University	Research Funding: NIH, ACF
Kali Lindsey amfAR, Foundation for AIDS Research	None
Christine Markham, PhD University of Texas Houston	Research Funding: NIH, ACF, OMH
Shruti Mehta, PhD, MPH Johns Hopkins Bloomberg School of Public Health	Research Funding: NIH, USAID Materials Support For Research Studies: Abbott
Johanne Morne, MSED AIDS Institute, New York State Department of Health	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program
Kneeshe Parkinson Washington University/Project ARK	Research Funding: HRSA/Ryan White HIV/AIDS Program Parts A, B, C, and D
Robert Riester Denver Element	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program, Part A
Leandro Rodriguez, MBA Latino Commission on AIDS	Research Funding: HRSA/Ryan White HIV/AIDS Program, CDC, SAMHSA, Gilead, ViiV
Samuel So, MD Stanford University	Research Funding: CDC, NIH

Ex-Officio members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA), Dr. Maureen Goodenow of the National Institutes of Health (NIH), Dr. Neerja Gandotra of the Substance Abuse and Mental Health Services Administration (SAMHSA), Ms. Kaye Hayes of the HHS Office of HIV/AIDS and Infections Disease Policy (OIDP), Mr. Rick Haverkate of the Indian Health Service (IHS), and Dr. Richard Wild of the Centers for Medicare and Medicaid Services (CMS). Liaison member Dr. Ada Steward of the

Presidential Advisory Council on HIV/AIDS (PACHA Liaison Representative) organization, Eau Claire Cooperative Health Centers, receives Ryan White Funding Parts B and D.

Dr. Mermin confirmed that a quorum of 22 was achieved and that CHAC could move forward with conducting its business on April 26, 2022.

Welcome and Agenda Review

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Gayles and Anderson welcomed everyone to the April 26-28, 2021 CHAC meeting. Dr. Gayles thanked CHAC members, federal officials, CDC and HRSA staff, and the general public for their attendance and commitment. He expressed particular gratitude to Dr. Stewart for her efforts to promote vaccination in the pediatric population, as well as her commitment across the full breadth of public health issues. He reviewed the agenda for the day, pointing out that it highlighted the continued need to be nimble and versatile in the ever-changing post-COVID world with the increased attention on public health issues and budget demands and supplies. He observed that many of the topics to be discussed during this meeting demonstrated how CHAC must continue to evolve in terms of considering what should be included in a comprehensive STI testing program in 2022, determining the types of policies that need to be put into place to impact service delivery in a more meaningful way, and examining how federal policies might influence the delivery of those services. As always, they looked forward to great presentations, robust discussions, and tangible action items.

CDC DFO Welcome and Updates

NCHHSTP Update

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

CHAC Designated Federal Officer

Dr. Mermin welcomed new CHAC Voting Members, Mr. Kali Lindsey and Dr. Christine Markham. He also welcomed Dr. Maureen Goodenow, Director of NIH's Office of AIDS Research, who is replacing Dr. Paul Gaist as the NIH *Ex-Officio* member.

To update CHAC correspondence, responses were sent on March 7, 2022, for the HIV and HCV classification letter; the Viral Hepatitis Workgroup (WG) letter; the Youth Engagement letter; and an interim response to the Perinatal Infection WG letter. CDC and HRSA are working on a detailed response currently and hope to have that finalized in the next couple of months.

In terms of COVID-19 pandemic, the number of deaths officially attributed to COVID-19 is close to 1 million in the US and there have been over 80 million total cases. Although mortality and hospitalizations decreased with the decreasing incidence of COVID-19 in the early part of 2022, cases and hospitalizations increased as the new subvariant began to spread. Challenges continue for all of public health and clinical care, as well as policies and other aspects of trying to keep America healthy in an environment where there are various other pressures

simultaneously. NCHHSTP continues to have multiple deployments for the COVID-19 response, with over 700 employees deployed since the beginning of the epidemic, over 1600 cumulative deployments, 53 people currently deployed, and 17 staff soon to deploy. NCHHSTP also is taking responsibility for several aspects of the incident management structure as CDC begins to reorganize its response to COVID-19, with the understanding that this is going to be a long-term effort.

NCHHSTP's Equity Initiative Strategy launched in 2021. This long-term strategy is intended to help achieve workplace equity and eliminate health disparities by addressing racism and other systems of oppression that hinder the center's mission. An implementation plan was developed that outlines the first steps of this process, though NCHHSTP already has been implementing many of the strategies. The overall goal is to help integrate health equity and equity in the workplace as core activities to which NCHHSTP is committed. NCHHSTP is focused on pervasive disparities associated with HIV, viral hepatitis, STDs, and TB, as well as adolescent health. The Equity Initiative involves all aspects of the center, with each division developing action plans that they have been implementing for some time.

An assessment was completed of external work for improving public health, internal workforce, organizational change, and analysis. Based on the analysis of the workforce, over 50% of NCHHSTP's staff are racial/ethnic minorities and close to 70% are women. The proportion of racial/ethnic minorities has increased at least 20% over the past decade. NCHHSTP also was the first group at CDC to conduct a survey of staff regarding sexual orientation and gender identity. Approximately 18% of NCHHSTP staff identified as LGBTQ (lesbian, gay, bisexual, transgender, questioning), with that proportion being the same in lower and higher General Schedule (GS) levels. NCHHSTP is committed to continue to perform these demographic analyses, develop fact sheets, and improve the inclusiveness of the day-to-day experience of staff within the center.

Part of the Equity Initiative is the development of an external public health dashboard that assesses the overarching measures of inequity in the diseases under NCHHSTP's purview. There are relative comparative measures and absolute measures, which follow current scientific practices for analyzing inequities. While these measures vary for each condition and population, the center is committed to reducing health inequity.

CDC's cross cutting strategic plan to reduce the infectious disease consequences among people who use drugs is complete. The mission is to decrease morbidity, mortality, and incidence of infectious diseases associated with injection drug use, as well as stigma experienced by people who use drugs. Several strategic priorities have been identified, including expanding the infrastructure of syringe services programs (SSPs) nationwide and integrating SSPs into the public health system, and establishing coordinated surveillance, monitoring, and program implementation. "Strengthening Syringe Services Programs" Notice of Funding Opportunity (NOFO) was issued recently that will expand SSP and support a network of SSPs across the country.

Additionally, this year CDC is implementing the 6th surveillance cycle among people who use drugs via the National HIV Behavioral Surveillance or NHBS which monitors prevalence and trends of HIV infection, risk behaviors, and prevention services among populations at increased risk for HIV, across 20-23 cities in the US. CDC is also launching the Microinfluencing project with the CDC Foundation and the Public Good Projects. This is a pilot to engage social media influencers to grow support for SSPs starting in West Virginia and other jurisdictions across the country. The campaign launched mid-April called "Appalachian Influencers," recruiting both paid

and volunteer influencers to begin posting messages, focusing on 4 audiences including law enforcement, health care, faith leaders, and community leaders.

Similar to what has been experienced in other infections, tuberculosis (TB) cases decreased in 2020 for a variety of reasons that are still under exploration and increased by 9% in 2021, however, not to the levels of 2019. Factors likely contributing to the observed decline include delayed or missed TB diagnosis due to disruptions in health care access, underdiagnosis, or a true decline from the reduced TB transmission due to pandemic mitigation efforts and fewer new arrivals from high TB incidence countries. TB incidence in the US continues to decrease over time, but not at the pace that would be necessary to achieve TB elimination goals.

Division of Adolescent and School Health (DASH) Update

Kathleen Ethier, PhD

Director, Division of Adolescent and School Health
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Ethier reminded everyone that DASH has been presenting to CHAC for a number of years about what has been observed through the Youth Risk Behavior Survey (YRBS) regarding the health and wellbeing of young people in the country. New data recently were released that were collected through the Adolescent Behaviors and Experiences Survey (ABES), a version of the YRBS that was implemented in Spring 2021. Students were recruited through schools, same as is done for the YRBS, but they were able to complete the survey online instead of in a classroom. This engagement allowed sample students who were learning virtually, as well as those who were learning in-person in school to participate.

These data reveal the magnitude of challenges that youth are experiencing, particularly related to mental health, experiences of abuse in the home during the pandemic, experience of racism in schools, and a variety of other issues. There is a continuing mental health crisis among youth, which was seen prior to the pandemic, particularly among female students and students who identify as being LGBTQ. These data show 26% of students who identify as LGBTQ attempted suicide in the year prior to the data collection during the pandemic and more than 50% of all students experienced emotional abuse in the home (e.g., verbal abuse by a parent or other adult), speaking to the level of stress experienced by students and families. Among respondents, 64% of Asian students and 55% of Black and Multiracial students reported having experienced racism in school not related to the pandemic.

Youth who identify as LGBTQ have been disproportionately impacted by the pandemic, experiencing higher levels of poor mental health, more than 3 times the likelihood to have attempted suicide in the past year, and more emotional abuse at home during the pandemic compared to their heterosexual peers. This data shows that access to schools and other places in the community where students can be supported is critical and was limited due to the pandemic. One of the hopeful findings was that connectedness mitigated mental health issues. Students who reported that they felt connected were less likely to experience mental health problems and were less likely to consider or attempt suicide. At the same time, students who identify as LGBTQ and students who experienced racism were less likely to feel connected to others at school. This sets up a challenge for those who work in schools in how to make schools safer and more supportive, particularly for those youth.

CDC's "What Works in Schools" approach improves adolescent health and wellbeing. This approach includes quality sex education, systems to connect youth to services, and a set of activities around improving school connectedness and providing support for LGBTQ students. In schools implementing this approach within CDC-funded districts, students were less likely to have ever had sex, have 4 or more sexual partners, be currently sexually active, miss school because of safety concerns, be forced to have sex, and/or use marijuana.¹ Sexual assault is known to be a predictor of lifelong trauma as well as posing STD and HIV risks.

Schools that put a set of policies and practices in place to support LGBTQ students such as identifying safe spaces, having professional development for educators, and having anti-harassment policies that are enforced leads to improvements in mental health outcomes and reductions in suicidal thoughts and behaviors. Improvements are observed in all students including LGBTQ in schools that put these policies and practices in place. The reverse is also the case—that when these policies and practices are not in place, mental health problems are exacerbated for students who identify as LGBTQ and also for heterosexual students. This has significant implications for the currently state of schools across the country. As schools are made less toxic for the most vulnerable students, schools are made less toxic for everyone and the reverse is also the case.²

Division of HIV Prevention (DHP) Update

Demetre Daskaliakis, MD, MPH

Director, Division of HIV Prevention

National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Daskaliakis reminded everyone that has CDC requested \$310 million in the FY23 President's Budget in order to continue its focus on the 4 pillars of EHE, as well as to amplify these efforts by investing in key strategies to advance health equity. Some of the highlights are to focus efforts on increasing access to testing by scaling up self-testing, and to think specifically about the use of self-testing in high impact settings such as community-based organizations (CBOs), LGBTQ-focused clinics, correctional facilities, and SSPs. Syndemic approaches would be expanded to create efficiencies and broaden the reach to many key populations. Lessons learned during the COVID-19 pandemic will be assessed to identify ways to better improve capacity in small priority population-focused CBOs to increase the benefit of EHE prevention and care services. The focus on PrEP uptake would continue to be promoted and delivered, including a newly available injectable PrEP and working on increasing delivery of tele-PrEP. This funding also would support expanding implementation of innovative status neutral approaches to care delivery by providing peer-to-peer training and implementation support to health departments that currently are not providing such services. This all part of EHE and is one of the 5 equity interventions and is part of the focus to increase the reach of HIV prevention and care services to Black, Brown, and LGBTQ people as well as other priority populations.

¹ Robin L, Timpe Z, Suarez NA, Li J, Barrios L, Ethier KA. Local Education Agency Impact on School Environments to Reduce Health Risk Behaviors and Experiences Among High School Students. *J Adolesc Health*. 2022 Feb;70(2):313-321. doi: 10.1016/j.jadohealth.2021.08.004.

² Centers for Disease Control and Prevention, National Youth Risk Behavior Survey (YRBS), 2015 & 2017; Centers for Disease Control and Prevention, School Health Profiles (Profiles), 2014 & 2016

DHP is in the midst of a renaissance of community engagement with a focus on 3 types of engagement:

1. Information gathering, an example of which is a refresh of the domestic HIV program strategic plan
2. Topic-specific discussion, examples of which are cluster detection and response and status neutral approaches
3. Ongoing community-centered engagement. Community-centered engagement began in March when regional Town Halls were convened to educate, encourage, and focus on empowering local community implementation of the EHE Initiative. The goal is to work together to understand and address longstanding inequities and strategies that can be used to further nuance addressing those inequities.

At the beginning of April, CDC funded 36 CBO grantees in 18 states with \$400,000 in funding per grantee to focus on HIV prevention with young men of color who have sex with men and young transgender persons of color.³ Since the last group of grantees, 6 more organizations were identified, and each received an increased funding level. CDC also recently announced and received applications for a funding opportunity⁴ to support organizations that work in transgender clinics and partner with CBOs that focus on transgender populations to develop community-to-clinic models to integrate status-neutral HIV prevention and care services where people seek gender-affirming care. This takes advantage of navigation and other strategies that are designed to increase knowledge, confidence, and use of PrEP and other interventions.

One of the great innovations that came out of the COVID-19 pandemic was the self-testing program, which is being expanded and will be funded over the next 5 years to distribute 150,000 self-tests per year. Conversely, there were significant interruptions in care services due to the pandemic that have made surveillance data harder to interpret and more complex. The HIV Surveillance Data Tables will be released when the full reports are available and the commentary is able to guide how this is interpreted. Because of the disruptions, there are some derived estimates (incidence, knowledge of status, prevalence) that will not be possible to produce for 2020. Work is underway to update data collection to better capture these data, for which approval is expected by the end of 2022 from the Office of Management and Budget (OMB) and collection will begin in early 2023.

Division of Viral Hepatitis (DVH) Update

Carolyn Wester, MD MPH

Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Wester shared some of the work that the DVH has accomplished recently to address health disparities in viral hepatitis (VH). VH elimination has moved from risk-based to universal recommendations among adults. In November 2021, the Advisory Committee on Immunization Practices (ACIP) voted unanimously to update the hepatitis B vaccination recommendations to include the following recommendations:

1. All adults 19-59 years and adults ≥ 60 with risk factors should receive hepatitis B vaccines
2. Adults ≥ 60 without known risk factors may receive hepatitis B vaccines

³ <https://www.cdc.gov/hiv/funding/announcements/ps22-2203/index.html>

⁴ <https://www.cdc.gov/hiv/funding/announcements/ps22-2209/index.html>

CDC formally published these guidelines in the *Morbidity and Mortality Weekly Report (MMWR)* on April 1, 2022.⁵ The move away from risk-based recommendations will help reduce health disparities by eliminating the need for patients disclose potentially stigmatizing risk factors and also provide healthcare providers with a simplified vaccine decision-making process.

As reported during previous CHAC meetings, CDC is currently updating its hepatitis B screening recommendations from risk-based to universal recommendations as well. This will complement the vaccination approach, as well as the hepatitis C and HIV screening guidelines among adults. The proposed updated recommendations are 2-fold. The first recommendation is that screening be performed at least once in a lifetime for all adults ≥ 18 years of age and the second is to expand existing risk-based testing recommendations for ongoing testing for additional groups, including people who are currently or formerly incarcerated people with a history of STIs, and people with a history of hepatitis C virus infection. These recommendations are currently available on the *Federal Register*⁶ for public comments, which closes on June 3, 2022. Formal publication of this update is anticipated later in the year.

The prevalence of hepatitis C is increasing among reproduction aged individuals and pregnant persons, with approximately 6% of perinatally exposed children becoming infected.⁷ Of the recommendations currently available, the most consistent is to test exposed children with a hepatitis C antibody test at or after 18 months of age. There is no clear guidance regarding hepatitis C RNA testing beginning at 2 months of age despite the fact that this testing may possibly decrease loss to follow-up and misidentification. CDC is working to develop evidence-based hepatitis C testing recommendations for perinatally exposed children to ensure that exposed infants and children are appropriately tested and linked to care and curative treatments. Peer review and public comments for these recommendations are expected to take place in Fall 2022, with publication anticipated in early 2023.

Viral hepatitis cannot be eliminated without also addressing the challenges posed by the national opioid crisis. People who inject drugs (PWID) are at high risk for viral hepatitis, HIV, and other infections. They also experience unique barriers to testing and treatments. Harm reduction service programs are a proven effective component of community-based programs to prevent the spread of infectious consequences from injection drug use. In 2019, the DVH established the National Harm Reduction Technical Assistance Center (NHRTAC) to strengthen the capacity of SSPs.⁸ DVH first partnered with the National Alliance of State and Territorial AIDS Directors (NASTAD) to build the infrastructure of this center. As the program grew, partnerships were expanded to include the National Harm Reduction Coalition (NHRC) and the University of Washington. Now in Year 3, the center has broadened involvement of the NHRTAC to include CDC's Injury Center and SAMHSA and National Association of County and City Health Officials (NACCHO) and 6 additional TA-providing organizations are joining for bridging expanded expertise and offering harm reduction from health departments and recovery communities, as well as experts from SAMHSA's Addiction and Prevention Technical Training Centers.

As part of the effort to build up comprehensive programs to support the needs of PWID, CDC released a NOFO in March 2002, Strengthening Syringe Services Programs (CDC-RFA-PS22-2208), with 2 key components that will increase access to harm reduction services for PWID. Component 1 will support the development of a national network of SSPs to facilitate

⁵ <https://stacks.cdc.gov/view/cdc/115806>

⁶ <https://www.federalregister.gov/d/2022-07050>

⁷ Centers for Disease Control and Prevention. 2019 Viral Hepatitis Surveillance Report. <https://www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm>

⁸ harmreductionhelp.cdc.gov

communication among SSPs and other harm reduction programs and health organizations trusted by the PWID community and improve data about SSPs by conducting an annual national survey of SSPs to document capacity, needs, access, and service gaps. Component 2 will increase support and resources to SSPs for implementation of these programs, including syringe distribution and disposal, testing, treatment, and prevention of the infectious complications of infections of injection drug use. This program will enhance and expand harm reduction services leading to reductions in new viral hepatitis infections.

In conclusion, the DVH will continue to promote innovative and holistic approaches to reduce health disparities and meet the needs of people living with or vulnerable to viral hepatitis.

Division of STD Prevention (DSTDP) Update

Leandro Mena, MD, MPH, FIDSA

Director, Division of Viral Hepatitis

National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention

Dr. Mena reported that DSTDP is in the process of developing a new division strategic plan for 2022-2025. This effort will include alignment with the Sexually Transmitted Infections National Strategic Plan for the United States | 2021–2025.⁹ The new proposed goals will be to:

1. Prevent new STIs
2. Improve the health of people by reducing adverse (harmful) outcomes of STIs
3. Accelerate progress in STI research, technology, and innovation
4. Reduce STI-related health disparities and health inequities
5. Achieve integrated, coordinated efforts that address the STI epidemic

The new plan is projected to be finalized in early Fall 2022. DSTDP envisions a whole nation response to preventing and controlling STIs in the US that goes beyond disease to address the health and wellbeing of the individual, recognizing that this will require support of partners and collaborators.

The National Strategic Plan and the DSTDP strategy call for reductions in disparities and health inequities. This key approach will be reflected in NOFOs and activities to ensure that there is high population-level impact. The strengthening of STD prevention and control for health departments has had a tremendous response, with an additional \$200 million going to recipients each year for the next 5 years for which there is an emphasis on expansion of the workforce and to strengthen disease outbreak and response capacity by bringing on an additional 1800 staff members. DSTDP continues to strengthen its supplemental surveillance projects, including strengthening US surveillance of drug-resistant gonorrhea with the use of whole genome sequencing (WGS) to better understand the epidemiology of gonorrhea. Investments are being made in innovation, particularly in syphilis diagnostics and in training of Disease Intervention Specialists (DIS). Some of these innovations and trainings will be funded from the \$1.13 billion that was allocated to DSTDP last year through the America Rescue Plan Act.

⁹ <https://www.hhs.gov/sites/default/files/STI-National-Strategic-Plan-2021-2025.pdf>

The 2020 STD Surveillance Report¹⁰ was released in early April 2022 along with preliminary 2021 syphilis data. In 2020, there were increases in gonorrhea, syphilis, and congenital syphilis. Increases are being seen in syphilis and congenital syphilis for 2021 as well. Conversely, there was a 12.7% decline in cases of chlamydia from 2019. This decline is likely due to decreasing STD screening and diagnosis during the pandemic rather than a reduction in new infections since chlamydia is usually asymptomatic. While syphilis cases are increasing, they do present an opportunity for HIV prevention. Since 2015, the number of primary and secondary syphilis cases reported among HIV-negative MSM has surpassed the number of cases reported among HIV-positive MSM. While overall cases reported among HIV-positive MSM may be leveling off, there are no signs of syphilis slowing down among heterosexuals. Reported cases of primary and secondary syphilis cases increased 420% among women from 2011-2022. The intersection of HIV and syphilis presents a clear opportunity in which syndemic approaches can be beneficial to addressing these infections, as well as the conditions that contribute to their occurrence.

Along with the new plans, some key actions DSTDP is taking include identifying opportunities for collaboration and integration of services, increasing access to stigma-free healthcare, expanding partner services and DIS programs, improving STI diagnostics and therapeutics, and enhancing surveillance systems to inform public health actions and better understand root causes of increasing STIs at the national and local levels. For each of these activities, DSTDP is committed to a process that prioritizes access to and extension of services that address disparities and inequities. Social health services can be a gateway for overall health and wellness. DSTDP will move from a disease-focused approach to a social health promotion and wellbeing framework.

HRSA DFO Welcome and Update

Laura Cheever, MD, ScM

Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration
CHAC Designated Federal Officer

Dr. Laura Cheever extended her welcome to new CHAC Voting Members, Mr. Lindsey and Dr. Markham. She also welcomed new NIH *Ex-Officio* member, Dr. Goodenow, and expressed her gratitude to Dr. Gaist for his years of service to CHAC as the NIH *Ex-Officio* member.

Dr. Cheever announced that Carole Johnson was named the HRSA Administrator in January 2022. Before coming to HRSA, Ms. Johnson served as the Testing Coordinator on the White House COVID-19 Response Team. She also served as the Commissioner of the New Jersey Department of Human Services, leading the state's largest agency and providing healthcare and social services to 1 in 5 New Jerseyans. During her tenure as Commissioner, the Department expanded Medicaid coverage of mental health and substance use disorder (SUD) services, created new Medicaid benefits to improve maternal health outcomes, and integrated Medicaid into the newly launched state-based Affordable Care Act (ACA) marketplace. Ms. Johnson served for more than 5 years as the Domestic Policy Council public health lead in the Obama White House, working on the Ebola and Zika responses, implementation of the ACA, and combatting the opioid epidemic. In addition to several key positions on Capitol Hill, Ms. Johnson was Policy Director for the Alliance of Community Health Plans, Program Officer with the Pew Charitable Trust health program, and Senior Government Relations Manager with the American Heart Association (AHA). Dr. Cheever welcomed Ms. Johnson back to HRSA where

¹⁰ <https://www.cdc.gov/std/statistics/2020/default.htm>

she previously worked in workforce policy, and she thanked Diana Espinosa for leading the agency as the Acting Administrator for the last year and a half. HRSA is fortunate to have someone with Ms. Johnson's experience and deep knowledge of HRSA's programs, as well as her passion about health equity in the work the agency does.

HRSA's HAB vision is optimal HIV care and treatment for all to end the HIV epidemic in the US. The mission is to provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities. Health equity is a core concept of the RWHAP, which has been working many years to reduce disparities. It is very exciting to have a new environment in which health equity is in the forefront across the entire federal government.

HRSA is excited that the HAB website has been officially relaunched with a new look and the new URL of <https://ryanwhite.hrsa.gov/>, which should help people searching for information on the Ryan White HIV/AIDS Program (RWHAP). The website navigation has been updated and the content has been reorganized to help visitors find information and resources more efficiently.

Since the last CHAC meeting on December 1, 2021, the *National HIV/AIDS Strategy (NHAS, the Strategy)*¹¹ was released and provides stakeholders across the nation with a roadmap to accelerate efforts to end the HIV epidemic in the US by 2030. In order to guide the nation toward realizing the vision, the strategy includes 4 overall goals, which are to:

1. Prevent new HIV infections
2. Improve HIV-related health outcomes of people with HIV
3. Reduce HIV-related disparities and health inequities
4. Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and stakeholders

The strategy has been used across HRSA and government to help focus efforts and refine the work that is being done in this area.

HRSA is developing an NHAS Implementation Plan that outlines specific actions to achieve the Strategy's goals and objectives. Representatives from across HAB and HRSA have been working to identify strategic policies, programmatic activities, and initiatives to leverage support of the goals, objectives, and strategies outlined in the plan as part of the Strategy implementation. Partnering across the federal agencies is a very important part of this step in the work. HRSA has actively engaged CDC, Administration for Community Living (ACL), Housing and Urban Development (HUD), and others in thinking about the work that needs to be done in order to achieve the goals. Given the Strategy's whole of society approach, HAB leadership conducted a series of listening sessions to engage directly with the RWHAP stakeholder community to hear thoughts and ideas on ways HRSA can support the goals and objectives outlined in the NHAS in the effort toward EHE. Key stakeholder groups included patient advocacy organizations, HIV provider organizations, constituency-based organizations, and coalition groups. Dr. Cheever expressed gratitude for the contributions of the many divisions and offices that took part in this collaborative effort, including HRSA's regional offices and CDC that were part of all sessions.

¹¹ <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>

The NHAS also calls for the development of a quality of life (QOL) indicator. The White House Office of National AIDS Policy (ONAP) asked CDC and HRSA to Co-Chair a federal WG to make recommendations. The WG's charge from the White House was to use existing federal datasets that include measures of QOL or measures that can assist in gauging QOL. ONAP held a community listening session to receive input on these datasets. The WG was asked to complete its work by May 2021. QOL has been part of the fabric of the RWHAP over many years. In the absence of a method to measure QOL, HRSA has been addressing it through various domains, such as housing instability, employment, and food insecurity. Critical thought also is being given to domains around health, wellbeing, and psychological factors and work has begun on a framework to conceptualize the efforts and identify work that still needs to be undertaken.

HAB has a relatively new and productive partnership with ACL. ACL's mission is to foster safe, high quality health care for the aging population. This is particularly important for the RWHAP where many clients are aging with HIV. In 2020, about 48% of clients in the RWHAP were over 50 years of age. The goal of this partnerships is to work together to share resources among recipients and cultivate partnerships with other federal and non-federal partners. HAB and ACL have collaborated on several webinars to share information about the RWHAP and to hear from ACL about their programs and services. HAB and ACL also have teamed up with training for ACL grantees and Ryan White recipients on the Older Americans Act (OAA) and Area Agency on Aging (AAA). There is a tremendous amount of expertise in the community on aging, which should be leveraged in the efforts to expand the work in the RWHAP in order to improve services for older people with HIV quickly.

HAB also has a longstanding committed partnerships with HUD. HAB is currently assessing how the RWHAP can better address the housing needs of people with HIV. Because HAB is not primarily a housing provider, they are grateful for the partnership with HUD. The focus traditionally has been on the federal Housing Opportunities for People with AIDS (HOWPA) program. HAB also is working to expand its efforts with HUD beyond the HOWPA program and to continue to work together to address the needs of RWHAP clients. HAB and HUD will continue to partner on educational events at the intersection of housing and HIV and other opportunities broadly across HUD programming.

The 2022 National Ryan White Conference (NRWC) on HIV Care & Treatment will be convened August 23-26, 2022. Dr. Cheever thanked the RWHAP community providers, recipients, and partner organizations who submitted a total of nearly 400 abstracts for consideration in the 2022 conference. Abstract approvals were sent out the week of April 12, 2022. In light of the constantly evolving COVID-19 pandemic, HAB has made the decision to host the 2022 NRWC virtually. This is a shift from the initially proposed hybrid format that included both virtual and in-person components. The conference dates will remain the same, but times will be adjusted to accommodate the different time zones. Recognizing the unpredictability of the COVID-19 pandemic over the last several years, HAB holds true to its commitment to providers, recipients, stakeholders, partner organizations, planning council members, and more than the half million people they serve every day to reduce any risk of potential COVID-19 transmission. All of the recipients, providers, stakeholders, and people with HIV who are a part of the RWHAP will have an opportunity to attend the conference and not be taken away from the communities HAB serves. This means that the RWHAP part-specific caps that were applied to the hybrid format no longer apply. The virtual format will utilize the same platform as the 2020 conference that had incredible engagement during the chat as sessions were occurring. All breakout sessions will be pre-recorded.

Turning to policy updates, transgender people with HIV continue to be a priority for HAB. There are tremendous disparities for this particular population. In December 2021, HAB released a letter to RWHAP service providers reaffirming the importance of providing culturally-affirming health care and social services to the transgender community as a key component of improving the lives of transgender people with HIV and eliminating health disparities. The letter is not a new policy or approach to the services delivered by the RWHAP, but builds upon HAB-funded initiatives that support patient-centered, trauma-informed, and inclusive environments of healthcare for people with HIV to help reduce medical mistrust and other barriers to adherence from transgender populations.¹²

To highlight a few RWHAP updates, 2 new Executive Summary documents have been published that are on the RWHAP website. The first is a high-level summary of what was learned during the 2021 EHE in the US listening sessions with public health leaders and communities mentioned earlier. This document discusses the key themes from those sessions and provides a high-level look at how HAB is moving forward to build on what has been learned. The second Executive Summary is based on the telehealth white paper that shares how RWHAP have been leveraging telehealth during the COVID-19 pandemic. Both of these publications should be useful to RWHAP.¹³

Moving to data updates, all states showed improvements in viral suppression among RWHAP clients by state from 2010 to 2020. However, some states continue to have room for improvement—particularly in the Southeast US. Also notable was a significant improvement in viral suppression in 2020 even though at that time, states and recipients were responding to the COVID-19 pandemic. Among key populations served by the RWHAP, viral suppression of all RWHAP clients was 69.5% in 2010 and 89.4% in 2020. The improvement in suppression occurred across all key populations. However, it is important to note that challenges remain in achieving viral suppression for certain populations. Most notably in 2020, there were disparities in viral suppression overall for African Americans and Blacks at 86.7%, transgender clients of 84.5%, youth 12-24 years of age at 81.5%, and clients with unstable housing at 76%. This illustrates that more work needs to be done.

Viral suppression increased for all RWHAP clients nationally by about 19.9 percentage points from 2010-2019. Key populations had even greater improvements in viral suppression. For example, viral suppression increased by 23.4 percentage points among African Americans. This demonstrates that while disparities remain, the disparity gap has been decreased. Among youth transgender populations and people who are homeless, larger disparities remain with significant work to do.

The inaugural *2020 HRSA HAB Ending the HIV Epidemic in the U.S. Data Report* was released and is posted on the HRSA HAB website. This is the first publication to highlight data submitted through the EHE Triannual Module data system. This module collected aggregate-level data 3 times a year on the number of new and existing clients receiving services and the number of clients prescribed antiretroviral therapy from EHE-funded providers. EHE recipients, sub-recipients, and stakeholders have been doing important work in response to the COVID-19 public health emergency to meet the needs of clients during that emergency while simultaneously doing incredible work in this new EHE Initiative that launched in March 2020 simultaneously with the COVID-19 pandemic nationally and submitting high-quality, complete EHE triannual data to HRSA HAB.

¹² <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/hiv-care/gender-affirming-care-rwhap.pdf>

¹³ <https://targethiv.org/library/innovation-rwhap-telehealth>

Many EHE recipients used their EHE funding to expand and innovate the delivery of existing RWHAP service categories. For example, RWHAP EHE recipients focused on what could safely be accomplished during the pandemic such as emphasizing self-care within the community, leveraging virtual spaces, and staggering or scaling back activities in order to provide them safely. Recipients also introduced flexibilities that prioritize health and safety, such as offering telehealth and remote work for staff, contactless prescription delivery, e-prescribing, providing 90-day supplies of antiretrovirals, and delivering socially distant case management and navigation—something most providers had not done previously.

EHE recipients scaled up services to address new activities or activities where there was greater demand, such as transportation, rental assistance, emergency financial assistance, and food or delivered meals. Recipients also worked to streamline the client experience, including consolidating services in clinics and creating policies and procedures to simplify future client interactions. Beyond EHE, recipients were able to leverage their existing RWHAP knowledge, partnerships, experiences, and resources so their jurisdictions could respond to the COVID-19 pandemic. It is amazing what recipients have been able to achieve throughout this pandemic.

CHAC Member Discussion On CDC & HRSA Updates

The following questions, observations, and suggestions were raised:

- Dr. Gayles observed that all of the teams demonstrated the ability to be flexible in pivoting to new ways to deliver services to meet the needs of those who utilize CDC and HRSA services. Mental health crisis in children was significant before COVID-19 and is further exacerbated. This is a key moment in terms of responding to this need in terms of building infrastructure. Equity remains important as disparities continue to be seen in incidence across populations and continued gaps in access to services such as PrEP. There are exciting new funding opportunities from CDC and HRSA and continued inclusion of the SDOH and the impact that those play on service delivery. It also was affirming to hear the continuing commitment from both agencies in providing affirming services to different communities, given the political environment in many places across the country that potentially affect the way services are delivered. Given the increased attention on mental health in young people and the impact that mental health issues can play on risk-taking behaviors, he inquired as to how services are being implemented across the board in various divisions in thinking about rolling out new projects.
- Dr. Ethier said that from a school health perspective, DASH has layered in additional resources received from Coronavirus Aid, Relief, and Economic Security (CARES) Act dollars to transition some of the school services into the virtual setting and to help support the infrastructure that already had been created to connect youth to sexual health services and to mental health services. Schools received an influx of funds and an array of additional resources, but it is not clear whether they were able to use those funds effectively toward these efforts. There have been discussions with partner organizations to establish services outside of schools and determine the best way to connect with school districts. As often is the case with community-based services, a 2-pronged approach is needed. Something is needed to motivate the school district to create infrastructure to connect to services in the community, but that is not sufficient. It is also important to make a connection to the community to help them establish connections in schools. They have consistently seen that it is not going to be possible to “mental health professional” our way out of this. There are not sufficient trained mental health providers to be able to deal with the influx. Mental health services are just not available for adolescents. This also speaks to the pipeline issues. In

order to convince providers to train or retrain to work with youth, the mental health professional pipeline has to be made possible, affordable, and attractive.

- Based on the data Dr. Cheever presented, Mr. Driffin noted that close to 90% of people living with HIV return back to care. He wondered whether the data team would pose additional inquiries to determine why those individuals decided to stop care and ultimately return to care during the pandemic or connected to EHE activities, and how those findings could be incorporated into better healthcare delivery for people living HIV.
- Dr. Cheever indicated that they are not collecting this from the recipients. The reporting is kept high-level because of the burden on recipients. Many EHE programs do inquire about what keeps people out of care so that they can better respond in the future. A challenge over time has been the difficulty in finding people who are out of care, understanding who they are and the challenges they face. Dr. Cheever will take this idea back to the Project Officers.
- Dr. Mermin observed that the viral load suppression data highlighted by Dr. Cheever showed remarkable increases in viral load suppression with a 30-point absolute increase in 10 years and an almost elimination of racial and ethnic disparities in viral suppression. He wondered what the most important factors were that led to that increase, as well as how to get to the next 10% to achieve 100%. He also requested an update on the HRSA-initiated hepatitis C program that screened, diagnosed, and cured people in RWHAP of hepatitis C.
- Dr. Cheever noted that HAB has been focused on data quality and quality improvement. There have been several large collaboratives with hundreds of thousands of patients in which individual recipients assess their data and then experts, including people with lived experience, to help figure out what works through a quality improvement rapid cycle. A number of these over the years have been successful and the rates of improvement in these initiatives have been remarkable. That is why they are adamant about developing best practices communication so people can demonstrate improvements by publishing what works in this key population so others are able to replicate. There is some improvement with easier drugs to take, but overall improvement is due partly to specific quality improvement activities. The hepatitis C chart abstraction work slowed down during the pandemic because it is difficult to collect data at the national level, especially regarding treatment and sustained viral response. HAB has a chart abstraction contract through which these data were going to be collected in individual clinics, but that was delayed significantly by the pandemic. All they have at this point are anecdotal inputs.
- Given that many cities are experiencing increasing problems with homeless populations, Dr. So inquired as to whether CDC has programs to try to improve prevention, testing, and treatment for HIV and hepatitis in homeless populations and whether SSPs across the country are experiencing any pushback by states.
- Dr. Mermin indicated that there is a lot of interest in homeless populations at CDC. They have been engaging with HOPWA and HUD in general, and DDID has taken on a role of looking across the agency to determine whether there are ways to work at the more fundamental social determinants side. Housing and homelessness affect almost all aspects of public health, so CDC is increasingly trying to work in that field. In terms of SSPs, it is a project that takes concerted effort and continual monitoring and support over time. In some places, SSPs have been initiated and expanded and sometimes there is not a lot of pushback. SSPs become normalized with engagement with the community and law

enforcement, and when there is supportive legislation in the state or local areas that enable SSPs to continue over time. There are other places where SSPs are going well and then there is pushback for a variety of reasons (e.g., political conflict in the community, certain events that result in loss of trust with law enforcement or politicians, et cetera). There are a lot of services that cannot be offered now due to minimal resources, lack of technical capacity, and or lack of infrastructure.

- Dr. Daskalakis added that really great work is occurring with HUD beyond HOPWA in a more status-neutral space. One exciting area is the work with HOPWA to think about housing as an outbreak intervention which is moving in a great direction. They are looking at ways testing interventions can be deployed specifically in those environments as social determinants are also being addressed. DHP's most recent NOFO for young MSM and transgender women of color has a component that asks the grantees to select areas of social determinants to pursue, one of which is housing.
- Dr. Wester added that people who use drugs, injection and non-injection, and people experiencing homelessness are some of the populations most heavily impacted by the multistate outbreaks of hepatitis A, which now include 37 states and over 44,000 cases. The TA efforts that have been provided to states and other jurisdictions experiencing that have made a lot of inroads into those communities.
- Dr. Anderson emphasized how impressive the increases in viral load suppression and reduction in disparities were that Dr. Cheever presented. She asked how DASH plans to follow up on the data regarding mental health issues among adolescents, particularly the data on LGBTQ adolescents and the outsized concerns in these issues. This includes more than individuals who are HIV-affected. She asked whether the data on LGBTQ includes transgender and lesbian, gay, bisexual or if they were separated out. The issues are probably slightly different.
- Dr. Ethier indicated that for the ABES data, they were not able to include a question on transgender identify. At this point, that question is on the state optional list. However, they were able to include the transgender identify question on the ballot process for the questions to be included in the 2023 YRBS. They are optimistic that this question will be included on the national survey. Hopefully for the next CHAC meeting, she will be able to provide an update on some of the improvements they will be able to make for the 2023 survey. ABES was done in Spring 2021 and the regular YRBS was moved to Fall 2021. Approximately 30 states and locals included the transgender identify question on the state YRBS. This allows them to group those data together to look in more depth at those students.
- Mr. Lindsey noted that substance use is an area that has not had as much data to contribute to prevention efforts and healthcare engagement efforts, and that he was happy to hear about the marijuana data in Dr. Ethier's presentation. Particularly given the increase in stimulant use over the past couple of years due to isolation and other social dynamics that have arisen, especially in urban communities. He wondered if they have been able to or plan to collect those data.

- Dr. Ethier indicated that they do assess stimulant use as one of the substances. They did not find an impact of the program on stimulant use, but that could be because it was relatively low for young people—at least when those data have been collected. Prior to the pandemic, all substance use apart from alcohol and marijuana had been decreasing. They have not collected opioid data for long enough to know whether there has been an increase or decrease.
- Dr. Daskalakis added that the National HIV Behavioral Surveillance (NHBS) survey is able to tease out stimulant use, which is something that DHP is following.
- Dr. Cheever added that they are taking a deeper dive into SUD and what people are actively using in their chart abstraction survey, so that will be a topic every other year.
- With the current political climate regarding LGBTQ in Florida, Dr. So asked Dr. Ethier whether she is worried about the coming year in terms of how much progress can be made. Already there are mental health issues. He wondered whether the politicians know how much harm they are doing. He also asked whether it would be appropriate for them to raise this concern through a CHAC statement, perhaps.
- Dr. Ethier responded that as a federal employee, she was unable to comment on any particular state law or policy. She said that she is extremely concerned about whether the gains made over time in implementing the policies and practices that she mentioned are effective for all youth with respect to mental health and wellbeing. In 2018, close to 80% of schools had safe spaces for LGBTQ students, more than 90% had anti-harassment laws, and about 75% had professional development on inclusivity for teachers. That had improved dramatically over time, but now changes have been made to directly take some of those important practices out of schools. She is extremely worried about the mental health crisis for young people. Taking away those supports will be threatening not only for LGBTQ students, but also for other students. As she mentioned earlier, making schools more toxic for anyone makes them more toxic for all students.
- In terms of whether there is something CHAC can do, Drs. Gayles and Anderson will discuss this offline and will get back to the group about what is/is not within CHAC's purview as a committee.
- Mr. Riester noted that a bill recently passed the House that would criminalize certain amounts of fentanyl, which could increase the number of people who are incarcerated and also would require mandated substance use counseling. There is a very large problem with fentanyl across the country, so this is something to think about in the future. Regarding mental health status and LGBTQ youth, he asked whether there is a correlation to visibility, inclusion, awareness, and/or a specific geographic prevalence.
- Dr. Ethier responded that the ABES data is nationally representative, so it does not tie back to specific geographic areas. They do not ask about visibility, inclusion, and awareness in this survey. Therefore, they do not know whether the more "out" someone is increases the reaction and stigma associated with their identity. However, this is a very important question. It might be possible to look at some of these difference by state in the 2021 YRBS data. This did come up to some extent with regard to parental abuse questions related to

issues around whether healthcare providers and school personnel are required to report back to parents if they have conversations with young people about their sexual identity. They do not ask these questions, but it is difficult to imagine that there is not some aspect of being out to one's family and then experiencing abuse, otherwise they would not see the difference between students who identify as heterosexual and those who identify as LGBTQ.

- Dr. Markham added that as a youth sexual health researcher in Texas, she echoed Dr. Ethier's concerns. They hear a lot from school-based personnel and clinicians that the climate in Texas is definitely a concern in terms of the mental health of youth and also their families trying to be supportive of them. With the abuse cases and reporting cases, it is getting quite dire. Whatever CHAC might be able to do, she would love to be part of that. She also expressed interest in information about additional initiatives for provider training, influences, and other programs to address rises in congenital syphilis, for which Texas may be #1. There also is an overlap with teen STI rates in Texas.

Panel 1: Strategizing an Approach to Providing Comprehensive STI Services

Moderator: Robert McDonald, MD, MPH, LCRD, USPHS; Medical Officer, Division of STD Prevention, NCHHSTP, CDC

Addressing STIs in Mississippi

Thomas E. Dobbs, MD

State Health Officer

Mississippi Department of Health

Dr. Dobbs first shared a photograph from an 1881 photograph atlas on cutaneous syphilis to illustrate that history is reality and that a lot of work remains to be done. For instance, based on the 2020 published STD rates, Mississippi ranked first in chlamydia per capita by a substantial margin of almost 100/100,000 population higher than Louisiana, ranked second highest for gonorrhea, and tied for first place in primary and secondary syphilis rates. This is the worst STI performance he has seen during his tenure at the State of Mississippi. While that is awful and embarrassing, there are interventions for improvement.

There has been a transition in the landscape of care. The health department and its STD clinics traditionally have been thought of as a go-to location for STD treatment and diagnostics in Mississippi. However, data by ordering facility type in 2020 showed that the majority of STD cases were being identified primarily in private physician offices and other health clinics. Some reasons for this are the general transition away from public health services for clinical care and funding issues. Compared to 10 years ago, they have half of the nurses they had in 2010. They have less nurses now in 2022 than in 2019—even with the COVID-19 pandemic funds. While there is a paucity of providers in general, nurses are responsible for much of the frontline work in STI treatment. If the Mississippi Department of Health is addressing only 10% of the pie, they are missing 90% of the opportunity and must rethink how to address STIs in Mississippi.

To demonstrate a parallel lesson, the fertility rate in Mississippi has been declining gradually since 2001 other than an interesting increase from 2006 to 2008 that was observed across the country for unknown reasons. There also has been a decline in teen births in Mississippi, with the exception of an increase in 2007. Although fertility and teen birth rates have been

decreasing, the health department has been losing ground in providing reproductive health services. This suggests that there are solutions to the problem that transcend what a county health department or STD division can do, but depending upon third parties who do not have the same authorities or a more holistic view of STI intervention also raises a number of challenges in addressing STIs and HIV.

Community health centers offer an opportunity for interventions in Mississippi where there are 11 Federally Qualified Health Centers (FQHCs) that operate 69 school-based clinics. This presents an excellent opportunity to provide sexual health resources to young people who are at risk. The majority of chlamydia and gonorrhea cases occur among older teens and young adults in their early 20s. While there are only 69 school-based clinics currently, there are 530 high schools in Mississippi. This means that there are many uncovered locations that could be served.

As pointed out in Healthy People 2020, one of the correlates associated with STD transmission is social determinants of health (SDOH). Mississippi Department of Health has struggled to expand its role beyond just STDs. While they can get shots in people's arms, test for chlamydia, et cetera, they must address SDOH—most of which pertains to racial and ethnic disparities. Otherwise, they will continue to try to “bail water from a sinking ship.” The majority of STD cases are now among African Americans, which are a minority population. SDOH issues must be addressed to get ahead of the problem. These include racial and ethnic disparities, structural issues (including structural racism), poverty and marginalization, access to healthcare, substance abuse, stigma pertaining to sexuality and secrecy and/or HIV transmission, risky sexual network, and so forth.

Most adults and the vast majority of children in Mississippi have health insurance. However, about 24% of adults are uninsured. Mississippi adults 19-25 years of age represent a high-risk group who do not have access to care and impoverished communities are over-represented. There are multiple difficulties in Mississippi. They do not have contact tracing and treatment, especially within private clinic settings. If someone is diagnosed within the health department, they will be given a referral card. While Mississippi does not yet have partner expedited therapy, an effort to offer this option is underway. The private clinic setting does not have the same public health focus that county health departments and STD-focused clinics have. Stigma and reluctance to discuss sexual health among patients and providers is a major problem, especially in the era of a 15-minute medical visit—10 minutes of which are spent on a computer. Ensuring that clinicians are up front diagnosing people with STIs and that there is access to care are critical issues. Mississippi is a non-expansion state with no anticipation of that changing in the near future. This state also has a very high poverty rate, is a rural location, and has a low provider to population ratio. People with STIs or symptoms do not want to go to a local clinic for various reasons, which results in major delays in care.

There are many potential opportunities, such as using some of the lessons learned from the COVID-19 pandemic to move forward. COVID-19 provided an opportunity to build remarkable new partnerships that included making remarkable inroads with the Spanish-speaking community, faith communities, local leaders, and others. These partnerships should be fostered and translated into successes in sexual health and STI prevention, treatment, and diagnosis. Continued work must be done to advance partner expedited therapy, though it is going to be challenging to move that outside of the health department to places where the majority of people are being seen. Mississippi plans to perform targeted contact tracing. For a small state with a shrinking workforce and 30,000 cases of chlamydia, comprehensive contact tracing poses a major challenge, but an effort must be made to try to interrupt some high-risk sexual networks.

Telehealth offers a major opportunity. While Mississippi Department of Health already offers universal PrEP through free telehealth, it is currently underutilized. It also is important to break down silos such that all services are providing comprehensive care that are not focused only on STIs or HIV. Mississippi has a major challenge within its epidemiology infrastructure and is underfunding its workforce. Mississippi has one epidemiologist for HIV/STDs. The state also is traditionally unfriendly to government employees and tries to keep the wages artificially low. Hence, people who complete top-notch training programs are not flocking to the Mississippi workforce. Despite the challenges, Mississippi will continue to seek opportunities for improvement.

Innovative Models to Support New York City (NYC) Sexual Health Clinics

Joaquin Aracena, MA

Assistant Commissioner, Division of Disease Control
New York City Department of Health and Mental Hygiene

Christine M. Borges, MPH

Director of Program Implementation and Evaluation
New York City Department of Health and Mental Hygiene

Dr. Aracena described innovative models that the NYC Department of Health and Mental Hygiene (NYC Health) have incorporated during the COVID-19 pandemic to reach and continue to serve New Yorkers with sexual health services. NYC Department of Health went through a reorganization during the pandemic, so the Bureau of STI no longer exists and the clinics have been folded into the Bureau of Public Health Clinics (BPHC). Bringing innovative services to the community was done through innovative approaches such as telemedicine, an STI Hotline, STI Quickie, and a COVID-19 Pivoting Model.

The BPHC was created on July 1, 2021 and oversees the health department's clinics that offer direct services to New Yorkers. This includes 8 Sexual Health Clinics (SHCs), 4 Tuberculosis Chest Centers, and 9 COVID Express Testing and Vaccination Clinics. The rationale behind this reorganization was that under centralized clinical operations, they are in a better position as a bureau and agency to achieve their goals to integrate services where common interventions are effective; create new pathways to expand services, especially telehealth services that are new for NYC Health; implement innovative approaches; and improve resilience to budget challenges.

Pre-pandemic in 2017, NYC Health serviced close to 80,000 patients. Among them, 53% are MSM and 47% percent are men who have sex with women (MSW). The 4 clinics operating in 2021 saw less than 50,000 patients, the demographics continued to narrow, and they were still reaching similar populations. Interestingly, there was an increase in MSW presenting for services or who received services via telemedicine. In terms of the SHCs' annual volume, there was a peak in 2019 and a major decline in 2020 during the height of the COVID-19 pandemic. Clinic visits and telemedicine visits began trending back up in 2021. In terms of efforts to reduce sexual health disparities, the clinics offer same-day HIV testing and PrEP and post-exposure prophylaxis (PEP) and PrEP Jumpstart. Other services include STI screening and treatment, condoms, partner services, emergency contraception, QuickStart contraception, crisis counseling, and substance use services.

In terms of the impact of COVID-19 on SHCs, the BPHC is within the Division of Disease Control. Therefore, many NYC Health staff were deployed to the pandemic response and 7 of 8 clinics had to be closed as part of the deployment and lockdown. The Chelsea clinic in Manhattan remained open and NYC Health quickly had to identify a model on how to continue to serve New Yorkers during this time in the absence of the clinics. The telemedicine operation was launched by the end of March 2020 to provide all EHE services. Not only were they able to assess individuals during this time, but also they were able to prescribe. They quickly published an RFP to contract with a pharmacy to deliver medications to individuals' homes at no cost to the patient. An additional layer was added to the pharmacy delivery that included home HIV test kits.

In May 2020, they were able to reopen the Fort Greene Clinic with limited services, given that many staff were still deployed to the COVID response. In June 2020, express visits resumed, and long-acting reversible contraception (LARC) services resumed at one clinic. Express visits and LARC services resumed in the 4 currently operating SHCs in July 2020. The Jamaica clinic reopened in July 2020 with limited services and telemedicine was expanded as staff came off of deployment. By August 2020, COVID Express Clinics were opened in SHCs and Tele-PrEP began. They had about 12 weeks to convert spaces that were not previously laboratories into laboratories to be able to respond to COVID testing. Morrisania opened in November 2020 for limited services, so now there is representation in 4 of 5 boroughs. They do not have a presence in Staten Island. In July 2020, they were able to pivot one of the instruments being used for COVID testing to be able to do STI testing in parallel.

Telemedicine services included management of positive/abnormal STI tests results, with HIV treatment initiation for those diagnosed with HIV who wished to start HIV treatment for the first time; consultation for PrEP initiation for NYC residents ≥ 13 years of age, including daily PrEP and PrEP on demand; medical evaluation for those who think they have signs or symptoms of HIV; medical evaluation for those who might have or have been exposed to a HIV; contraception services, including emergency contraception and consultations for other contraceptive methods (e.g., pills, ring, patch, shot, LARC); and prescriptions for STI treatment and HIV home test kits. To highlight telemed trends, there was an increase in the volume of calls during the peak of the pandemic. However, this declined when clinics began to reopen and it was possible to work with community partners to link individuals to services. There were 523 Tele-PrEP visits in 2021. Among these, 376 (72%) patients visited a SHC post-telehealth visit within 14 days of the telehealth visit and 332 (88%) patients received PrEP medication on the day of their visit.

Services offered at STI Quickie Clinics include provision of services such that individuals are in and out of a clinic within a cycle time of under 30 minutes compared to 1.5 hours in regular SHC. Services offered include HIV testing with 1-minute results; and CT/NG testing with 24-hour or less results; syphilis serology testing and hepatitis serology testing for HEP A-B-C with results in 3-5 days. There continues to be an increase in STI Quickie Clinic visits that now reach capacity each day. The positivity rate of either gonorrhea or chlamydia is over 13%, which provides an opportunity to test/diagnose someone who is asymptomatic and engage in conversations with them on PrEP and additional services they may need. BPHC now operates 8 Covid Express clinics across Bronx, Brooklyn, Manhattan, and Queens within existing SHCs.

To highlight some expansion plans, STI Quickie Services will be scaled up in the outer boroughs with Fort Greene anticipated to come online in Summer 2022. A patient-facing scheduling platform will be implemented. A PrEP Continuity Clinic will open in Summer 2022. There are plans to build up an Emergency Response Unit to allow for pivoting between COVID

Express Clinics and STI services as needed, and future reagent cartridges will be explored for implementation as they are FDA-approved.

Minnesota Community Care

Erica Drake APRN, CNP

Medical Director, Health Start Clinics-School Based Health Clinics
Minnesota Community Care

Sandy Naughton, BA, CCE

Health Education, Health Start Clinics-School Based Health Clinics
Minnesota Community Care

Ms. Drake and Ms. Naughton described Minnesota Community Care's Health Start Clinics-School Based Health Clinics in St. Paul Public Schools (SPPS) and their comprehensive STI outreach. The Health Start School-Based Clinics began as a maternal and child health (MCH) organization housed in a hospital across the street from a high school. They realized quickly that teens, especially pregnant teens, were not keeping their appointments, even though the organization and school were across the street from each other. They were then given space within the school and now have 10 school-based clinics. Young people who have access to school-based care have much better health outcomes, and the mantra at the time was to make those clinics acceptable, accessible, and available and they still view their provision of services this way.

The clinics are designed with an integrated team approach that includes an Advanced Practice Provider, Mental Health Provider, Health Educator, Registered Dietician, Medical Assistant, and Clinic Coordinator. One of the school-based clinics is open to adolescents 13-22 years of age regardless of ability to pay. Confidential care is provided under the Minnesota Minors Consent Law, without notification to adolescents' families. Given that the Health Start School-Based Clinics can help to provide this care for free, it overcomes a barrier in other types of clinics that may bill insurance and send home an explanation of benefits (EOB). The 10 clinics within the SPPS see an average 4,000 unique patients a year between the 4 disciplines and have a total of approximately 25,000 visits.

In addition to the 4,000 students seen in the clinics, about 100,000 students are seen through classroom visits provided all year. They are often invited to Health and Social Studies classes to talk about a variety of topics (e.g., hygiene, risk reduction, risk management et cetera). Each year, CRUSH (Community, Restoring, Urban Youth, Sexual, Health),¹⁴ a partnership of youth serving organizations and community members, holds a statewide STI Day in June. CRUSH focuses only on chlamydia and gonorrhea on the day that youth come in. During the summer, 3 clinics are kept open so that young people never lose their access to health care. Even though the focus is on chlamydia and gonorrhea on the testing day, adolescents are invited back for a fuller panel of testing. On the CRUSH testing day, clinics can see as many as 50 to 70 young people in this stigma-free situation. When this began, the idea was to do testing for students who felt they might need testing. That felt very stigmatizing, so now it is presented as visiting the clinic to talk about staying safe for life.

¹⁴ <https://www.health.state.mn.us/diseases/chlamydia/crush.html>

This teen-friendly, stigma-free introduction to the clinics that focuses on outreach into the classrooms and beyond the clinic walls, offers walk-in testing and basic sexual health screening, and makes it fun and exciting (e.g., decorate the clinic, play music, have a raffle for attendees, provide treats, incentives, et cetera). These testing days are the first time some young people visit the clinic. This is the first time that they have visited the clinic, so there is visibility. While this was the first clinic to open in a school building, there are now thousands of school clinics. This is a wonderful way to provide adolescent healthcare. The SPPS school-based clinics are holistic in that they teach, test, and treat in a stigma-free manner. A longer screening form has been shortened just for CRUSH STI Day. Every adolescent who attends completes the screening form, which helps to determine what kind of care they need and provides contact information so that they can be reached for follow-up care if needed. They do make it clear that adolescents do not have to have had sex to attend a CRUSH STI Day, because it also includes education and outreach.

For ease of flow, only a urine screen is done for chlamydia and gonorrhea. The screening tool is used to schedule further education and screening for additional STI testing, including blood draws and throat and rectal screening. Condoms are provided to all students and as noted, the clinics can provide care for all students regardless of parental consent under the Minnesota Minor Consent law. The clinics within SPPS require parental consent for all services except reproductive healthcare. Clinic staff can help uninsured students apply for the Minnesota Family Planning Program (MFPP)¹⁵ to help assist with reimbursement rates for the services the clinic is able to provide.

The last CRUSH STI Day event was in Spring 2019 because SPPS did not return students to in-person education until the middle of April 2021. CRUSH STI Day 2022 is now being kicked off. During these events, approximately 400 teens are seen and about half of them are screened based on their sexual history and risk factors. There is about a 10% positivity rate.

CHAC Member Discussion on Panel 1

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. How can CDC/HRSA support the expansion of STI care to include ART and PrEP services in clinical care sites and service areas?
2. How can CDC/HRSA support the integration of comprehensive care into school health clinics?
3. How do we equip school districts with a means to improve the linkage of healthcare in communities?
4. What else does CDC/HRSA need to consider when expanding STI care?

The following questions, observations, and suggestions were raised:

- Dr. Gayles noted that during COVID times, health department directors often have been met with surprise and confusion from political and community leaders for not having tons of contact tracers or a sophisticated surveillance system to follow COVID cases, which health department directors frequently pointed out that this was a side effect of years of budget cuts due to under development/underfunding of public health infrastructure. He asked how NYC was able to leverage CARES Act funding to support their rebranding and if they were

¹⁵ https://www.dhs.state.mn.us/dhs16_137813

able to identify new potential funding streams for other public health programs to support their work.

- Mr. Aracena indicated that there was a lot of cross-collaboration among agencies and hospitals throughout the city leveraging any current infrastructure.
- Dr. Dowler reported that North Carolina also is a non-expansion state, and they experienced a lot of the same issues as Mississippi. She has worked very hard over the last couple of years to expand PrEP access within the Medicaid family planning benefits. While this is a much smaller benefit, she encouraged Mississippi to reach out to their Medicaid partners. North Carolina was able to get everything within that program except for the drug, which can be obtained through HRSA's program to make it reimbursable for folks and to encourage health departments and FQHCs to reach out to that population that is essentially uninsured. An important part of North Carolina's initiative was that men need family planning as well.
- Dr. Dobbs indicated that Mississippi does have a full benefit for a family planning waiver for PrEP and they pay for the medicine as well. The problem is that it is underused.
- In terms of EOBs, Dr. Dowler indicated that North Carolina has viewed the EOBs being suppressed as a requirement for any Medicaid Claim. Particularly for managed care companies, EOBs cannot go out to the homes because North Carolina Medicaid does not want that to be a barrier for care. They want school-based health clinics or health departments to bill Medicaid as a payer source whenever possible so they can save their dollars for the uninsured. Some areas of the country experience barriers with school boards as well.
- Ms. Drake clarified that the public assistance program does not send home EOB, but private insurance does. Minnesota has only a handful of Planned Parenthood and other types of clinics left since so many have been closed over the last 10 years. Adolescents without access to school-based clinics suffer even more without access to other types of clinics. They are able to have a pharmacy in their school-based clinics through their 340B funding that permits them to provide various types of oral contraceptives, and they work with their obstetrics team to get IUDs placed.
- In terms of CHAC's role on advising CDC and HRSA, Dr. Greene inquired as to how the committee could support expansion and perhaps advise on how federal support could help with the interplay with local or state policies that are more restrictive. Given that the workforce is a challenge across all sectors right now, she also wondered what would help to increase the workforce or work in Mississippi or other areas that perhaps are not as desirable.
- Dr. Dobbs said that while he knew it was a pipe dream, the most beautiful thing that happened during COVID-19 was the HRSA portal. People used that like it was a de facto way for things to happen. His dream would be to have a HRSA portal for these other needs. In a non-expansion state, there are still major financial barriers for people to get access even to FQHCs. People who are undocumented are really in trouble because they do not have proof of income and are paying market rates for healthcare in a community health center. It would be helpful to find a way to have no cost visits for community health centers. The health department is the only place with no cost care, except for a few free clinics that do not provide reproductive health services. A lot of activities must happen, but there often are not enough people to get to the desired depth. Part of the issue pertains to deciding

what to do and handing off other activities to partners who are better suited for them. The issues with the epidemiology component involve low pay and the need to create a training program locally since people in Mississippi tend to stay there. Some strides have been made in pay, but now they do not have enough human resources (HR) staff to bring on new people. It is literally like trying to build a sandcastle in a hurricane.

- Dr. So commended NYC Health for thinking about expanding the usage of the laboratory capacity they built for COVID-19 to test for other diseases. He asked whether hepatitis A, B, and C testing is offered to all the patients who have no history of previous testing, infections, and/or who have not been vaccinated. CDC recently published a study that showed that in addition to the current recommendation, offering people a one-time hepatitis B test also would identify an estimated 1000 people every year who acquire hepatitis B from sexual activities and will save vaccine doses if they already have been infected or have immunity.
- Mr. Aracena said it was based on certain categories originally. Recently, they began offering testing and vaccination to all patients.
- Mr. Lindsey pointed out that while there is discussion about “risky sexual networks” and “social sexual networks” in the HIV area, he had not heard that as much in terms of STIs. He wondered whether there were opportunities to evolve the language to talk about “open sexual networks” instead of “risky sexual networks” in the future in terms of engaging communities in thinking about getting tested for STIs. He asked whether prophylactic interventions are a dead conversation in terms of STIs, even after the success of COVID-19 vaccines and some promising thoughts about the potential for an mRNA HIV vaccine. Consideration also should be given to work that is being done at the global level and whether that might make sense for local communities, such as the Dean Street Clinic in Atlanta that used some of the resources from the EHE planning. There are a lot of advantages to 24/7 online access to schedule STI screening and treatment, order HIV self-tests, order condoms and lubricants, obtain information to connect with health literacy training online or in-person, et cetera.
- Dr. Dobbs noted that Mississippi is making an effort to implement interventions in the community at the highest impact points. Part of that involves targeted contacts investigation and work with community partners to find the engagements that can pay the most dividends. When there are many bottlenecks, it creates “inverse energy” and more bottlenecks. Mississippi cannot even do GIS mapping because they cannot assemble staff. There is a lot of infrastructure to build out, but this is hard, laborious, boring, and no one wants to fund generalized infrastructure that is self-sustaining and builds on each piece.
- Mr. Aracena noted that like the Dean Street Clinic, the Quickie model was born out of being so busy during that pandemic that there were no opportunities for static. They were able to innovate and continue to evolve to try to stay ahead of the curve of not just the pandemic, but also in order not to lose sight of EHE as well. They were fortunate at NYC Health to have one STI Quickie model at Chelsea that they were quickly able to mirror and convert to a COVID-19 express testing model, which gave them the opportunity to expand out and extend their vision. It would have taken decades to stand up laboratories at all of the SHCs. Due to the pandemic, all sites have them. Now it is a matter of finding the funding to be able to turn them on and pivot them to extend the service.

- Dr. Gayles emphasized that with the pandemic funding streams drying up, consideration must be given on how to sustain the work that everyone has put in place. This is likely to be an ongoing conversation. As Mr. Lindsey raised earlier, what happened to creative science and technology to improve and prevent STDs and HIV (e.g., better diagnostics, point-of-care self-tests, better vaccines and more of them for a lot of infections, better treatments, et cetera)? These are all areas that respective parts of NCHHSTP have been exploring in terms of their role in moving these efforts forward, including working with NIH, FDA, and industry partners. This is a nascent topic that is ripe for growth, and it is possible that in the next CHAC or the one after that, it may be possible to talk more practically about what can be done about it. CDC is going to be funding new diagnostic research into syphilis testing.
- Dr. Mermin observed that telemedicine is a great opportunity to provide services and reduce inequities. One of the biggest obstacles for Tele-PrEP is the diagnostics. That is also true for STD diagnosis. There are good scientific data showing that the OraQuick® HIV test is insensitive compared to other tests in early infection and that it can be problematic particularly in regard to PrEP. Some anecdotal cases have reported several months before seroconversion with OraQuick®. He asked whether NYC Health has capacity to use surveillance and/or other data sources to look back at all of the people who participated in Tele-PrEP and use some form of person years of PrEP use and then HIV seroconversion rates. If it is low, that could be very useful for other jurisdictions that are considering this kind of programming and it could be compared to people who are taking PrEP in-person.
- Mr. Aracena clarified that their Tele-PrEP was more of a consult in which everything would be started for the individual, but it would not be initiated until the first day at the clinic. The at-home test kits were provided with a prescription for any STI treatment. They are still considering ways to evolve their Tele-PrEP initiative.
- Ms. Borges added that they did perform a surveillance match with their colleagues in HIV to assess HIV seroconversion.
- Dr. Anderson observed that the presentations offered nice snapshots of the urban, rural, and school-based settings. She asked whether the individuals presenting the Quickie Clinics differ from those who are accessing different services, and whether they were advertised differently. She asked to what extent each group was using peers or community-based workers in all settings, which could be enormously helpful in extending health services, reducing stigma, education, and using a task-sharing and task-shifting model.
- Mr. Aracena indicated that the demographics of the people accessing the Quickie and COVID Express services were very similar. When they expand to Fort Greene in the summer, they will be able to do further comparisons. NYC Health funds a lot of community organizations, FQHCs, and various institutions, so there is a lot of cross collaboration in NYC and they also have CBO liaisons within the BPHC who work closely with community partners. During this pandemic, they have been able to expand their reach and collaboration in different settings that they did not work closely with previously, so they want to continue to leverage those partnerships going forward as they begin to pivot their instruments as well.
- Ms. Naughton indicated that Minnesota Community Care was partnering with a college in St. Paul on a Youth Advisory Board (YAB) that was taking off and doing well until COVID hit, so it all has been very distanced. Before COVID, they had representatives in each of the schools working with these college students who helped develop materials that are used in

the clinics, as well as advising them on activities they can host, distance learning, et cetera. They plan to continue this YAB work as COVID restrictions are lifting.

- Dr. Anderson asked whether anyone was using Peer Navigators (PN) as part of a telehealth system for education, counseling, linkage to care, et cetera.
- Ms. Naughton said that they have done a great deal of peer education around issues of sexual safety, especially in terms of HIV. They have not done this in telehealth, partly because of the need to be careful about not providing incorrect information. In previous peer education, a professional staff member went with peer educators to assist them with answering questions.
- Dr. Akolkar asked if/how compliance is being monitored of those people who are receiving PrEP via telehealth.
- Dr. Dobbs said it is early and they do not have enough data to support it, but it is challenging for them to keep folks on PrEP regardless. Telehealth is no different.
- Ms. Borges said that in New York they are not currently retaining patients who they start on PrEP. They start it and then refer to a community provider. The most they do is make sure the patient attends the appointment made for them. They are given a prescription for the first month, except during COVID-19 it was 3 months because it was a lot harder to get a quick appointment in most places. Once they are connected to their community provider, they are no longer a patient.
- In terms of funding streams, Dr. Mermin pointed out that they are interested in becoming as efficient as possible with providing holistic services to certain people and in certain venues. That applies to STIs at STI clinics, community health clinics, or student health clinics. Yet the funding streams tend to come from multiple sources. With that in mind, he asked what could be done better.
- Dr. Dobbs suggested finding a clearer way to braid funding. Project Officers see things very black and white, it is almost impossible to blend multiple streams of funding.
- Ms. Naughton added that something that makes school-based clinics work so well and have such good outcomes is that the team is very integrated. That is always hard to find support for, especially considering the effects of SDOH on every kind of behavior and health outcome. They are very attached to their integrated program and when they have had a chance to do that in their larger ambulatory care sites, they find better outcomes as well.
- Mr. Aracena noted that because things are so selective in these buckets, they have to continuously seek additional funding to complete the wheel on the vision and the pathway they are trying to reach.
- Ms. Borges agreed, emphasizing that they all do their best to piece together different funding sources. That can be complicated in terms of reporting and justifying/explaining to Project Officers the best they can.

- Dr. Gayles asked Ms. Drake and Ms. Naughton to speak more about having achieved a higher level of integration of services in the school-based program comparable to community services and to share more about how within that integration, how they have tapped into the community resources to improve and enhance linkage to care services and any particular best practices that could be scaled up into a community model that CDC and HRSA could support.
- Ms. Naughton indicated that within their own system, they have a very comprehensive health history and they are very careful about linking within their own system to all the disciplines and they have developed community resources that go beyond what they can do within their clinics, which are widely available to everyone within their full organization. That is a constant build and a constant nurturing of those resources.
- Ms. Drake added that having the services that are most needed for adolescents within the school-based program results in easy access to care (mental health, nutrition, therapist for counseling, et cetera) and students do not have to leave school to go outside for services. While the mental health team is able to bill and get reimbursed, health educators and registered dietitians cannot except through private insurance. There is a lot of frustration with medical assistance and public funding in terms of not getting reimbursement for those services. Seeking funding for these services is a never-ending process.
- Mr. Lindsey asked whether the NCHHSTP retired program coordination and service integration (PCSI) in the reorganization.
- Dr. Mermin indicated that PCSI is not retired and is a core part of the center's strategy. They prioritized certain aspects of PCSI that they thought would make the biggest difference, but then COVID hit, and people were shifted in general. They have a new reinvigorated conceptual framework that initially was called PCSI 2.0, but now they are thinking of pulling in the conceptual framework of syndemics because it is very similar but more cutting-edge and pulls in a slightly different concept of population health and holistically valuing people, groups of people, and populations. PCSI was focused more on structured service provision. There is a lot of support from the Division Directors, but NCHHSTP recognizes the difficulty in identifying the specific interventions, research areas, programmatic areas, and policy areas that will make the biggest difference. That was part of the reason he asked the question about just funding streams, because that comes up a lot and has been insoluble at times. Congress allocates funds by diseases and conditions, but public health thinks about health by individuals, populations, and sometimes geography. COVID showed the importance of the skills, energy, and smarts of DISs. The new resources CDC has for DISs which Dr. Mena discussed is a comprehensive approach to COVID, infectious diseases, and STIs. Regardless of size, most health departments focus on at least HIV and STDs and sometimes venture into hepatitis and TB. They might be able to build on that.
- Dr. Anderson encouraged everyone to think about the advice that has been requested from CHAC by CDC and HRSA and potential motion, action items, suggested WGs, et cetera that they might discuss during the business meeting.
- Dr. Dowler emphasized the importance of standardizing payment for testing more broadly. Right now, this is very limited. She is in a state with 100 counties and every health department has its own funding stream that is different from the one next, none of which is patient-centered. A gold standard is needed for screening availability and provision of tests

for everybody regardless of where the testing is done (e.g., home, laboratory, clinic), geographies, political issues, or financial status.

- Dr. Gayles summarized that this panel discussion highlighted significant continued funding needs, the need to be flexible and nimble in services provision, reimbursement issues, the need to define what is included in a post-COVID approach, et cetera. Just as a zip code should not determine life expectancy, it also should not determine what type of STI services, testing, et cetera are available. Consideration should be given to the potential impact on the incidence of new cases that could be arrested and curved if services were readily available.

Panel 2: Leveraging Policy to Advance HIV, VH, and STI Priorities

Moderator: Michael Williams, MPH; Office of Policy, Planning, and Partnerships, NCHHSPT, CD

Hepatitis C: State of Medicaid Access

Adrienne Simmons, PharmD, MS, BCPS, AAHIVP
Director of Programs National Viral Hepatitis Roundtable

Julia Harvey, JD
Clinical Fellow, Center for Health Law and Policy Innovation
Harvard Law School

Dr. Simmons and Ms. Harvey provided an overview of a 5-year project called *Hepatitis C: State of Medicaid Access*,¹⁶ recent progress and the current state of hepatitis C treatment access in Medicaid programs; remaining barriers to care; and next steps for this project. To provide a brief history of hepatitis C treatment access in Medicaid, the first direct-acting antiviral (DAA) Sovaldi came to market in 2013. It was commonly known as the “thousand dollars a day pill.” Due to the high cost of treatment, most payers imposed restrictions on access to treatment. In 2014, a group of researchers published a preliminary review of Medicaid coverage policies, which showed that restrictions to hepatitis C treatment were common and commonly enforced by prior authorizations. In 2015, CMS issued guidance to states that Medicaid must cover medically necessary DAAs in the hope that Medicaid programs would voluntarily loosen their restrictions. Following little voluntary progress, in 2016 Washington Medicaid was sued for requiring severe liver damage in order to access hepatitis C treatment. In 2017, the Center for Health Law and Policy Innovation (CHLPI) and the National Viral Hepatitis Roundtable (NVHR) launched *Hepatitis C: State of Medicaid Access*, which detailed Medicaid restrictions by state.

At its core, the *Hepatitis C: State of Medicaid Access* project was developed in direct response to treatment restrictions occurring in the Medicaid Program. The project conducts individual state-by-state assessments of treatment access policy and tracks national trends in treatment access over time. This project is meant to serve as a resource to state officials and advocates to help provide a comparative lens across Medicaid programs as to the state of hepatitis C treatment access, and to identify clear opportunities for policy improvement within state Medicaid programs. Historically, this project has tracked 3 primary types of treatment restrictions in hepatitis C treatment Medicaid programs. The first type is restrictions based on fibrosis score or the amount of liver damage a patient would have to have before they were eligible for treatment. The second type is restrictions based on patient abstinence from alcohol

¹⁶ www.stateofhepc.org

and drugs, most often implemented as a required sobriety period of 1, 3, or 6 months to access treatment. The third type is restrictions based on which providers are eligible to prescribe treatment. In some cases, states would narrow the pool of providers eligible to prescribe (e.g., hepatologist, gastroenterologist, infectious disease doctors). These restrictions have been tracked because federal agencies and courts have declared that they are incompatible with federal law, and it is known that these types of restrictions have had severe impacts on individuals who are trying to access care who otherwise certainly would benefit from treatment.

In terms of progress over the last 5 years, there continue to be severe restrictions and states that have been hard-hit by hepatitis C. In terms of prior authorization (PA), 12 states now allow access to hepatitis C treatment without requiring a PA for most patients. Those states include: Washington, Louisiana, New York, California, Indiana, Wisconsin, Missouri, Michigan, Rhode Island, Virginia, Alaska, and Massachusetts. Oregon will soon be the 13 state to join this list. The majority (67%) of these states removed PA without using a subscription or what is called a “Netflix model.” This is a tremendous improvement that will help streamline access to treatment by eliminating burdensome paperwork.

Moving to fibrosis, the most progress made to date has been removing this barrier, with 33 states having either eliminated or reduced their fibrosis restrictions. Only 2 states have restrictions remaining. Regarding sobriety, many states have required patients to abstain from substances or alcohol for a specific period of time before approving hepatitis C treatment despite injection drug use driving new infections. Fortunately, 29 states have loosened their sobriety restrictions and the majority of states no longer require a minimum period of abstinence. While many improvements have been seen with restrictions related to substance use, this remains the most widespread barrier of the barriers that are currently tracked. Important improvements have been seen in removing prescriber restrictions, with 28 states having scaled back on prescriber restrictions. However, barriers remain in 18 states that require specialist involvement to prescribe hepatitis C treatment and 1 state that requires prescriptions to be written by a specialist.

Despite the progress that has been made in terms of access to hepatitis C treatment within Medicaid programs, it also is known that fibrosis, sobriety, and caregiver restrictions are not the complete universe of barriers to hepatitis C treatment. Over the last few months, in an effort to understand what some of these barriers are and specifically how they impact patients, the project team has been soliciting input from patients, providers, policy-makers, and others with the goal of understanding how to improve tracking and reporting out on state Medicaid programs to best meet the needs of individuals seeking access to hepatitis C treatment. Over the last few months, the team hosted a public listening session, disseminated a public survey, and convened a provider-led steering committee to identify the most pressing barriers. In terms of the breakdown of the 275 individuals who participated in the survey, the majority (~52%) of responses were from providers and other members of the healthcare team, followed by government staff (~23%), advocates (~11%), individuals personally impacted by hepatitis C and others (~6%).

What was learned from these conversations was that there are many key barriers to hepatitis C treatment and access beyond what has been tracked to date. Many of these have not previously been comprehensively tracked across Medicaid programs. This is not a complete list of everything that was identified, but barriers include the PA process, chronic infection diagnosis, time-based laboratory values, genotype reporting requirements, adherence assessments, retreatment restrictions, specialty pharmacy requirements, and differences in requirements between Medicaid fee-for-service and managed care. Responders indicated that all of these really play a role in meaningfully inhibiting access.

In terms of the impact of these barriers, they have heard anecdotally and objectively that these barriers result in delays, denials, and interruptions to care and ultimately impede the ability to eliminate hepatitis C by 2030, particularly among communities who are disproportionately impacted by hepatitis C. Rhode Island estimated that PA can take between 45 to 120 minutes per patient, not including time addressing denials and appeals. Patients are frequently lost to follow-up due to administrative barriers at every step of this process. The following quotes from the survey describe the impact of these barriers:

“In my state, there is actually investigation into adherence for other medications for the patient. For instance, if a person has picked up their diabetes meds late before, [Medicaid] will deny [hepatitis C] treatment.”

“The burdens include the wasteful cost of repeat labs and negative impact on patients regarding cost and access to transportation. Genotype results have a long turnaround time, sometimes creating delays.”

“Some of the specialty pharmacies have requirements to speak with the patient before mailing the medication. It becomes a barrier, and possibly even a delay in treatment.”

The impact of these barriers also is evident in data recently published by CDC, which shows that the number of people who initiated hepatitis C treatment in the US declined from 2015 to 2020.¹⁷ The National Academies of Sciences, Engineering, and Medicine (NASEM) has estimated that at least 260,000 people must be treated each year to eliminate hepatitis C by 2030. However, only 120,000 people on average are treated each year and that number continues to decline in the context of the COVID-19 pandemic.

In terms of next steps, the project team is currently in the process of updating *Hepatitis C: State of Medicaid Access* project to reflect what has been learned about these other barriers to care and to include many of them in the assessment process moving forward. Based on the stakeholder input received, the state evaluation criteria have been updated and the project team is in deep data collection mode. The release of the updated report cards and full report is targeted for late May 2022.

Senate Bill 159 (SB 159) HIV PrEP & PEP For California Pharmacists Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment

Marisa Ramos, PhD

Chief, Office of AIDS

California Department of Public Health

Dr. Ramos presented on Senate Bill 159 (SB 159), HIV Pre-Exposure and Post-Exposure Prophylaxis (PrEP & PEP) For California Pharmacists. As a reminder, oral PrEP is a once-a-day pill (Truvada/Descovy) that can reduce a person’s risk of acquiring HIV by up to 99% from sexual contact. Among individuals who inject drugs, there is a 70% reduction in acquisition of HIV. PrEP provides maximum protection when taken daily for 7 days after engaging in anal sex and 20 days for vaginal sex or injection drug use. It is important to note that while an injectable version of PrEP given once every 8 weeks has been approved by the FDA, it is not relevant for SB159. Pep is a regimen to reduce the risk of contracting HIV after an exposure. PEP is the

¹⁷ Eyasu H Teshale, MD, Henry Roberts, PhD, Neil Gupta, MD, MPH, Ruth Jiles, MS, MPH, PhD, Characteristics of persons treated for hepatitis C using national pharmacy claims data, United States, 2014–2020, Clinical Infectious Diseases, 2022; ciac139, <https://doi.org/10.1093/cid/ciac139>

“Plan B” of HIV that reduces the risk of contracting HIV if taken in the 72-hour window from the moment of possible exposure. PEP is most effective when started as soon as possible and typically consists of Truvada or Descovy plus another agent, which is usually an HIV integrase inhibitor. Unlike PrEP, PEP is a complete antiretroviral regimen against HIV. Once prescribed, it must be taken for 28 days.

SB 159 was introduced by State Senator Weiner and was signed into law on October 7, 2019. SB 159 provides authority for pharmacists to determine if patients meet clinical criteria for PEP or PrEP and allows them to furnish 30 or 60 days of PrEP once every 2 years or furnish 28 days of PEP. The pharmacist must inform the patient’s primary care provider (PCP) or provide the patient with a similar report to give to their provider themselves. The law also requires that before providing PrEP or PEP, pharmacists have to complete training that is approved by the California Board of Pharmacy or that is delivered by an accredited provider. Free training is available.¹⁸ Participants must pass a quiz with a 70% score, maintain the record of training for 4 years, and retrain every 4 years. There is a website¹⁹ to find pharmacists who are permitted to provide PrEP/PEP and who have signed up for the website. It is important to note that pharmacists are not automatically enrolled in this website.

Patients must meet certain conditions to qualify for pharmacist-furnished PEP. The pharmacist must screen the patient and determine that exposure occurred within the previous 72 hours. The patient must meet the clinical criteria for PEP consistent with CDC guidelines, and there must not have been any signs or symptoms associated with acute HIV. Given that education must be provided, the patient may not waive the consultation with the pharmacist. The pharmacist is required to provide information to the patient’s PCP or provide the patient with a list of where to seek care or start PrEP if they do not have a PCP. PEP initiation should not be delayed for baseline laboratory testing, but the patient should follow-up with a provider for laboratory testing.

To qualify for PrEP, the patient must have a negative HIV test in the previous 7 days (negative antigen/antibody test or negative rapid test) and no signs or symptoms associated with HIV infection. The patient must not be taking any contraindicated medication. As with PEP, the patient must receive education and may not waive the consultation. The patient must consent to follow-up with a PCP for additional prescriptions. The pharmacist must maintain a record of the prescription provided and provide information either to the PCP if the patient has one or provide a list where the patient may seek additional care for PrEP.

In summary, pharmacists have played an important role in HIV prevention for decades. They provide condoms, sterile syringes, and supporting adherence to HIV treatment. The notion behind SB 159 is that pharmacists are uniquely situated to improve access to new preventive tools, PrEP, and PEP—especially for patients who are underserved. There are typically pharmacies within walking distance or nearby. Pharmacists also have relationships with prescribers and can support linkage to care for ongoing PrEP prescriptions, HIV testing, and laboratory monitoring. Financial assistance is available on the PrEP-AP Webpage.²⁰ Evaluation of implementation of this program begins this year to assess use, barriers, and facilitators.

¹⁸ https://www.pharmacy.ca.gov/licensees/webinars/hiv_prep_pep.shtml

¹⁹ https://www.dca.ca.gov/webapps/pharmacy/services_search.php

²⁰ <https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAadap.aspx#prep>

Leveraging Policy Changes for STI and VH Prevention, Testing, and Treatment**Rachel McLean, MPH**

Chief, Policy and Viral Hepatitis Prevention
 Sexually Transmitted Diseases (STD) Control Branch
 California Department of Public Health

Ms. McLean reported on additional policies and laws passed in California, as well as their implications. In terms of background, STD rates increased significantly in California between 1990-2019. As syphilis rates increased among people of childbearing age, congenital syphilis cases increased as well to an alarming 446 cases in 2019. This is included cases of fetal demise and stillbirths, which are preventable and should never have happened. California also bears a significant burden of chronic hepatitis B and C based on the most recent data. From 1989 to 2016, the cumulative total of chronic hepatitis B cases newly reported to CDPH was 287,087. From 1994 to 2018, the cumulative number of chronic hepatitis C cases reported to CDPH was over 700,000. This does not take into account the many people living with hepatitis B or C who remain unaware of their infection, meaning that these are probably under-estimates. STI testing volume decreased during the COVID-19 pandemic, which highlighted the need for alternative testing options.

Within that context, there has been interest in creative strategies that can be used to increase all hepatitis testing. Two bills were signed into law, Senate Bill (SB) 306 (Pan, Chapter 486, Statutes of 2021)²¹ and Assembly Bill (AB) 789 (Low, Chapter 470, Statutes of 2021)²² that healthcare providers (HCP) in California are now required by law to follow. Effective January 2, 2021, California law now requires syphilis screening in pregnancy per CDPH guidelines. This includes third trimester screening in pregnancy. SB 306 also provides liability protections for prescribers and pharmacists dispensing expedited partner therapy (EPT) for chlamydia and gonorrhea. This is very exciting, given that prescriber concerns about liability have been a barrier for a number of years. California also had stricter laws related to the use of Clinical Laboratory Improvement Amendments (CLIA)-waived rapid tests. SB 306 now will allow HIV test counselors who are trained and certified to use CLIA-waived rapid tests. AB 789 requires primary care facilities to screen adults for hepatitis B and C, which was modeled after the law in New York and appears to be the first law that requires screening for both.

SB 306 also requires health plans to cover at-home STD tests, which is particularly important due to the increased use and comfort that arose with home tests for COVID-19 that could help pave the way for at-home tests for other diseases. The SB 306 definition of at-home STD tests is, "A product used for a test recommended by CDC guidelines or USPSTF that has been CLIA-waived, FDA-cleared or -approved, or developed by a laboratory in accordance with established regulations and quality standards, to allow individuals to self-collect specimens for STDs, including HIV, remotely at a location outside of a clinical setting." CDPH has spent a lot of time examining each word in this definition, given that it is somewhat cryptic. It has been reported that FDA is working closely with companies to help them achieve FDA approval standards for at-home tests. The SB 306 at-home STD testing coverage requirement is complicated. Specific coverage requirements vary by payer depending on which state agency regulates their products. Medicaid (Medi-Cal) does not have to reimburse for at-home STD tests until specific billing codes are created, including American Medical Association (AMA) Common Procedural Terminology (CPT) Codes and CMS Healthcare Common Procedure Coding System (HCPCS) Codes.

²¹ SB 306 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB306

²² AB 789 full text: https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB789

In terms of next steps, CDPH is in the process of developing fact sheets to summarize various aspects of SB 306 and AB 789 for dissemination to HCP, payers, local health departments, and CBOs. The fact sheets are now going through the clearance process. They also are monitoring testing company efforts to request new CPT and HCPCS codes that will be needed for at-home test reimbursement. CDPH has a formal evaluation plan in place and is exploring options for how to evaluate the impact of these bills.

Louisiana's HCV Elimination Plan

Anthony James, MS, MA, MSHCM

Deputy Director of Programs
STD/HIV/Hepatitis Program
Louisiana Department of Health

Mr. James reported on the progress that has been made on Louisiana's HVCV Elimination Plan that was launched in July 2019 and is rooted in several strategies. One of the primary strategies is the establishment of an innovative payment model. The plan also seeks to expand provider capacity to treat hepatitis C; educate the public related to the availability of a cure; expand screening and expedite linkage to HCV treatment; strengthen surveillance systems to identify and diagnosis; and link those who are identified to care and treatment as part of Louisiana's "Big Bet." As part of the Big Bet, Louisiana Department of Health (LDH) has undertaken several large-scale projects to improve health conditions within Louisiana. Since the launch of the Big Bet in 2019, a total of 10,759 persons have access to treatment for hepatitis C. That includes 9,302 persons within the Medicaid population and 1,457 persons who are incarcerated.

In terms of the breakdown of characteristics of Louisiana's Medicaid and corrections populations, the majority of folks (60%) who have access within the Medicaid population are male and 40% are female. In the incarcerated population, 96% have been male and only 4% have been female. While there is a fairly good distribution race and ethnicity, approximately 59% of those accessing Medicaid treatment are white and 60% of those within the incarcerated population are Black. It is important to have that historical context to understand that a disproportionate number of persons of color are incarcerated compared to those who identify as White. The largest distribution of those accessing treatment within the Medicaid population are between 30-59 years of age, with a similar trend within the corrections population.

As everyone knows, even the best laid plans have hiccups. Since the launch of the plan in 2019, one of the biggest hiccups has been COVID-19. Being a Southern Gulf state, hurricanes also impact Louisiana significantly. Hurricanes Ida, Laura, and Zeta and an ice storm all had major impact on the Southwestern portion of the state in 2020 and 2021. Prior to this prescription model, about 61 persons on average were accessing a hepatitis C treatment. That number increased significantly to about 390 persons on average. Due to COVID-19 spikes, that average decreased to about 290. It is important to note that for persons on Medicaid, treatment is calculated using DAA claims data. Due to delays in reporting of claims data, numbers from recent months are preliminary and are an undercount.

Since July 15, 2019 over 9,300 persons have accessed treatment for HCV through Medicaid; 9,133 persons have started treatment for HCV through Medicaid for the first time; 7,930 persons who have accessed treatment have completed it; 6,394 persons have accessed treatment because of Medicaid Expansion; 612 providers have written prescriptions for DAAs for the first time; and last HCV RNA was positive for 585 persons who did not complete treatment. In order for all of this to work, it was necessary to examine some policy changes.

Several of those dealt with Medicaid in terms of lifting provider restrictions and the sobriety and fibrosis requirements.

It is important to understand that while over 9,300 individuals have been treated, others have been identified who are currently enrolled within the Medicaid group who are accessing one of the 5 managed care organizations (MCOs), which helps fulfil Medicaid's charge. Close to 16,000 persons with a positive RNA have been identified who are currently enrolled but who have not been treated. In terms of the last 2 years of this iteration of the statewide elimination plan, a lot of energy and attention will be placed on examining this group in more detail and on examining additional strategies that can be put in place to help lead these folks to a cure.

Based on data from July 15, 2019 through August 31, 2021, over 8,100 individuals in Medicaid had started treatment. Of those, over 7,000 (87%) completed treatment and over 5,200 (65%) had sustained virologic response (SVR) testing performed. Of those, approximately 4,700 (90%) achieved SVR and 514 (9.8%) had a failed SVR. Examining the Medicaid population by birth sex, 88% of females who started treatment completed treatment and 87% of the population of who started treatment completed treatment. There was a larger rate of SVR failure within the male population (10.5%) compared to the female population (8.7%).

By race and ethnicity, 93% of American Indian/Alaskan Natives (AI/AN), 87% of Blacks, 83% of Hispanic/Latinx, and 8% of Whites who started treatment have completed treatment. Of those who failed treatment, 10.2% were White, 9.3% were Black, 9.3% were Hispanic/Latinx, and 7.7% were AI/AN. By age, 80% of persons 18-29 years of age, 84% of persons 30-39 years of age, 89% of persons 50-59 years of age, and 88% of persons ≥60 years of age completed treatment and achieved SVR. Among those who experienced failure, the highest failure was among persons 18-29 years of age at 19%, followed by persons 30-39 years of age at 11.6%, persons 40-49 years of age at 9%, persons 50-59 years of age at 8.9%, and persons ≥60 years of age at 6.6%.

Assessing completions and failures by regions helps LHD prioritize regions that may be experiencing more difficult challenges. Also of interest is that 653 providers have prescribed for the first time. Determining where those providers sit within the state and using provider details can help identify and work with the regions with slower increases in new providers prescribing DAAs for the first time. From a regional perspective, Region 9 (13.7%), Region 2 (11.9%), and Region 1 (10.8%) had the highest rates of failure. Regions 4 (6.6%), 5 (6.9%), and 6 (6.5%) are doing somewhat better. Region 7 (3.7%) has had the most success, which is the Shreveport/Monroe area. Among persons who have identified as having an opioid use disorder (OUD), 84.9% have completed treatment versus 93.2% with no OUD. The completion rates for males and females seem to be fairly consistent, while there is slightly variation in terms of race and ethnicity and by age group. There are some variations from a regional perspective as well.

To summarize, Louisiana has made significant progress in addressing that HCV epidemic. If not for COVID-19 and severe weather conditions, it is anticipated that more people would have been treated. Based on data received earlier in the day, the number of individuals accessing treatment from the Medicaid and corrections populations is close to 11,000 combined.

Transitions Clinic Network**Shira Shavit, MD**

Family Physician

Executive Director & Co-founder

Transitions Clinic Network

Dr. Shavit explained that the Transitions Clinic Network (TCN) is a national non-profit organization that supports health system transformation for primary care clinics that are serving communities disproportionately impacted by incarceration. In San Francisco in 2006, TCN developed an evidence-based model of primary care for people returning home from incarceration. All of the community health centers employ CHWs with histories of incarceration within primary care teams to address the health and well-being of people returning from incarceration. To date, they have worked with 48 primary care clinics in 14 states and Puerto Rico.

People who are incarcerated are disproportionately impacted by a variety of chronic medical conditions, HIV, and substance use. People who are incarcerated have 3 times the prevalence of HIV, a much higher prevalence of hepatitis C with rates approaching 30% to 40%, and increased risks of STIs of 30% to 40%. Incarcerated people also have higher rates of chronic medical conditions and high rates of SUD and mental health conditions. With 95% of people returned home, the primary care system is a natural place to think about providing care to these individuals since they have multiple, complex, comorbid conditions. It is important to remember that in terms of cross-sector collaboration and working across systems, the carceral system and the health system have very different cultures and that really dictates a lot of what can be done and how. The punitive aspect of the carceral system sometimes plays out significantly and can impact what is known to be best practice for caring for people in the health system.

While people may not receive great care while they are incarcerated, people's health actually worsens when they are released from incarceration. Their HIV or SUDs may become worse, their viral loads may increase, they are more likely to be hospitalized post-incarceration, and they are more likely to die. A seminal study showed that people were 12 times more likely to die in the first 2 weeks post-incarceration from drug overdose, cardiovascular disease (CVD), suicide, or cancer. While great strides have been made on a policy front via ACA and Medicaid Expansion, many people who previously did not get Medicaid now have Medicaid and are eligible for services upon release. Having that Medicaid card is not always enough to get people in the door to treatment and it does not always translate to increased engagement or use of services.

That is because people face tremendous barriers when they come out of incarceration that are not just about access to care or having insurance. There is little continuity of care between systems. People may not even get medications or if they do, they get a shortened supply of medications that is not enough to bridge them to the health system. They have competing priorities, with all of the SDOHs evident (e.g., housing, employment, food on the table, stigma and mistrust with the health system due to negative experiences prior to incarceration, et cetera). These are Black and Brown communities that have experienced discrimination at the hands of health systems and then have negative experiences in the carceral system, so it is no wonder that they have a healthy mistrust of systems when released. They also face a lot of challenges in navigating complex services and services in the community that may not meet their needs.

The TNC Model of Enhanced Care was created to try to build capacity in the community health side. While it is easy to point the finger at the carceral system as not being a robust health system, the outside health system also was not meeting the needs of people returning home. Services need to be enhanced in community health systems to provide patient-centered services and engage people into care. In collaboration with communities, the TNC Model of Enhanced Care was created. This model is based on existing primary care clinics where each clinic hires CHWs who have experienced incarceration in prison or jail, most of whom have felony convictions. TNC also works with the clinics to ensure that they are providing patient-centered services like treatment of hepatitis C, HIV, OUD, behavioral health conditions, et cetera. They also work with the clinics to build cross-sector collaboration with the criminal legal system, as well as many other systems to address SDOH (e.g., re-entry organizations, community networks, faith-based networks, family systems, behavioral health system, public health system, tertiary care system, housing system, et cetera). This forces clinics to open their walls and be more contiguous with these important systems in supporting the care for people who are coming home.

This model has been successful because it follows what the community dictated as being needed. They have iterated on the model and have studied it, which has shown that this is an evidence-based model of care. Hiring CHW with lived experience in incarceration and embedding them into clinics has reduced urgent care utilization. For instance, a randomized control trial (RCT)²³ was conducted in San Francisco that assessed 200 people with chronic medical conditions or >50 years of age just released from prison. All of them were engaged into care by CHWs with lived experience. They were then randomized to either staying in the TNC or receiving primary care in the remainder of the system. They found that patients in the program had 50% fewer ED visits in the first 12 months post-release, and that having CHWs engaged study participants at much higher rates into primary care than is seen in the community.

Some information has come from unpublished administrative data from one of TNC's programs in Santa Clara County in California that works very closely with their jail.²⁴ Their health system is part of the jail health system as well, so they were able to make appointments in the jail for people pre-release, but only 33% of people were going to their appointments. When CHWs with lived experience go inside and meet people in the jail, the appointment attendance rates increased to 70%. This demonstrates that the CHW component is critical in bridging systems and engaging people in care.

A propensity-matched study²⁵ in Connecticut of enhanced primary care on contact with the criminal justice system among individuals recently released from prison to New Haven compared to individuals who were released to Hartford where there was no transition clinic program. This study found that individuals in the TNC program had fewer preventable hospitalizations and fewer probation and parole violations. They were spending 25 less days re-incarcerated in the first year post-release. The takeaway from this is that when investments are made in the health system to support these populations, costs can be reduced and outcomes can be improved in other sectors.

²³ E.A. Wang, et. al. AJP 2012 Jul 19

²⁴ Data provided by Dr. Ari Kriegsman, Santa Clara Valley Health & Hospital System 2017

²⁵ E.A. Wang, et. al. BMJ Open 2019

The last 2 years have laid the groundwork for the opportunity to build more bridges between carceral systems and health systems. Because of COVID-19, correctional leadership for the first time really understood what it meant to the importance of bridging these systems. Like everything else in the pandemic, many of these disparities and the need to address them became evident. Many of the statewide systems within TCN built stronger bridges with their carceral systems to be able to connect with people pre-release and provide care coordination systematically from those systems back to community health systems, and back to networks of patient-centered services in the community.

The timing of that groundwork has been fortunate in that some major policy shifts are emerging in the country, such as policies to waive the Medicaid inmate exclusion policy. When people are incarcerated, they are excluded from using Medicaid for their routine services. The idea would be to turn on Medicaid 30, 60, 90 days, pre-release from incarceration to allow health systems or other entities in the community to help provide care coordination from one system to the other. Another policy opportunity relates to providing targeted services to people returning home from incarceration. In California, individuals returning from prison or jail are eligible for enhanced care management services, which is a team-based approach to support people in navigation of the health system and around SDOH. Recent legislation that was passed and pending supports the idea of Section 1115 Demonstrations that would allow for states to turn Medicaid on at some point pre-release to bridge the carceral system and the community health system.

On paper this sounds feasible, but it is important to recognize that it requires a lot of system transformation. The primary care system requires tremendous system transformation to successfully care for this population. In the carceral system, there are many barriers to cross-sector collaboration and a lot of transformation is needed there as well. It is important to recognize that some of the barriers are structural. For instance, having 35 prisons across a very large geography could be a major barrier for local entities that support individuals coming out in terms of meeting with patients and supporting them in the transition home. Other barriers that may play a role include the leadership in place, lack of discharge planning services, lack of meaningful health information exchange, absence of timely identification/access to patients, lack of telehealth services, limited access for all types of community service providers, the siloed nature of carceral systems, patient mistrust, and/or isolation from/lack of community partners. Much remains to be done to build better capacity within the carceral system to enable partnerships with health systems.

The TCN has demonstrated that the policy strategy of supporting the integration of CHWs into health systems who have lived experience of incarceration means that these individuals can give back to their communities to make a difference to improve health outcomes, and health systems can contribute to reversing the harms of mass incarceration by providing job opportunities for people who normally are excluded from health systems because of their criminal record. This really is a win-win.

CHAC Member Discussion Panel 2

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What policy changes are needed to improve access to care and prevention services and tools for HIV, other STIs, and viral hepatitis among populations disproportionately affected by these infections?
2. What policy-making partnerships should CDC/HRSA establish or expand to improve care and prevention among these populations?
3. What are the opportunities for CDC/HRSA to inform and collaborate with states on evidence-based policies that establish enabling environments to decrease HIV, other STIs, and VH?

The following questions, observations, and suggestions were raised:

- Regarding non-viral hepatitis and hepatitis C, Dr. Mehta said it is clear that barriers are disproportionately faced by PWID and other marginalized populations. Related to the barriers pertaining to testing, genotyping, and pharmacy pick-ups described, a recently published study demonstrated that in a global population, people with chronic hepatitis C can be treated with minimal initial monitoring and providing all 84 tablets with little in-person contact. The study demonstrated that it was safe and that SVR rates were comparable to other real-world studies of persons with hepatitis C. This is important to think about in terms of policies going forward and data collection on barriers and acceptability of providers on such an approach.
- Dr. Dowler emphasized that getting Medicaid Expansion in every state would be amazing and that establishing CPT and HCPCS codes for at-home testing is critically important in terms of billing and reimbursement. CHAC probably could have some influence on this effort and perhaps could make a recommendation about this.
- Dr. Mermin asked what advice Dr. Simmons and Ms. Harvey could give to CDC and CHAC about how the agencies could help states and local jurisdictions do X, Y, and Z to make a major difference in terms of helping them make the changes recommended.
- Ms. Harvey emphasized that there are many reasons why policies changed over the last 5 to 7 years. For instance, prices have changed, the Center for Health Law and Policy Innovation brought litigation in a lot of states based on the fact that the restrictions were illegal, and there has been a ton of very forceful patient advocacy around these issues. Thinking about the specific questions Dr. Anderson read is that federal guidance in this space would be very valuable. Thinking back to the 2016 Bulletin that was jointly put out in the HIV space around treatment and prevention by CDC, HRSA, and CMS has been an essential tool in some of her other work to help move the needle on Medicaid access. There is an opportunity for a similar initiative in the Hepatitis C space as well.
- Dr. Simmons added that another helpful tool states had over the last few years was the HHS Hepatitis C Medicaid Affinity Group (Affinity Group), which engaged in collaborative efforts between Medicaid, departments of health, corrections, et cetera to discuss innovative payment models. Many have cited this group as a catalyst for demonstrating that evidence-based policy change and evidence-based programming can make major impacts.

- Dr. So noted that it would be beneficial to know how many state Medicaid programs are covering hepatitis C treatment among incarcerated populations, particularly given that over 20% of incarcerated populations are estimated to have hepatitis C. It is clear that evidence-based policy change has made an impact, such as requiring pregnant women to be screened for syphilis, hepatitis B and C screening law, and linkage to care law. He emphasized the need to address health disparities/inequities and incentives/laws for providers to incorporate recommendations from various bodies (CDC, HRSA, USPSTF) into health records, waivers, and screening recommendations/requirements. CDC and HRSA should reach out to electronic medical record (EMR) providers to incorporate recommended screenings, linkage to care, and clinical support/decision tools to ensure that patients are identified and receive appropriate treatment.
- Dr. Anderson agreed that while there may be guidance or policies in place, in hectic daily 10- to 15-minute visits with patients, it is difficult for this to rise to a priority. Also, there may be issues related to lack of knowledge. Having decision aids in the EMR is invaluable.
- In terms of Dr. Shavit's comments about the policy suggestion Dr. Wester made during her presentation about ensuring the best price restrictions in Medicaid do not preclude access of strategies for incarcerated populations at the state or county level justice-involved populations, particularly for hepatitis C treatment and other expensive medications. Louisiana has used 340B pricing, but she asked whether there are any examples of jurisdictions that have successfully been able to put waivers in place for that.
- Dr. Shavit clarified that in the study in which they were assessing cost savings for patients who were receiving care in their program compared to other programs, they did a propensity match for another city in Connecticut and found that they had a reduction in preventable hospitalizations and parole probation violations. The cost savings was primarily on the criminal legal side with 25 days or less incarceration. While she was not specifically talking about pharmaceuticals, investments in Medicaid saves costs in other sectors. No states have successfully waived the Medicaid exclusion policy yet. CMS had a listening session and is developing some guidance based on that. Multiple states have applied, including California, but none have been approved yet to her knowledge. However, it is an emerging opportunity.
- Dr. Wester asked whether there has been any integration of a requirement for hepatitis C screening among pregnant persons. Through claims data, they are seeing about a 30% uptake of hepatitis C screening among pregnant persons and they would like to see that increase quickly.
- Dr. So indicated that the California law is based on recommendations from the USPSTF, which recommends screening for all adults for hepatitis C. Because universal screening has become the law in California, it makes it much easier to implement screening in EMRs. He has been trying to convince Kaiser and other large groups to introduce all of the USPSTF recommendations into EMRs. As of this month, Stanford has incorporated universal hepatitis B and C testing, even though the USPSTF recommendation is not quite universal for hepatitis B.
- Dr. Ramos indicated that they started a pilot project in Orange County, California to provide medication to individuals who are HIV-positive within that county incarceration system. It is paid through the CDPH AIDS Drug Assistance Program (ADAP), which is a mixture of general funds versus HRSA funds. They are currently going through an estimate package.

It looks like they will be able to expand to more counties if they are interested in participating in the program. Some of the more conservative counties were not testing everyone for HIV as they entered some of the jails. To ensure that screening is done, treatment for those found to be positive will be paid for by CDPH versus using the county's general funds. The hope is to expand to at least 6 more counties that have shown interest.

- Dr. Anderson said she was impressed with the recent state laws in California and their innovations have moved this topic along. She observed that one barrier seems to be that there are so many different county and state laws. While it is not clear if/how CDC/HRSA could impact that, perhaps a central compilation of innovative strategies as laws arise could be beneficial. Access to knowledge about innovations in some states might be very appropriate in terms of pushing the discussion forward in other states.
- Mr. Williams indicated that NCHHSTP funded the National Conference of State Legislatures (NCSL) to create a Legislative Data Tracking System.²⁶ That is exactly what the system is designed to do, and the system refreshes every 2 weeks. As states introduce pieces of legislation that fit certain key words across all of these areas, including laws that affect healthy youth and sex education curriculum, these will be displayed. It is easy to ask NCSL to make adjustments to the system to ensure that everything is captured.
- Dr. Dowler pointed out that even when there are laws, they are very hard to track and enforce. She noted that the Guttmacher Institute maintains a good listing.
- Dr. Mermin said he was intrigued by the differential aspects of the pharmacy program for PrEP that Dr. Ramos described. Based on the examples presented, it seems that the emergency aspects of receiving PrEP through pharmacies is harder than receiving PEP. The ongoing benefit of having a pharmacist as a provider is lost if they can give only a starting dose. While receiving a starting dose can be helpful, he wondered why the PrEP restriction of 30-60 days once every 2 years was included and whether it could be changed.
- Dr. Ramos indicated that there is a history. Originally, there was a push from some of the clinics that had a pharmacy within their organization since it would be easy for someone to present, be started on PrEP, and then go next door to see their PCP. While she did not have the data, PrEP has been under-utilized from what she has seen. However, the specialty pharmacies within those clinics would not like it to go away because they can administer and at least start PrEP. Implementation has been slow. The state is seeing more dispensing for PEP than for PrEP. Because of COVID-19, this was averted to do the training that is required.

Wrap Up Day 1

Travis Gayles, MD, PhD
CHAC Co-Chair, CDC Appointee

Jean Anderson, MD
CHAC Co-Chair, HRSA Appointee

Dr. Anderson observed that it had been a tremendous day with a lot of information that began with reports from CDC and HRSA. They heard some statistics on continued increases in syphilis and congenital syphilis, as well as increases in adolescent mental health concerns and

²⁶ <https://www.ncsl.org/research/health/state-public-health-legislation-database.aspx>

the need to find ways to address these. Some of these negative statistics were offset by the data CHAC heard about the dramatic improvement in viral load suppression overall and in key populations; demonstrable reductions in disparities; and very impressive successes reported in CDC-funded programs in schools to decrease risky sex behaviors, safety concerns, and sexual assault. She congratulated CDC and HRSA for their work and deep thinking in terms of integration and collaboration strategies and the use of the syndemic approach to deal with these interrelated problems, which is critical. In the afternoon, they heard about innovative models of care and continued challenges. Some of the innovations and the ability to address challenges are constrained by state- and county-level policies and legislation, funding, and lack of time or knowledge on the part of physicians. They also heard about a lot of flexibility and innovation during the COVID-19 pandemic and in many cases inspired by it. They heard about the role of integration of different relevant infections, as well as issues related to SDOH.

Dr. Gayles expressed his gratitude for the great presentations and for the work everyone does on a daily basis in order to be able to present the data that you provide. He further emphasized the continued notion of evolution in terms of the need to be modern and think outside the box moving forward with regard to funding to sustain programs and to continue to pivot to keep efforts moving. This includes the ability to speak fluently to young people to make sure that they are engaging and they are able to effectively communicate their needs in safe spaces. With regard to engaging in conversations about increasing services that folks need, it is important not to use mental health as a crutch to not do the necessary work to root out racism, systemic issues, bias, transphobia, and all of the other things that significantly influence the potential success of projects in the future in terms of being able to sustain funding and considering the significant variability in terms of the differences in geography and the level of services available. A lot of tremendous work has been done but there are still many headwinds in the way moving forward.

Adjourn

Dr. Mermin officially adjourned the meeting for April 26, 2022 and CHAC stood in recess until 11:00 AM ET on April 27, 2022.

Day 2: Welcome and Roll Call

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

The proceedings were called to order at 11:00 AM ET. Dr. Mermin welcomed participants to the second day of the CHAC meeting. He conducted a roll call and asked members to disclose any new COIs. COIs did not differ from the previous day and are reflected in the table on page 8 of this document. He confirmed that 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 27, 2022.

Special Presentation: Turning the Tide on Self-Testing and Sample Collection

Moderator: Elizabeth DiNenno PhD; Division of HIV Prevention, NCHHSTP, CDC

FDA Regulation of HIV Self-Testing Devices and Self-Collection Kits for HIV Diagnosis

Julia Lathrop, PhD

Associate Deputy Director
Division of Emerging and Transfusion-Transmitted Diseases
US Food and Drug Administration

To lay the groundwork Dr. Lathrop explained that in vitro diagnostic devices (IVDs) are medical devices per Section 201(h) of the Food, Drug & Cosmetic Act (FD&C Act) [21 CFR 809.3] that defines medical devices as: “Reagents, instruments, and systems used in the diagnosis of disease or other conditions . . . in order to cure, mitigate, treat, or prevent disease intended for use in collection, preparation, and examination of specimens from the human body.” Clearly, self-testing and self-collection kits are considered to be medical devices. As such, they are subject to the provisions of the FD&C Act. It also means that regardless of whether a device is regulated either in the Center for Biologics Evaluation and Research (CBER) or the Center for Devices and Radiological Health (CDRH), it is subject to the provisions of the FD&C Act.

The review of all IVDs, regardless of where they are reviewed or what their use is, is based on the balance of the benefit and risk to the individual and that the data provide a reasonable assurance of safety and effectiveness of the device. A risk for an IVD is providing an incorrect result to the individual. For an HIV diagnostic, that would be a false positive or false negative. Risks from receiving a false negative could be that an individual is denied life-sustaining treatments and could transmit a life-threatening disease. The risk for having an incorrect result, especially a false negative for HIV, is very high. One element of assessing for reasonable assurance of safety and effectiveness and the balance of benefit/risk pertains to whether the device does what it is intended to do.

All IVD reviews begin with a review of the intended use because this is where the determination of the risk lies. Intended use pertains not only to the HIV diagnosis, but also the sample type, population, conditions (e.g., professional use only or self-collection). The risks all lie in the intended use and it is from the intended use that the review logically flows. It is important to keep in mind that one device may have more than one intended use and those uses can have different risks. For example, HIV diagnostics and viral load monitoring have very different risks

associated with incorrect results. The risk involved and what is necessary to mitigate the risk determine whether a device is categorized as a Class I, Class II, or Class III. Colloquially speaking, those mean low, moderate, and high risk, respectively. However, that is not entirely accurate because there can be a high-risk device like an HIV diagnostic that can be safely regulated as a Class II device. FDA is in the process of reclassifying HIV diagnostic supplemental and viral load tests from Class III to Class II. The risks associated with an incorrect result have not changed; these are still high-risk devices. Having approved many devices over many years allows FDA to establish special controls, which are provisions associated with the demonstration of the safe and effective use of the device. Establishment of special controls allows for successful mitigation of the risks in order for FDA to safely review these as Class II devices requiring a PMA. Special controls can be requirements such as performance criteria, post-market reporting, et cetera, that are necessary to provide reasonable assurance of safety and effectiveness of the device. Because reviews are based on intended use, there is no expectation that all Class II devices should have the same special controls since the risks associated with each intended use differ.

Turning specifically to FDA regulation of HIV self-testing devices (HIVST), HIV devices are Class III devices that require approval of a PMA before they can be marketed. There is one approved self-testing device on the market, the OraQuick® HIV self-test approved in 2012. HIVST devices were not included in the reclassification of HIV diagnostic, supplemental, or viral load tests due to a lack of sufficient experience with these devices to write special controls that will safely mitigate the risks so that they can be regulated as Class II devices. FDA does agree wholeheartedly that there is an urgent need to improve access to self-testing for HIV. To that end, FDA is working with manufacturers to consider alternative validation strategies and streamlining of the review and approval process to expedite entry into the market. When the OraQuick® HIV self-test was approved, the process was very laborious and very careful because there were a lot of concerns, even with the whole concept of self-testing, but HIVST has since been demonstrated quite clearly to be safe and effective. Thus, many of the concerns that caused the original process to be so laborious have been mitigated through experience with the devices. FDA has been working with manufacturers to determine ways they can use existing data, for example, especially if it is an already approved point-of-care device, and adding a self-testing claim to that. This differs from a manufacturer who is submitting a brand-new device never approved before.

HIV self-collection kits also require FDA approval. All self-collection kits are medical devices that require FDA authorization before they can be distributed regardless of their intended use, but the review pathway can vary based on the intended use of the device. For example, a device might be intended for home use or use in a clinic for self-collection that is supervised or unsupervised based on disease indications. The reason that FDA needs to review these devices is that adequate and appropriate sample collection is essential for device to meet performance expectations. Self-collection means that an untrained individual is collecting their own sample, so there is no automatic assurance that collection has been performed properly when the sample arrives at a laboratory. FDA reviews instructions for sample collection and the device's performance with the intended sample type to ensure a reasonable assurance of safety and effectiveness of the device.

In terms of the current landscape, FDA recognizes there is a need for self-collection kits for HIV diagnosis for individuals who are unable or unwilling to attend a clinic. However, HIV self-collection kits require approval of a PMA or clearance of a 510(k) following reclassification of HIV diagnostic device to comply with the FD&C Act. Distribution of unapproved HIV self-collection kits is a violation of the Act. There are no FDA-approved HIV self-collection kits that use blood samples currently on the market. FDA's goal is to bring unapproved/uncleared

devices into compliance with the law and regulations. In the interest of public health, FDA is committed to working with device developers to meet the requirements.

Turning the Tide on Self-Testing and Sample Collection Background and Need

Michele Owen, PhD

Associate Director of Laboratory Science
NCHHSTP, CDC

To ensure that everyone was on the same page, Dr. Owen first shared the following terminology and definitions:

- **Point-of-Care Test (POC):** Conducted near an individual also referred to as point of contact or rapid tests administered by trained staff or health care providers
- **Self-Test:** A complete test conducted by an individual for their own knowledge—also referred to as an over-the-counter test (OTC) or direct-to-consumer test (DTC).
- **Self-collection (self-collected test):** A scenario where an individual collects their own sample, and hands it off or ships the sample to a laboratory for testing

There are many considerations for self-testing and self-collection testing. It is very important for populations where clinic or laboratory testing is difficult or not feasible. However, it is very important to provide clear information regarding assay limitations. For example, the oral fluid assays will detect some early infections.²⁷ These are never the final diagnosis. They are used in conjunction with clinical testing for a definitive diagnosis. Ideally, these tests should be available at a price point that will allow wide access for many people to have the ability to use them. As noted, OraQuick® is the only FDA approved HIV self-test. This is an oral fluid test that costs about \$35 to \$40 retail. It is important to note that this test does not detect acute HIV infections (e.g., up to 90 days for positive result post infection) and there are limitations for its use in the context of PrEP. Based on delayed reactivity shown in PrEP trials, this test is not optimal for prescribing PrEP. There are currently no cleared self-tests for STIs or viral hepatitis.

In terms of HIV self-testing data in the US, CDC in conjunction with Emory University conducted a longitudinal randomized control trial (RCT) known as eSTAMP²⁸ that demonstrated the feasibility, acceptability, and benefit of distribution of self-test kits. The study used the FDA-approved OraQuick®, a fingerstick test under IDE (Sure Check®), and a dried blood spot (DBS) test. Infection was identified in first time testers and social contacts and no harmful adverse events (AEs) were reported. A partnership with CDC's Let's Stop HIV Together Campaign-to launch TakeMeHome distributed approximately 100,000 HIV self-test kits through a portal on the CDC website.²⁹ This event demonstrated that self-testing serves people who might be reluctant or unable to seek clinic- or community-based testing. This tool was identified by 80% of jurisdictions that are part of the EHE as being very important for their community EHE plans.

The World Health Organization's (WHO's) stance of self-testing is informative. WHO has made recommendations twice that self-testing should be part of eliminating HIV or identifying people and getting them into treatment. The first recommendations were in 2016. After reviewing the data in 2019, the WHO updated their recommendations to make a strong recommendation for HIV self-testing. They also pointed out that testing in this manner reaches high-risk people who

²⁷ Stekler et al, JCV 2013 and 2016; Luo et al JCV 2013

²⁸ MacGowan et al. JAMA Intern Med, 2019

²⁹ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7038a2.html>

might not test otherwise, so it should be an ongoing approach for testing services.³⁰ There are a number of HIVST products available outside of the US with WHO pre-qualification.³¹

As mentioned earlier, there are no FDA-cleared self-collection test for HIV and Home Access is no longer on the market. Commercial laboratories have set-up laboratory-developed test (LDT) services, primarily because of testing during COVID for HIV, STIs, and PrEP initiation because it was known that people were not getting tested. This also was done for hepatitis B and C antibody tests. Multiple studies have been conducted on STI self-collection inside and outside the US. WHO also funded a meta-analysis of STI self-collection tests³² after which they published recommendations for self-collection testing for STIs. Similar to HIV self-collection, WHO pointed out that self-collection of samples for *Neisseria*, gonorrhea, and chlamydia are very important and reach people who might not normally be tested.

In the US, various institutions have set up programs for self-collection for STIs.³³ One of the most well-known program is I Want the Kit³⁴ that came out of Johns Hopkins where they are doing chlamydia and gonorrhea testing. Originating in Baltimore, this testing has now been expanded to Maryland, Alaska, and Arizona residents. The District of Columbia (DC) conducted a similar type of project called GetCheckedDC.³⁵ This is a mail-in STI testing program. Both programs have reached priority populations and data indicate that the methodology is feasible.

CHAC Member Discussion on Special Presentation

To focus the discussion, Dr. Gayles reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. How important is self-testing and self-sample collection to overall public health efforts?
2. Are there specific analytes (e.g., antibody or antigen tests for HIV, HCV or treponemal/non-treponemal test for syphilis) that CHAC would consider a priority?

The following questions, observations, and suggestions were raised:

- Dr. So emphasized that there is a lot of value in having rapid tests for home use and use at outreach events for HIV, STIs, and hepatitis. He asked whether one reason for not having more approved rapid tests and self-tests was because industry is not submitting applications and if FDA should be sending out notices to welcome industry to submit applications.
- Dr. Lathrop indicated that FDA has engaged in increasing outreach to manufacturers to encourage them to submit all of these devices. There tends to be a lot of mythology around what FDA will and will not consider in terms of data. Some of that is because that is the way it used to be and some of it is because people talk amongst themselves and have decided this, or they may have gotten an unhappy answer and then decided that FDA would never consider using data from outside the US. In some cases in the past, that might have been true. However, FDA has been working hard to open up alternative validation strategies that might not have been considered in the past, and is trying to engage outreach to get people

³⁰ WHO recommends HIV self-testing. (2016) World Health Organization. <https://apps.who.int/iris/handle/10665/251549>; Consolidated guidelines on HIV testing services. <https://www.who.int/publications/i/item/978-92-4-155058-1>

³¹ Latest list of WHO prequalified products: https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

³² Ogale et al. BMJ Glob Health 2019

³³ Kersh et al: J Clin Microbiol, 2021

³⁴ <https://iwantthekit.org/>

³⁵ <https://www.getcheckeddc.org/>

to come in. Fundamentally, FDA can only review what people submit. People also can simply start conversations with FDA regarding what is/is not required. There is a pre-submission process that is simple and can be informational. They want people to talk to them about what they have and what the expectations are. There is no penalty or user fee to clarify what is needed. In a pre-submission, FDA's feedback is binding. If they say that a study design is acceptable, they cannot change their mind later unless the science changes. It also is confidential on the part of FDA.

- Dr. Anderson observed that there seemed to be no question about the need for self-testing and self-collection devices for various infections. Perhaps the barrier at this time is that more data are needed for validation. She wondered whether manufacturers and laboratories do not have the protocols, are not interested, et cetera. Obviously, the need for more data has cost implications. While FDA is reaching out to individual manufacturers for technologies that are already developed and being used abroad, she wondered what realistically could be done to move this along in the US such as some sort of incentive structure. It sounded to her like a lot of data already have been generated, at least in a global setting, some of which may be useable for US approval. She clarified that when she said "incentivize," she was not suggesting that they pay manufacturers. She just wondered what outreach mechanisms might be available.
- Dr. Lathrop said she could not speak to whether FDA has the ability to incentivize manufacturers and they do not sponsor trials. Manufacturers may assume that the barriers are so high that they could not possibly get approved, but validation is validation. FDA recognizes Clinical and Laboratory Standards Institute (CLSI) standards for measuring assay precision. These are voluntary standards, but they are best practices developed by the device manufacturers. CDC and FDA are on the panels for some of the standards and follow those principles. Good device validation follows the CLSI standards to be properly validated in many cases. FDA has a number of roundtables that are designed specifically to engage in open discussion with manufacturers. She agreed that finding ways to reach out to various manufacturers who are developing these tests is crucial.
- Dr. Owen added that CDC also has tried very hard to engage in outreach with manufacturers by interacting with the Advanced Medical Technology Association (AdvaMed) to discuss the needs for HIV, STI, and HCV tests. In addition, CDC recently convened a diagnostics conference that they have had for many years. Most manufacturers either attend and/or have booths. Manufacturers have said that they will not bring a test to the market if they do not see a market share for that. They are private companies and they want to make money. It is important to continue to emphasize the need for these devices and that there will be a market for them.
- Dr. Dionne-Odom inquired about the role of clinical investigators who design RCTs. In order to reach this vulnerable population who is at-risk and not accessing care, self-testing for HIV and STIs is critical. If researchers receive funding for trials from NIH to conduct this type of research with donated kits from companies that have told them the bar is high for validation through the FDA, she wondered whether that would be the type of data that would be compelling or if the real work needs to be done at the level of the company to put their specifications and QI in place.
- Dr. Lathrop indicated that the clinical data is part of the package, but someone has to actually sponsor and submit the application. There is nothing that says a clinical laboratory or a university cannot do that, but they have to have all of the information that supports the analytical validation for the device as well. That can be challenging. A kit can be made that

works on an already approved instrument, and that a laboratory or university could submit that as their test and take responsibility for it. It does not have to be the manufacturer. While there are some risks associated with that, it can be done. It is difficult when someone is just doing the trial component, because they may not have access to all of the information needed. That would have to be acquired from the manufacturer or the researcher working with the manufacturer to provide that for an FDA application. The data generated in those kinds of studies, if well-designed and potentially can be submitted to FDA in the end, speaking very generically, should be usable.

- Dr. Mermin observed that while the efforts to reach out to manufacturers are appreciated, it is extremely expensive to put forward an application for PMA for a Class III device. For a university to want to conduct the clinical trials is not an easy process, for HIV in particular.
- Dr. Lathrop indicated that the user fee for a PMA is substantial. One benefit for reclassification is that when diagnostics are 510(k), it is a much lower user fee. At the moment, a self-collection kit is a PMA because the assay is a PMA. Once the assays are reclassified as Class II, the self-collection kits can come in as a 510(k). FDA is awaiting the finalizing of the reclassification, but when that occurs, it should lower the financial cost. The clinical studies still need to be done with performance criteria that are in the special controls, but certainly the submission and maintenance of that application are much lower.
- Dr. Markham reported that the IWantTheKit program from Johns Hopkins has made an incredible impact in reaching Native American and Alaska Native communities working with colleagues at the Alaska Native Tribal Health Consortium (ANTHC) and the Inter Tribal Council of Arizona, Inc. (ITCA). They are expanding their work to the Southern Plains Tribal Health Board (SPTHB) in Oklahoma. This has been a phenomenal program and working with the Johns Hopkins team has been outstanding. Testing is only one part of it. There also is a need for funding the culturally sensitive outreach and marketing, because those testing kits are only as good as the folks that they reach. It also is important to have support to linkage to care in local communities. For remote tribal communities where youth do not want to go see their Auntie at the local clinic because that is not going to be confidential, the importance of having that self-testing and anonymous/confidential access and linkage to care is critical.
- In terms of the mention earlier that different centers within FDA have adopted different approaches, Dr. Mermin asked whether thought has been given to aligning the requirements of both centers so that there is more consistency.
- Dr. Lathrop clarified that they do not have different interpretations. They have different intended uses. The requirements for an HIV diagnostic will differ from the requirements for an HCV diagnostic because the risks associated with the intended uses are different. Both centers are assessing them in the same way in terms of the potential impacts of the incorrect results to the individual. For instance, the risk from an incorrect result for a viral load monitoring test versus a screening test are very different. The centers talk all of the time and try to align as much as possible.
- Dr. Mermin indicated that CHAC, CDC, and HRSA have discussed that they do not believe the distinction between hepatitis C and HIV diagnostics at the point of use are different. They talked with FDA about that as well. They are left with a situation in which they are an organization trying to get testing out to the people who need it, but see different routes being required by different centers in the FDA even when it is not clear why one is being treated differently than the other.

- Dr. Lathrop said she understood why it appears that way sometimes. FDA's feeling is that the risks from a wrong result for HIV are not the same as the risk of a wrong result from HCV, especially in terms of a false negative and a person believes they are not infected and go about their life. HIV is treatable when people know they are infected.
- Dr. Dowler expressed an interest in understanding from the payer perspective how they can pay for these tests so that companies will invest the resources to go through the process. No Medicaid program is going to pay for a self-collected test with no incentive to do that. There is an opportunity for CHAC to assess the rigor of going through the approval process, incentives for industry to want to do that, and making sure that tests are equitably distributed and accessible to various communities in terms of being offered and the payment structure.
- Dr. Daskalakis shared a resource for HIV self-testing:
Issue Brief: <https://www.cdc.gov/hiv/policies/data/self-testing-issue-brief.html>

Panel 3: Applied Syndromic Approach to HIV, VH, and STIs: Focusing on People

Moderator: Demetre Daskalakis, MD; Director, Division of HIV Prevention, NCHHSTP, CDC

Comprehensive Harm Reduction Supports Navigation to Curative Hepatitis C Virus (HCV) Treatment and Syphilis Services

Andrew Gans, MPH

HIV, STD and Hepatitis Section Manager
New Mexico Department of Health

Josh Swatek

Hepatitis and Harm Reduction Program Manager
New Mexico Department of Health

Mr. Gans and Mr. Swatek presented on comprehensive harm reduction supports navigation to curative HCV treatment and syphilis services provided by New Mexico Department of Health. Typically, when speaking about harm reduction and high-volume, high-quality, low-barrier harm reduction programs as a great access to services, it is normal to assume that there will be hepatitis C, maybe HIV testing, and syphilis services to build trust in the community. Unfortunately, with the release 10 days ago of the STD surveillance data for 2020, New Mexico is number one in congenital syphilis. Small number, high rate, and very alarming.

New Mexico is able to do navigation because they have such a high-volume harm reduction program. While previously they were performing rapid HIV and hepatitis C testing, they have moved away from rapid hepatitis C testing because they have clients who have been antibody tested repeatedly over a decade or more, but it does not actually get them into care. It is expected that all harm reduction includes navigation to substance use services. New Mexico's enhanced model is about navigation to services rather than just referrals. As part of the hepatitis C elimination plan, it is necessary to get people into curative treatment. This involves getting them insurance, getting them into primary care, getting them medication opioid use disorder (MOUD) treatment, syphilis services, and ensuring that the DIS who are involved in a lot of these services can be doing partner services, testing, and linkage to STD or hepatitis treatment as well.

New Mexico wants to be among the first, if not the first, to eliminate hepatitis C as a public health threat by 2030 meeting national and international goals. New Mexico has 5 wins and innovations in the state that really place them ready to do this:

1. Project ECHO, which was founded in New Mexico at the University of New Mexico specifically to increase access to HCV treatment.
2. New Mexico Corrections Department (NMCD) is actually providing STD treatment actively and was doing antibody testing upon entry for almost a decade, switched to do confirmatory testing as well, and now has funding in the legislature to do curative treatment for about 2,800 inmates.
3. New Mexico has one of the most progressive Medicaid policies, which opened up for hepatitis C treatment without pre-authorization, fibrosis restrictions, or sobriety restrictions in 2015. The consultant who pulled off this amazing feat is now their Cabinet Secretary for Health.
4. New Mexico has an innovation with a high-risk pool, which they have been using to ensure that everybody living with HIV has insurance coverage, even if they are categorically ineligible due to immigration. The New Mexico Medical Insurance Pool (NMMIP) was approved at the end of 2019.
5. Comprehensive harm reduction services are available statewide.

Project ECHO has a peer education program working with state corrections, which does a lot to promote referral to hepatitis C treatment. They have the funds now and the 340B discount, which has allowed them to increase from about 150 inmates being treated for hepatitis C prior to this innovation to an average of about 600 a year. They have to motivate people to ask for it. It is not just for people with advanced disease, fibrosis, et cetera. It is for everybody, but not everybody knows they need it. NMCD has a plan for HCV elimination and received a very large allocation of funds. Project ECHO is a key part of that in terms of consultation and includes the NM Peer Education Program that educates the population on HCV screening and treatment. Partnerships are highly essentially in New Mexico. New Mexico's innovative policies for hepatitis C treatment that began in 2015 increased access to treatment for Medicaid recipients. They have good coordination that is constantly improving with Medicaid MCOs, which helps somebody who leaves corrections who did not start or complete treatment get community treatment as well. A lot of people are cycling through jails where there is less excellent coverage, state prisons, and then back into the community for Medicaid.

New Mexico's innovative high-risk pool has done very well with wrap around insurance. Before ACA, New Mexico was a state that never had an HCV drug assistance program waiting list, because with this high-risk pool, they were ensuring everybody with HCV who could not get insurance 10 years ago. When ACA rolled out and there was Medicaid expansion, a lot of folks with HCV moved to Medicaid or to an ACA plan. Others still have employer insurance. The NMMIP is still the last option. There are only about 200 people with HCV in the state, but the hope is to be able to serve 50 to 100 people with hepatitis C who cannot get any other insurance. The exciting part is that they thought this would be a treatment model where the state health department and public health offices would be the wrap-around safety net. In some communities, one of the few providers in the county is the Department of Health Public Health office. Even in some of the larger communities, there may not be a lot of providers who are willing to provide hepatitis C treatment, so they hope to ramp this up. While they got set back about 2 years by the pandemic, they have a protocol for hepatitis C simplified treatment and can serve a lot of people who do not have advanced disease right in their health offices to be that safety that helps people get access to MOUD, which is essential for a lot of the population. New Mexico has comprehensive harm reduction program services available statewide. More than 18,000 unique people were provided with syringe services in 2021. An important piece of

that is that 87% of people have been tested for hepatitis C, but only 24% have had access to treatment. Harm reduction programs are a key place to provide services for viral hepatitis. Component 3 through the 2103 CDC DVH grant has allowed New Mexico to expand its services, which is essential for preventing reinfections.

Some of the strengths of the New Mexico model are negotiated exchange, which allows tailoring to client needs while still striving to maximize collection of used syringes. Services are comprehensive. Locations at NMDOH Public Health Offices offer HIV, HCV, and STD testing and services, WIC (Women, Infants, and Children), family planning, et cetera. Many sites are within FQHCs or other health care providers. Services are low threshold, meaning that new clients can enroll with just a brief interview. The program is confidential, but unique client identification codes can be used to ensure immunity from prosecution for possessing syringes. Program sites were an ideal venue to provide hepatitis A vaccines during an outbreak among persons experiencing homelessness.

This is a comprehensive model that provides new, sterile syringes. Safe disposal of syringes can be done through both program interactions and community drop boxes. Small sharps containers are provided to participants to return to the program. There also is provision of other “works” needed to prevent the spread of infectious disease, as well as overdose prevention services. Referrals and navigation are provided to substance use services, public health interventions, and social services. Some people might not be ready for treatment because of the circumstances of their lives (e.g., lack of childcare, food insecurity, lack of housing, et cetera). Active navigation helps to address those gaps first, with the eventual goal of getting people into treatment.

In terms of messaging, New Mexico’s older campaign had 6 messages for people in their services who may not have thought of PrEP, PEP, curative treatment, or rapid testing. The new campaign is being rolled out as harm reduction across the state around maternal testing for syphilis, which is very important for responding to congenital syphilis. The issue with New Mexico’s congenital cases is that a lot of people are not in prenatal care, very often due to substance abuse.

The New Mexico Harm Reduction Act passed in 1997. It authorized the Department of Health to compile data to assist in planning and evaluation, provided immunity for exchange or possession of hypodermic syringes from the Controlled Substances Act for both participants and providers, and approved community providers across the state. Program operations started in 1998. There were a lot of problems with the original policy. Original state rules were detailed in terms of data collection and reporting. This necessitated long intake interviews and some irrelevant questions (i.e., sexual behaviors). Eligibility is only for state residents aged 18 and over. Some educational messages that became outdated (i.e., use of bleach) were written into initial regulations. Exchange was one-for-one only with a limit of 200 syringes per interaction (hindering secondary exchange). However, policy changes have increased the scope of harm reduction services. House Bill 52 passed in the 2022 legislative session, with a lot of bipartisan support. It allows NMDOH to promulgate rules that reduce negative health outcomes associated with drug use such as overdoses and infectious disease and reduce harm by improving participant engagement in harm reduction.

Harm reduction is now being used to respond to maternal and congenital syphilis. New Mexico has a lot of moms who are not accessing prenatal care due to immigration status, using substances, experiencing homelessness, engaging in transactional sex work, et cetera. They fear that if they get connected to a system of care, they will lose custody of their baby. A lot of training is being done for providers to make sure those who do come in are tested. Harm reduction efforts include strategies to engage at-risk persons in harm reduction, including meth users and those who do not inject; rapid and conventional syphilis testing; incentives for testing, including for male partners of persons of child-bearing age; social network strategies (SNS) to recruit; and integration with DIS to ensure treatment, disease investigation, and better quality services.

Corrections Health is Public Health for the Justice-Involved Community!

John J. Hagan, MD

State Correctional Health Authority

North Dakota Department of Corrections and Rehabilitation

Dr. Hagan noted that he has the privilege of leading a small but mighty team of medical and psychiatric professionals who provide care to a unique and vulnerable population. Together, they change the lives of residents in the North Dakota Department of Corrections and Rehabilitation (DOCR). There is an epidemic of incarceration, with 1.43 million adults held in federal or state prison facilities currently. There are about 735,000 persons in jails. Across the country, about 0.7% of the adult population are held in jail or prison. The North Dakota State Prison system houses 0.3% of the adult state population. That does not include folks on parole or probation. North Dakota is a very rural state of 774,000 total humans. The adult count in the prison system is very small at 1,685. They are happy to be small and are trying to go out of business if they can. Their average turnover is 1,500 admits per year, the median length of stay about 16 months, and the recidivism rate has been about 40% over 5 years.

North Dakota residents are a vulnerable and underserved population. People of color are over-represented in prison in probation and on parole. Someone who is Black in North Dakota is 4.2 times as likely to be under DOCR control compared to their White counterparts. Latino North Dakotans are 1.8 times as likely and Native Americans are 5 times as likely to be incarcerated. Residents arrive uninsured with very fragmented medical care. They suffer significantly higher rates of hepatitis C, SUDs, serious mental illness, diabetes, and hypertension. The goal is simple. The mission of the North Dakota DORC is to transform lives, influence change, and strengthen the community. They work hard because they believe the work is worth doing. They practice dynamic security, the goal of which is to create a humane, normalized environment to the extent possible. They have security available if having issues, but they found that when their patients are treated normally, they respond normally. They are trying to get folks ready to head home by creating an environment in which residents attain and practice prosocial skills in a setting where they are safe.

DOCR's plan for success in treating STIs, hepatitis C, and HIV is straightforward. DOCR is tremendously well-supported by the North Dakota Department of Health (NDDOH). DOCR partners with NDDOH to bring screening and treatment service to the DOCR system, and they form a large platform for DOCR's more comprehensive treatment programs. DOCR would have no opportunity to do this without the superb NDDOH, which underpins everything DOCR does.

One of the things that drives DOCR's programming at every level of operations and security is that their residents are going to become their neighbors. Of the individuals in DOCR's care, 98% will be discharged to North Dakota, South Dakota, or Minnesota. They ask themselves with their programming what kind of neighbors they want. They are very much person-centered rather than diagnosis-centric. DOCR considers what these folks need to be successful in the community, and challenge their clients to work to remodel and revitalize themselves. The testing and treatment programs that they offer are concrete actions that convey to the residents that DOCR is heavily committed to investing in their future. This is a great place to find and treat folks. Upon arrival, 31% of DOCR residents identify themselves as PWID. It is suspected that the numbers are higher. About 15% of the residents suffer from chronic hepatitis C with elevated viral load. In the last 10 years, DOCR has had 2,388 unique patients arrive with hepatitis C antibodies and 80% of them are typically HIV-positive. Only 0.6% of DOCR residents test positive for HIV. The chlamydia rate is 20.7/1000.

The goal is to build trust from day one. In the first 30 days, there is an orientation program during which the DOCR Nurse teaches health-related issues and answers questions. The result of offering a stable and humane environment is that residents asked for treatment on arrival. There is an opt-out program for testing. Virtually nobody opts out. For the first time in 6 months, only one individual in the state of North Dakota asked not to test, so the environment definitely is right for this. The only reason DOCR succeeds with this program is because of the unwavering support of the NDDOH. This translates to 20% of adult men on arrival are antibody positive and 15% overall have active virus, while 37% of women are antibody positive and 25% have active virus. This is known due to the ability to perform universal testing on arrival. The reason they can do this is because their cost for HCV antibody is \$26 underwritten by the NDDOH. The HCV RNA/Genotype is \$55. The average screening cost for hepatitis C is \$37 dollars per arrival. DOCR cannot come close to that anywhere in the private world, so that helps them a great deal. That turns out to be important because NDDOH reports that 15% of individuals in North Dakota who have an HCV positive laboratory result reported to NDDOH each year have at least one HCV associated laboratory report in a correctional setting.

DOCR cures hepatitis C. They have the support of leadership and their legislature. DOCR treats and cures 43% of the people who come through the door who are infected and they test everybody. Because we partner with the NDDOH and have access to 340B pricing, their average cost is \$12,560. Their 2021-2023 budget is \$1.9 million. For an additional \$2.4 million for a joint program, they can get to micro-elimination and treat everybody they see. This is a great opportunity to impact the state. Since NDDOH steeply discounts their laboratory costs through Section 318 of the Public Health Service Act (PHSA), DOCR's GC and chlamydia tests are \$10 and HIV tests are \$10. They treat by protocol for GC and chlamydia. As soon as they are notified, their staff completes Level I contact tracing on behalf of NDDOH. They also are the first to notify patients on HIV results on a regular basis. People have wanted testing, they have feared testing, but they feel safe at DOCR. Fortunately, they have immediate counseling, psychiatry, psychology, primary care, and infectious disease services available.

Prisons face challenges in treating justice-involved individuals. Most states do not have a unified system. Jails and prisons look the same on television, but they are not at all the same in real life. They are separate organizations. They speak to each other and about each other, but they are not in the same organizations. Jails are funded by county budgets and prisons are funded out of state budgets. The scope and breadth of services differ by county and by state. Some counties have comprehensive services, while some counties have no services. DOCR does not have direct control over prisons. They have a relationship, but programs written for jails and prisons may not work in one setting or the other.

It is important to note that justice-involved individuals are ineligible for Medicaid, Medicare, VA, or private insurance as soon as they are incarcerated—even if they are still paying premiums. States pay cash for all DOCR services. They negotiate and pay out of the general fund. Public funding opportunities for these services is fragmented and separate programs exist for hepatitis C, GC and chlamydia, HIV, SUD, serious mental illness, and wraparound services. For all of the issues that this vulnerable group is expected to have, support disappears when the door is slammed shut by law. Another challenge is attracting and retaining providers. Medical staff are state employees who are underpaid compared to the community. State medical and mental health case management for transition is badly underfunded in most states, so they do not have the services that are known to have a high impact. Jail resources for education, screening, and treatment are very sparse and jails are unable to shoulder the burden as a result.

The next step is to expand the import model. The ultimate goal is to engage the community and patients. That is working well. DOCR partner with federal, state, and local agencies to bring services that already exists into the prison system. The advantages include a steady and predictable volume for agency partners, a solid source of reliable care for this vulnerable population, and continuity of care on release. A great example is DOCR's cooperation with the UND Family Medicine Residency Program, which runs the Center for Family Medicine and also takes care of Custer Family Planning, which is the public health STD treatment programs. For its residents, DOCR also uses the HerCare clinic to bring in onsite prenatal/obstetric care and reproductive health services (e.g., LARC, reversible contraceptives, education). There also is continuity of care, in that those leaving DOCR's care are plugged into that service and they continue to work. Another example like this would be the use of methadone and opioid treatment providers in the community to perform services. DOCR's goal is to expand this important model.

The takeaway messages are that prisons and jails are ideal settings intervening in the syndemic of HIV, STIs, and VH. Justice-involved individuals are a vulnerable population at high-risk for these conditions and are eager to accept treatment. Corrections health is community public health in its purest form. It is important to remember that these individuals are not always in prison or jail. There are actions that can improve the health of justice-involved community members dramatically. While DOCR has 1,685 folks in prison and 800 in jail currently, the total count is 7,500 to 8,000 who are in prison or jail and on parole or probation. It is important to envision justice-involved individuals as a community, and jails and prisons as an ideal location to deliver impactful programming. Further developing programming to discount the cost of syndemic testing in jails and prisons has been highly effective. It is entirely the low cost that allows them to be universal. It is no longer risk-based, there is no stigma, and people are very accepting of it. Allowing flexibility to unify and align existing programs to meet the unique needs of this vulnerable population is very beneficial. Restoration of the HRSA/HPSA special designation for determining workforce shortages for jails and prisons that is independent of the surrounding community represents a major need. This is an incredibly effective way to add staff.

Providing Comprehensive Sexual Health Services to SFUSD Youth

Rosalia Lopez, M.Ed

Student Family Services Division
San Francisco Unified School District

Dr. Lopez shared information on how comprehensive sexuality education and how sexual health services or appointments outside of the school system work in the San Francisco Unified School District (SFUSD) in the context of policies and mandates that support programs, community partnerships, and the tier systems of support. It is extremely important to have intentional policies and mandates that support programs at the state, local, city, and school district levels. Several policies and mandates are highlighted below:

- **Health Education Content Standards for the State of California**³⁶ for which 2 examples of interest are: 1) 1.9.G, which explains laws related to sexual behavior and the involvement of minors; and 2) 3.2.G, which identifies local resources concerning reproductive and sexual health, including all FDA-approved contraceptives, HIV/STD testing, and medical care.
- **The California Healthy Youth Act (AB 329)**,³⁷ which went into effect in January 2016, requires that schools provide comprehensive sexuality education for students in grades 7-12 at least once in middle schools and at least once in high school.
- SFUSD Board Policy **6142.1 Sexual Health and HIV/AIDS Prevention Instruction**³⁸ requires comprehensive sexual health education and HIV prevention education shall be offered to all students in grades 7-12, including at least once in junior high or middle school and at least once in high school.
- **Sensitive Services/Minor Rights: California Family Law Code Section 6920-6929**³⁹ Parental/guardian consent is not required for minors under the age of 18 to access sensitive services. These services may include treatment having to do with drugs/alcohol, reproductive health, sexually transmitted diseases, and mental health.
- **Condom Availability Program - SFUSD Board Policy 5141.25, California Education Code 19-24- Sp1** requires a Condom Availability Program at all SFUSD Middle and High Schools; delineates guidelines, parent/guardian notification, exclusions, education component, and abstinence message; and creates alliance with schools and community health care providers.
- **Meeting the Needs of LGBTQ Students - SFUSD Board Policy 610-8A6, California Bill AB537** prescribes a variety of activities, interventions, accountability, and support to ensure that schools are a safe place for LGBTQ youth; and ensures that sexual orientation and gender identity be included as protected categories in all non-discrimination policies and procedures applying to all SFUSD students, teachers, staff, administrators and other employees.

³⁶ <https://www.cde.ca.gov/be/st/ss/documents/healthstandmar08.pdf>

³⁷ https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB329

³⁸ <https://go.boarddocs.com/ca/sfusd/Board.nsf/goto?open&id=BDVSWC74A618>

³⁹ <https://law.justia.com/codes/california/2005/fam/6920-6929.html>

In terms of partnerships, SFUSD has a cooperative agreement with CDC-DASH, San Francisco Department of Public Health (SFDPH), and other CBOs to implement programs that support sexual health, education, sexual health services, and safe and supportive environments. SFUSD uses a multi-tier system of support, including health education, wellness programs, and LGBTQ student services programs. Because of the partnerships with the SFDPH and other CBOs, SFUSD has been able to support comprehensive sexuality curriculum to ensure that there is a common language (Be Ready, Be Real for High School; Healthy Me, Healthy Us for Middle School; Healthy Me Resource Guide). Staff training is provided on policies and procedures to providing youth-friendly services; providing sensitive services and referring students to local clinics if needed; and logging services and follow-up one-on-one services to youth when needed.

The SFUSD team work closely with the Wellness Program and the LGBTQ Student Services Program for consistent assessment of the health education curriculum to determine where it needs to be updated to meet the needs of LGBTQ and all other students. One example would be if the topic of human trafficking is being discussed, a social worker is in the classroom in case students need services beyond just awareness. Because of policy, schools are not allowed to pass out condoms and the role of the teacher is just awareness. The nurse in the Wellness Center would provide students with condoms. Because a student would need to go to the Wellness Center to complete a quick needs assessment and receive condoms, there is relationship-building between the teacher, the nurse, and the students in terms of where students receive services. Those who need further services beyond what the Wellness Center can offer are referred to a local teen clinic.

SFUSD's Sexual Health Services & Multi-Tier Systems of Education has 3 tiers: Intensive, Targeted, and Universal. Health education is considered Tier 1, given that it is for everyone. Tier 2 is for those who need smaller social groups. Tier 3 is for those who need more support (e.g., testing, mental health services, medical issues, et cetera) for which students are referred out to partner organizations. This year more than ever, there is a lot going on in schools and the help of CBOs and health clinics has been key. Though it has been somewhat difficult to reconnect during the pandemic, this is a work in progress.

These innovative collaborations have yielded some excellent expected and unexpected results, including fantastic lessons, connecting classrooms to services, and increased collaboration of SFUSD partners with over 50 CBOs. The top 5 types of services based on number of students served include general counseling, case management, medical services, behavioral health counseling, and sensitive services.

Advancing Syndemic Approaches Through Cluster Detection and Response

Alexa Oster, MD, CAPT USPHS

Acting Chief, Detection and Response Branch
Division of HIV Prevention, NCHHSTP, CDC

Dr. Oster pointed out that cluster detection and response offers a framework to guide tailored implementation of proven HIV prevention strategies where transmission is occurring most rapidly. After an outbreak, detection helps to identify when HIV is spreading quickly and to work to stop that spread. The presence of a cluster or outbreak indicates a failure of care and prevention services that needs to be addressed to improve access to services, such as antiretroviral therapy, PrEP, and sub-transmission. This is an opportunity to identify the needs of affected communities and generate ideas for improving services, because cluster and outbreak response involves curating care and prevention services to be more accessible to the

people who need them most. Cluster response is an opportunity to identify gaps in services and curate tailored treatment and prevention interventions where standard population interventions have failed. Importantly, cluster detection and response involves adapting resources for those who use them rather than expecting people to adapt to access services in a system that has failed them.

Concurrent with the opioid crisis, there have been a number of HIV outbreaks among PWID in the US over the past several years, beginning with a large outbreak in Scott County, Indiana that was detected in 2015. PWID experience numerous syndemic conditions, including HIV, STDs, VH, SUD, and mental health challenges. In addition to these medical issues, they often face unstable housing, food insecurity, and other needs for social services.⁴⁰ Clusters and outbreaks affect a variety of populations, and these principles apply to sexual transmission as well as injection-related transmission.

In an example from Kanawha County, West Virginia, HIV diagnoses among PWID drugs increased rapidly beginning in 2019.⁴¹ As a result, the West Virginia Bureau for Public Health requested CDC assistance with an HIV outbreak investigation. CDC built its team with syndemics in mind. The CDC team, led by DHP, also collaborated with HRSA's HAB and the Department of Housing and Urban Development (HUD), both of whom have become very important partners for response support. This team collaborated to support the state and local health departments in conducting an investigation that included a medical record review and a rapid assessment with qualitative interviews. At the local level, a diverse set of partners from the state and local health departments and multiple other healthcare CBOs were involved.

To highlight some findings from qualitative interviews with 26 PWID and 45 key community members, many people described using substances to cope with feelings of hopelessness and despair associated with a confluence of health and social challenges, such as unstable housing, depression and anxiety, and unemployment. Among the numerous health and social conditions PWID faced at the time, HIV and SUD were just a couple of the many issues. This constellation of challenges underpins the complex needs of the populations served, as well as the challenges that can slow progress in implementing holistic approaches.

The medical record review, which included 496 healthcare encounters among 65 people with HIV, showed missed opportunities for prevention and care for a wide range of conditions, including low provision of naloxone and medication for OUD. Medical encounters for overdose and STIs were infrequent. Hepatitis C diagnosis was common and preceded HIV diagnosis by about 4 years. Most people were covered by Medicaid and housing instability and incarcerations were prevalent.⁴² Surge DIS staff from the Division of STD Prevention brought a syndemic approach to partner services, going above and beyond to ensure appropriate testing, treatment, and linkage to care for various syndemic conditions and working to meet a variety of other food and social service needs. The findings mentioned informed one of the team's recommendations, which was to improve access to HIV, hepatitis C, substance use, and mental health services through service integration by co-locating services and cross-training service providers to improve access to effective infectious disease prevention efforts. Co-location of services, along with multidisciplinary teams and intensive case management, can help to address important barriers to care for multiple conditions. Low barrier, one-stop-shop models can help. It also is important to involve people with lived experience in the development, implementation, and monitoring of programs.

⁴⁰ Lyss SB et al., JID 2020

⁴¹ Hershov R et al. MMWR 2022

⁴² Bonacci R et al. CROI 2022; Hudson A et al. CROI 2022; https://oeeps.wv.gov/hiv-aids/documents/data/EpiAid_Report.pdf

In terms of challenges to syndemic success, integrating data sources from multiple conditions can be difficult, but is essential to understand the various needs of the people served. Silos in data systems can reflect silos in programs, and bridging those programs silos can be critical to facilitating integration of data. Policy barriers also can be a major challenge. For example, expanding harm reduction services and SSPs was a primary recommendation of the investigation. Although SSP policies were changed where possible, state laws and city ordinances related to SSP limited the ability to expand these services to meet the need. Likewise, limitations to eligibility for hepatitis C treatment for people covered by Medicaid meant that testing and linkage ended up being deprioritized. Limited eligibility led to misconceptions that affected the care-seeking behaviors of even those who were eligible for treatment. Program and funding silos are an important consideration. This is relevant at a macro-level, including how federal funds are distributed, but also applies to how health departments are structured with separations between infectious diseases and behavioral health and also at a micro-level where providers and systems have incentives to only address immediate needs, including in EDs and correctional settings. Finally, health department capacity limitations also were a challenge. Even when funds are available, health departments sometimes have difficulty hiring and retaining staff, and this limits their ability to perform recommended activities, including partner services for every new diagnosis of HIV and syphilis. CDC can provide surge support to help address a backlog of cases or additional cases during an outbreak, and federal support provides an opportunity to build program and systems capacity, but this can be limited by other capacity issues at that health department.

It is important to note that although outbreaks among PWID have been highly visible due to concerns about rapid transmission in these populations, most clusters of rapid transmission are related to sexual transmission. Among 144 clusters first identified through molecular analysis in 2018-2019, 82% were primarily among gay and bisexual men. Among the largest clusters that had grown to more than 25 people as of September 2021, 72% were among gay and bisexual men. These clusters were typically small when they were first detected, but grew to be just as large as the concerning outbreaks seen among PWID. Many of the same syndemic issues and others apply to gay and bisexual men, who also face homophobia and other systemic injustice.

To share an example of a cluster related to sexual transmission that resulted in response to syndemic issues, Michigan identified a molecular cluster of rapid transmission in 2021 in Wayne County affecting a network that included Black or African American transgender women. About half of the network members indicated participating in sex work or having partners that engaged in sex work. The health department immediately began engaging with community partners that serve trans communities to talk through potential gaps in services and how to improve them. Over a few months, 13 meetings were held with these community partners. The health department also spoke with members of the network, who were supportive of the response efforts and willing to share information about the community's needs and also helped to indicate additional people in need of services. They indicated that there were not enough providers who provide gender-affirming care. As a result, Michigan has created a mobile services initiative to offer gender-affirming care that includes general health and wellness checks, immunizations, a food pantry, and HIV and STI testing. Michigan is also developing community-oriented social media and messaging campaigns developed with input from the trans community.

Although value and opportunity have been demonstrated in advancing syndemic approaches through cluster detection and response, there are a number of needs and considerations, most of which are not unique to cluster and outbreak response. Those at the federal level can support syndemic approaches by communicating the priority of a syndemic approach from federal funders to state and local recipients consistently across all federal funding programs

and partners. This work cannot be successful if driven by a single program. This includes working to minimize silos between federal funding that serves as a disincentive to collaboration. Teams need to be designed with syndemics in mind, modeling at the federal level what is thought to be needed at state and local health levels. This collaboration cannot occur only when there is an escalated response, but must involve long-term work to integrate and align programmatic guidance and technical assistance.

Additionally, policy issues are often at the heart of the most stubborn barriers and where possible, state and local partners must be supported to address these policy issues. It also is important to build systems to meet the needs of the people served rather than expecting people to adapt to systems. To do so, it is necessary to listen to people with lived experience. Qualitative interviews have been a powerful tool to identify what is broken in systems and get ideas for how to fix them. Often the barriers to delivering seamlessly integrated services are issues like funding, training, separate service organizations, time, or physical space. Funding and program requirements can help to dismantle these barriers. That core set of integrated services should be a primary goal and not a bonus or afterthought. Solutions need to address syndemic health conditions that people are facing, but that is not enough. Intervening only on health concerns may not be effective if social conditions are not considered and addressed.

Identifying partners well-equipped for syndemics is key to success. Local health departments, health centers, or community organizations that receive broader funding that is not siloed or who receive funds from various sources already are well-positioned to support this work. Likewise, providers that recognize their clients' holistic needs and meet clients where they are have the most success in linking and engaging them in services. Community outreach workers and partner services staff can embody this approach and this trust is so critical for populations stigmatized on many levels. Moving from the current systems to a gold standard syndemic approach, while an important goal, will take time, so it is important to be prepared to accept incremental progress. Setting expectations too high can sometimes have the unintended effect of disincentivizing staff from initiating response efforts and other work that can unmask the many changes that are needed. Syndemic approaches rely on building cross-cutting teams that can best support this work and the people served.

CHAC Member Discussion on Panel 3

To focus the discussion, Dr. Anderson reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What priority policies and actions should be considered in operationalizing a syndemic approach to service provision?
2. What settings should be considered for the highest public health impact?
3. How can CDC and HRSA make syndemic strategies and programs more common and effective?
4. What are the best practices for integrating non-HIV-specific services into HIV systems?
5. What strategies would better link youth to clinical services through school health programs with collaboration with public health departments?

The following questions, observations, and suggestions were raised:

- Dr. Anderson noted that one of the fun aspects of these meetings is hearing about all of these impressive programs that a lot of them would not hear about otherwise.
- Mr. Driffin said one of his finals for ethical consideration for one of his DrPH classes is on HIV sequencing and non-positive response. He wondered whether the presenters could share additional insight on racial and ethnic demographics that have been observed in response to the cluster response teams.
- Dr. Oster indicated that they looked at people who were in clusters of rapid transmission nationwide and found that about a third were White, about a third were Black or African American, and about a third were Hispanic or Latino. Rapid transmission is occurring in a variety of populations, and it is important to ensure that they are assessing the gaps that are driving this and supporting changes in programs and services along with those populations. In the analyses that assessed large clusters among gay and bisexual men, they found that most were in the South and West.
- Mr. Lindsey noted that a key barrier to syndemic approaches has been segregated funding streams in the past, which also was a barrier to personnel or workforces who are unable to work together because of segregated funding streams. He wondered whether it is all state funds or if there is anything else that can be done to address ideological or financial barriers to allow more of these population focuses and syndemic approaches to flourish.
- Mr. Gans responded that New Mexico integrated HIV, STD, hepatitis, and harm reduction into one section in 2015. Because they are a centralized health department, having all programs under one roof and operating on the statewide and local levels gives them a lot more flexibility. New Mexico is unique in a couple of ways. First, they have a lot of state support for a variety of programs and second, they have a lot of flexibility as long as they meet performance measures globally. For instance, they have had a long-term shortfall in their harm reduction budget, but they have about \$1 million in state funds in harm reduction. When he started it was \$4 million or \$5 million a year and now it is closer to \$12 million. It has dipped somewhat as people moved to fentanyl and smoking rather than injecting. While they could not afford that out of that budget, they could use state general funds in HIV prevention, HIV care, STD, et cetera. The other thing is that they have other revenue sources. They generate pharmacy revenue, which sustains a lot of HIV PrEP programs around the country, including community health centers. They do something similar with their direct services. Generally, they do not have a huge amount of flexibility in federal grants but when there is flexibility, they use it. They always have had fully integrated DIS who are largely funded in HIV and STD, and they are all cross-trained in HIV, hepatitis, harm reduction, and other navigation along with STD as the focus. New Mexico is always looking for ways to be creative. It is easier to have a syndemic approach at the local level, when they are all located in the same building and talk about their budgets all of the time across the agency.
- Dr. Hagan responded that they have syndemic issues with treating different illnesses. More importantly, most of their program availability begins and ends at their doorstep. There is a sharp cutoff when folks are detained or when they are incarcerated. When incarceration ends, the transition of services is a particularly weak section for them. That is where the natural silos have occurred as people try to create programs for incarcerated folks and folks in the community. That crossover is missing for them because there is not longitudinal thinking. They have the same problems in prisons and jails. When the door slams or opens,

programs begin or end and they are not well-connected. A lot of efficiency is lost that could be capitalized on. We track data out into the community and have tremendous longitudinal data for parole, probation, and recidivism, and recognize the continuum of care. We are taking actions based on the data. Prisons have the infrastructure, and it is shocking how much data they have, but do not crunch it. He can say which of his residents bought FUNYUNS® last week and other incredible data. They have to be careful with it, but they do have incredible data. They just do not use it as well as they might.

- Dr. Lopez stressed the importance of working together in order to provide universal services for everyone and to avoid duplication of efforts.
- Dr. Greene said she was hearing themes throughout about meeting people where they are, low barrier and low thresholds to care, flexibility, and how self-testing could help facilitate people where they are. As someone who works in geriatrics, she pointed out that this is very relevant to older adults, people with mobility limitations, and people with other issues that affect their access to care across all of these systems.
- Dr. Hagan replied that their approach in jails has been largely to try to get services. For instance, for some of the large local jails, they have worked hard to bring the university residents on site. These folks need customers, need to meet people, and need to understand their population. They do have folks with serious mental illness (e.g., schizophrenia, bipolar psychosis, major depression) who come off of their medication and cannot operate well within the social system. Once someone has had a single felony, they become felonized. He thinks there should a DSM-5 diagnosis called “felonized” because they never again will go to public health or mental health care. They will go to prison or jail. The first thing is linking work and bringing folks on site, irrespective of the ability to pay. In jails the focus is largely on getting patients what they need most and establishing trust. Some folks will be up to a year in jail depending on the jail, but most are not. The focus in jails is to get them basic services.
- Dr. So congratulated Dr. Hagen for running such a great program in the prison system. It is a model program. He asked whether they test their prisoners for hepatitis B and whether they are offered hepatitis B vaccination. Some prior CDC studies showed that about 2% of the incarcerated population have chronic hepatitis B and as many as 6% will develop acute hepatitis B infection in this country who have a history of prior incarceration.
- Dr. Hagan said that while they do not do universal testing, they do offer universal immunization. On arrival, they check everybody in the immunization registry, which is very complete in North Dakota. They are proud to be the state’s number one provider of adult hepatitis B immunizations. They have lost their funding for hepatitis A immunizations. The American Correctional Association’s goal is to fully immunize everybody for hepatitis A and B and fully test everyone for C. They do not do the testing unless there is a question clinically, but immunization is offered to everybody on arrival as a public health function.
- Dr. So suggested considering testing before vaccination, because the Medicare cost of a 3-panel hepatitis B test is only \$30. If they had prior infection or already have a chronic infection, it would save on vaccine cost since the vaccines are still very expensive. They also would pick up those who have chronic hepatitis B and may need antiviral therapy.
- Dr. Mermin said he was struck by the fact that in some ways, they were doing too good a job. Each of the presenters showed so much of what could be done with screening, comprehensive SSPs, comprehensive student health services, et cetera. He wondered

whether there were policies that would need to be put into place that would prevent people from getting hepatitis C, HIV, STDs, TB, et cetera—something that would have an effect even more upstream to make the work easier.

- Mr. Gans indicated that New Mexico wanted to get ahead on hepatitis C curative treatment to move towards elimination because they had some of the highest prevalence in the country. They are working to improve their surveillance system because the quality of active risk factor and race/ethnicity surveillance in hepatitis C is not the quality of HIV because it has not been funded as well. It is probably too late for the upstream changes, but they are probably a good model for all of the best policies He wished Medicaid expansion was universal, but it is not.
- Dr. Lopez said that while California has some of the strongest policies, the problem is that they are unfunded policies. That is well-intentioned, but it becomes challenging to address the policies.
- Dr. Hagan said he would like to see much better availability for needle exchange, which is still a taboo subject in his state. The state is really good at taking care of incarcerated folks. The rationale is simple. Everybody is someone's brother, cousin, uncle, daughter. Everyone knows somebody. He also would like to see better access to SUD treatment in the community. One place to focus is on jails since many people enter and cycle out of jails a number of times. Before they ever get to prison, they have been to jail 10 or 15 times.
- In terms of specific policies, Dr. Guilamo-Ramos said that from his point of view, the "low-hanging fruit" is to look at the workforce. The example shared about limitations on pharmacists and PrEP could be applied to other disciplines. The largest segment of the healthcare workforce is nurses, yet they have many regulatory limitations around the country that do not make any sense and limit the ability to improve access to prevention and treatment. Another thing that was striking to him in terms of settings was that he had not heard a lot about the important role of families, biological or non-biological. Families are an important setting, particularly for young people. Thinking about SDOH is impressive in terms of trying to integrate services, co-locating, and cross-training. Consideration must be given to how particular groups or communities thrive and overcome adversity despite significant challenges. He is a little concerned about the narrative, given that it has been focused on vulnerability but does not provide a path forward in terms of how to use the science of how people overcome and what has worked as being important to understand.
- Mr. Driffin suggested that more consideration be given to additional community engagement strategies that can continue to be lifted between CDC, HRSA, and other federal partners to ensure that communities move along with them to beef up strategies.
- Dr. Oster indicated that they are collaborating on some sessions with HRSA HAB for the Ryan White conference that relate to cluster detection and response. Some of the topics include community engagement, partnering with community organizations and providers, how everyone can come together to ensure that they are responding to clusters in a way that helps to make services better for these populations, et cetera. Community engagement around this topic is a major focus. She and Dr. Daskalakis have been spending a lot of time together working to have discussions with lots of different partners, community organizations, policy partners, healthcare organizations, and public health partners over the past few months.

- Ms. Hayes indicated that PACHA is hosting an HIV molecular surveillance small group think-tank that will include their community and federal partners.
- Dr. Anderson indicated that there is a current ECHO program related to the intersection of HIV, substance abuse, mental health, and intimate partner violence (IPV) for which she could share information.

Telehealth/Telemedicine WG Report

Dr. Shannon Dowler, Lead CHAC Telehealth WG

Dr. Dowler reported that the Telehealth WG had engaged in several meetings since its launch during the last CHAC meeting. The first thing the WG did was dig into the benefits and risks of telehealth and summarized their findings into potential areas of interest for CHAC. In terms of benefits, telehealth broadly has the potential to improve various types of access (e.g., geography, transportation, provider limitations, et cetera). Particularly in the sexual health space, telemedicine offers a unique opportunity to reduce stigma. It results in decreased costs, such as non-emergency transportation, lost work time, and practice infrastructure. It has the potential to close care gaps and improve health equity. Telemedicine also has the potential to improve retention in care, empower folks who are receiving services to take control of their healthcare, be more patient-centered, and increase provider productivity. There are many reports showing that patient no-show rates using telehealth are improved and that the barriers that keep people from getting to a scheduled office visit are mitigated with virtual care. As an example, North Carolina Medicaid wanted to know what was happening with its beneficiaries, so they added an adult experience and child experience with telehealth into their Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. They found that people were generally as happy with their care whether they had telehealth or in-person care. There was not a statistically significant difference for adults or children. Beneficiaries/patients seem to be happy with this modality of care.

There also are risks and challenges to telehealth. The WG found that there is disparity in terms of access to technology and broadband access depending upon where someone lives and the ability to pay for technology and services. Maintaining confidentiality and privacy in the home setting can be a risk and challenge. Not everyone has a large home in which they have the benefit of spreading out or going somewhere private for telehealth visits. There is a loss of ability to identify IPV. There is a risk of influence or manipulation by people who are not seen in the visit, which has significant implications. It takes time and energy to train people to use telehealth technology. There is a potential to break up services and have multiple visits, which may not be ideal. From the standpoint of fragmentation of care, there is always the risk of breaking up the medical home experience, not having good communication, and creating challenges in continuity of care—particularly when there is not shared documentation. There is a risk of losing some of the components of in-person care. This raises questions about the percentage of visits using technology versus in-person visits so that critical pieces of care are not lost. The issue of language barriers comes up repeatedly. In terms of the payment and integrity standpoint, there is a risk of fraud and abuse, particularly in the telephonic arena where it is not possible to confirm someone's identity.

Another challenge in the field pertains to the fact that everyone is using different terms and has different rules. Until everyone can come together nationally and agree on certain terms and on what is/is not covered, there will continue to be of mixed-metaphor of what people are saying. When the terms telehealth, telemedicine, or virtual health are used, everyone is saying and

allowing for different services or benefits. North Carolina Medicaid has 2.8 million beneficiaries. They began an evaluation to determine what was happening. There was a huge plummet in visits when the stay-at-home order was issued by the Governor. Simultaneously, there was an exponential and steep rise in telehealth. There were essentially no services prior to the pandemic, so the baseline was zero. The dramatic improvement in access would have been lost if people had relied on in-person visits, because it completely dropped off the radar.

After studying these data for over 2 years and looking at the relative probability of adults using telehealth services as a function of race, ethnicity, and geography, Black and Hispanic persons and those living in rural areas were less likely to engage and there was not a tremendous amount of improvement over time. While there is a lot of discussion about all of the great opportunities Telehealth offers to improve health equity and access, the lived experience in North Carolina is that the odds are still against closing those gaps. On the other hand, people with chronic conditions leaned in hard and fast to use telehealth early in the pandemic. Over time, that number decreased. In the rural/urban space, there has been an increase in the last 6 months with people beginning to use the technology more consistently in rural areas.

Looking at some specific codes, North Carolina assessed child developmental services to decide what would be kept as permanent policy versus what would not. Consideration was given to a service as a function of whether it changed geographic, racial, or ethnic equity. Consistently, the findings did not identify changes. They found that urban individuals were more likely to engage in telehealth even though they have more child development centers than in rural areas. The same patterns were observed by ethnicity in that someone who was not Hispanic was more likely to engage in child development virtually. The same difference was seen in terms of whether someone was Black or White. Gaps were not being narrowed in this area, and this pattern was reproduced across multiple codes. The data show that the same people who are using telehealth are the same people who are using in-person care, and that new patients are not being entered into care.

The WG talked specifically about opportunities to improve sexual healthcare in the context of modernization of technology and proposed a few areas they think are the most important. One opportunity is with home or alternate testing for STIs. The conversations over the last 2 days of the CHAC meeting aligned nicely with these recommendations. Consideration should be given to ways to normalize home testing and increase home delivery of medications, which could reduce the stigma of going into a pharmacy to ask for something. PrEP access could be enhanced to have a more patient-centered approach. Inequities around access to PrEP are significant and broad across the country, and PrEP is just not getting to people in an equitable way.

With this background information in mind, the WG developed the following recommendations and invited input regarding any priority areas for which CHAC thought proposals might be made to CDC, HRSA, or both.

- **Build on the PrEP letter that went out early in the COVID-19 Pandemic (CDC):**
 - Recommend that CDC launch a formal campaign to teach providers how and where virtual services can assist in the EHE goals specific to PrEP
 - Recommend the potential for the same initiative related to retention in care for HIV

- **Explore how virtual services can enhance routine STI screening for all populations (CDC):**
 - Recommend that CDC fund pilot home testing service delivery models broadly to seek to understand the impact of this model
 - Award sites based on factors such as poverty indicators, payer mix, population and geographic disparities
- **Study health equity as it relates to telehealth service provision (CDC/HRSA):**
 - Early data suggest that telehealth has not overcome barriers to access to care
 - A formal study could spawn interventions that might impact equitable service delivery more effectively
- **Deploy a Tele-PrEP initiative for FQHCs (HRSA):**
 - Recommend that HRSA fund a Tele-PrEP initiative for FQHCs to pilot focused on areas with high need to PrEP ratio

CHAC Member Discussion and Vote on Telehealth/Telemedicine WG

Dr. Gayles noted that while he and Dr. Anderson would moderate this discussion, they both recused themselves from participating in the discussion and any related votes due to COIs related to telehealth.

The following questions, observations, and suggestions were raised:

- Dr. Driffin said the only thing he would add, especially for others as they begin, was that the processes address the nuts-and-bolts questions around what success looks like for communities. This means ensuring that Black and Brown people have access to the internet, tablets, and/or whatever other vehicles are necessary to get them to the option of telehealth/telemedicine.
- Dr. Mermin noted that the data presented were very impressive and showed that a smaller proportion of certain populations participated in telehealth during the pandemic. He wondered whether they still participated in health visits and if those using telehealth were the same as those presenting in-person. He thought it would be beneficial to understand whether people who did not participate in telemedicine dropped out of care entirely or continued care through in-person visits.
- Dr. Dowler indicated North Carolina found that the same people who are using telemedicine are the same people who are presenting in person. The Duke-Margolis Center for Health Policy also performed a data analysis and came to the same conclusion that the same people who are using telehealth are the same people that are presenting in-person and new patients are not getting into care. People who are engaged in health care are engaging in health care maybe in more convenient ways or in different ways, but access to care is not actually being broadened. The exception to that seen in North Carolina was in primary care homes. Rapid adopters picked up telehealth really quickly and made it a large part of their practice, increased the number of patients they saw overall and improved access to care. Generally, the beneficiaries who are accessing care are just accessing care differently. In terms of whether people who did not participate in telemedicine dropped out of care entirely would have to be analyzed specifically. While they saw overall engagement, the beneficiaries did not change. North Carolina Medicaid

maintained a lot of telehealth services, but their commercial partners have not been as clear. The things that they are keeping would allow people to use their smartphone. In the sexual health arena, there are many positive opportunities because of stigma in that people will feel more comfortable in using self-collected tests and it would feel more patient-centered.

- Dr. Mermin emphasized that technologies are increasingly being seen as tools for helping people stay healthy. Perhaps providing someone with a smartphone and software might make a difference in people participating. Consideration would have to be given to whether there could be reimbursement by Medicaid or private insurance. The upfront investment could be prohibitive for both providers and individuals unless it was covered by insurance, but this could eliminate some of the obstacles for people—particularly those with limited resources.
- In terms of the idea of a more formal campaign to teach providers how/where virtual services can assist in the EHE goals specific to PrEP, Dr. Daskalakis indicated that NCHHSTP's Capacity Building and Technical Assistance Branch has materials⁴³ for providers that focus on telemedicine around PrEP, which probably could be nuanced more to specifically identify places where telemedicine may be more or less appropriate.
- Dr. Greene suggested that perhaps the proposed recommendation to study health equity as it relates to telehealth service provision should be elevated to the first bullet.

CHAC Action

Mr. Riester made a motion to approve the proposed Telehealth/Telemedicine letter, with the suggestion of moving health equity to the top bullet in terms of prioritization. Dr. Markham seconded the motion. CHAC approved the letter with 8 affirmative votes and 2 abstentions.

Public Comment Period

Mark Misrok

Executive Director

National Working Positive Coalition

I am Mark Misrok. I'm Executive Director of the National Working Positive Coalition (NWPC), which works to strengthen responses to the long-ignored employment needs of people living with or at greater vulnerability to HIV. I'm a person living and aging with HIV and a member of the Steering Committee for the US People Living with HIV Caucus (US PLHIV Caucus). Last Summer, the CDC released their most recent data report from their ongoing collection of surveillance data of people living with HIV in the US from their MMP, or Medical Monitoring Project, surveillance data. This latest data report is for 2019, the last full year before the impacts of the COVID-19 pandemic in this country. This most recent data report presented 41% of people living with HIV as unemployed prior to the impact on employment and the job market of the pandemic. This extraordinary high unemployment rate among people living with HIV in this era of care and treatment reflects the profound lack of access to employment-related

⁴³ <https://www.cdc.gov/hiv/effective-interventions/library/telehealth/implementation-materials/cdc-hiv-ei-telehealth-practitioners-guide.pdf>

information, services, and resources within HIV supportive services that has continued unchanged across all areas of the epidemic. We know that communities most vulnerable to HIV and most impacted by COVID and a host of health crises are always also communities with long histories of unequal access to quality education and to employment and economic opportunities. Meanwhile, the HIV/AIDS Bureau has kept directives in place since the 90s that ban use of supportive services dollars by Ryan White HIV/AIDS program grantees to provide employment or job readiness services, suppressing growth of responses to the employment needs of people living with HIV, that could grow organically and community-based programs most trusted and often most committed to communities not prioritized in mainstream workforce development or vocational rehabilitation initiatives. It is time that our leaders, and advisory bodies, and government agencies shaping the US HIV response end the cruel abdication from understanding and addressing the employment-related needs of people living with or at greater vulnerability to HIV that has been our long-sustained pattern. Thank you.

Amy Killelea

Killelea Consulting (PrEP for all)

Hi everyone. My name is Amy Killelea. I am a consultant and for the purposes of what I'm going to talk about today, I've been working with Johns Hopkins University over the past about 12 months working on a proposal for a national PrEP program. Thank you for the opportunity to speak to you all today. I want to highlight that we have got an opportunity presented to us in the President's Budget for FY23, which was released a few weeks ago. It includes an incredible opportunity to expand access to PrEP in this country and includes a call for Congress to enact a new \$9.8 billion 10-year national PrEP program for the uninsured and underinsured, coupled with significant reforms to ensure that people on Medicaid who need PrEP can easily access it. I want to focus my remarks on both the opportunity before us with the new momentum from the Administration as well as what I think is a growing and should be a growing sense of urgency around PrEP. PrEP uptake, as I am sure this body has discussed in meetings prior, continues to be very low in the US, with only about a quarter of folks who could benefit from PrEP actually taking it and growing disparities among Black, Hispanic, and Latino communities in particular. I think it is becoming more and more apparent that we will not end the HIV epidemic without a drastically different approach to PrEP. A few things to really highlight in terms of the systems failures when it comes to PrEP. One is that we have a system for PrEP access, particularly for those who are uninsured and even those on Medicaid that is fragmented, that is confusing, and that is incomplete. For those who are uninsured, the medication is often available through a different program and mechanism than the lab services, which may also be separate from the ancillary services for PrEP. We also have put our thumb on the scale of a largely clinical approach to PrEP heavily dependent on primary care, on community health centers, and 340b entities who are big and savvy enough to navigate the complexities of PrEP financing. And let me be clear, because we heard from the previous presentation about community health centers and telehealth clinical entities are necessary for PrEP access, but they are nowhere near sufficient. And so the opportunity before us, I think, is to re-envision what a national PrEP program and functioning system for PrEP access could look like. What was submitted in the public comment was a sign-on letter from over 20 national, state, and regional organizations that really outlined a set of principles that provide a foundation for a national PrEP program, so I want to highlight just a few of those. First is that the program has to prioritize equity, has to invest in mechanisms that increase access to Black and Brown communities, trans folks, cisgender women, folks in the South, and others who are currently failed by our current PrEP delivery systems. The program has got to be simple and it has got to be accessible and include medication, labs, and the ancillary services needed to support PrEP access. I think the accessibility part means that it has to be available through a greater range of community-based access points outside of just clinical delivery sites and community health centers. By expanding

those touch points, the goal is also to increase PrEP demand in communities who are not well-served by, and not touching frankly, traditional healthcare delivery sites. Finally, a PrEP program has to be sustainable and it has to be based on evidence. We have got a generic form of Truvada, TDF/FTC, that is safe. It is highly effective. It is incredibly cheap. It is clinically appropriate for the vast majority of folks. But we aren't maximizing that potential to open the floodgates for PrEP, largely because we have a current system that incentivizes brand name drugs at every turn. We are also going to fail to maximize some of the newer forms of PrEP like long-acting cabotegravir if we don't insure that that drug and the drugs that are coming down the pipeline are available at fair public health prices and through a much broader network of public health providers. I will close with just saying that this is an opportunity and it's a challenge. We have a tough political environment to get this ambitious proposal through Congress, but I hope that through the CHAC and the folks on this call today that we can harness the momentum that we have with the President's Budget and build a better system for PrEP access. Thank you.

Chris Jowett

Chief Commercial Officer
Visby Medical

Good afternoon. Thank you for the opportunity to summarize our recommendations committee. I'm Christopher Jowett and I represent Visby Medical. I am the Chief Commercial Officer with Visby Medical based out of San Jose, California. Accurate STI point-of-care tests can revolutionize patient care. The "CDC's 2021 STD Treatment Guidelines" recommend nucleic acid amplification testing (NAAT) for the detection of chlamydia and gonorrhea and specifically call out chlamydia and gonorrhea in symptomatic women. In the "STI National Strategic Plan," there is a recurring theme requesting innovative solutions and approaches to address the ongoing and emerging challenges in STI prevention and control. Specifically, it calls out the need to develop point-of-care diagnostic tools. Visby Medical has developed such a tool which delivers PCR results in less than 30 minutes in the palm of your hand and received FDA clearance and CLIA waiver in August 2021. Visby Medical developed this rapid point-of-care platform with substantial support from the NIH and yet there remains significant hurdles to deliver these tests equitably nationwide. The CDC and other government agencies can help in the following ways. Support implementation science studies to assess clinical adoption in various settings. Implement policies and funding to provide equitable access to technologies that can improve patient health. Understand the true prevalence of trichomonas, a silent epidemic and not yet reportable. Support reimbursement incentives to promote breakthrough innovations. Breakthrough technologies come at a cost. Extraordinary pressure to reduce testing costs comes at the expense of patient care. Rather than reimbursement based on reagent and operational costs, CMS should consider the value that rapid and accurate point-of-care diagnostics provide to the patient and to public health. Visby has engineered out the need for highly trained lab personnel to interpret and operate the results. This and enabling specific targeted treatment based on PCR diagnostic results at the point-of-care is better for the patient, reduces the risk of antibiotic resistance, lowers operational costs, and reduces spending over the long-term by preventing more expensive sequelae, like pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. As the CDC is focused on advancing health equity and insuring access to diagnostic innovations, the Visby medical sexual health test is designed to support that goal and can fundamentally transform patient care and the public health. This point-of-care test platform is patient-centered and convenient, which in-turn can address access and equity concerns across the country. We asked the committee to focus on the value of point-of-care diagnostic testing and consider how to incentivize its use to address the STI epidemic. We are eager to serve as a resource for you at the CDC, HRSA, and HHS to reduce and prevent STIs moving forward. We look forward to continued opportunities for collaboration

with the Visby medical sexual health preventive care product and our future direct-to-consumer STI product offering. Thank you.

Jules Levin

Executive Director/Founder
National AIDS Treatment Advocacy Project

Hi, everybody. This is Jules Levin. I'm the Executive Director and Founder of the National AIDS Treatment Advocacy Project (NATO). I come to you as a person today living with HIV for 40 years. I'm now 72. I've been an advocate for 25 years. I am HIV aging and am now what I call "elderly." I think the CDC, Jonathan, calls people over 65—that's the category "elderly." Over 50 is "aging." I also come to you as a person cured of hepatitis C 21 years ago with pegylated interferon and ribavirin. I'm going to discuss 2 things today, hepatitis C and aging and HIV in 3.5 minutes. Number one, hepatitis C. I think it's disgraceful that here in the United States where we have had a cure for a number of years for hepatitis C, where you can cure hepatitis C in an inexpensive, safe manner with 8 or 12 weeks of therapy that we don't have a national hepatitis C elimination program. It's beyond talk. It's beyond speech. The discussion over the past 2 days around hepatitis C at this CHAC meeting has not been fully comprehensive. The needs for people living with hepatitis C have not been adequately discussed or addressed. Curing hepatitis C requires, in my opinion, a program, a Ryan White Care Act type program, that can be done in 5 or 6 years of limited time or \$5 or \$6 billion dollars, which is in the full scheme of things nothing. A drop in the bucket for the federal government. We need full funding for screening. We need to use electronic health records. We already have new models of care that provide support services for IDUs that could be utilized. The CDC is not working. They are not doing their duty. They are not providing and meeting the needs of this community and what is needed. The CDC is not working with local departments of health, many of whom already have elimination plans. We need funding and the CDC does not seem to be working with the local and state DOHs to develop and push these programs forward and help support them further. They're not providing resources and collaborations. Yesterday, somebody said DAAs are expensive. Are you kidding? They're \$15,000 for a course of treatment. To treat someone like me with HIV for 20 years is \$400,000. Syringe exchange programs and needle exchange programs is only one issue in the full framework that needs to be addressed to eliminate hepatitis C. Aging and HIV. The response has been completely inadequate. It's also a disgrace that this CHAC meeting at CHAC meetings have not had a panel on aging and HIV. We are experiencing more comorbidities than people without HIV. We have reduced life expectancy. We're getting bad care. The 20-minute visit does not work. African Americans get the worst care. Suffice it to say and in summary, it's just really unfortunate and a disgrace that aging and HIV is not adequately addressed and is not part of the discussion in almost every circle that participates in that is a discussion amongst the leaders at the NIH, CDC, many circles around leadership and HIV, our federal government, and state governments as well. Thank you.

Lorren Sandt

Executive Director
Caring Ambassadors Program, Inc.

My name is Lorren Sandt. I am the Executive Director of the Caring Ambassadors Program in Portland, Oregon. We do education and advocacy for people living with hepatitis C and lung cancer since 1997. Dr. Mermin opened the meeting discussing the Center's equity initiative strategy to achieve equity and eliminate health disparities, and the need to address some syndemics. You said you wanted to become as holistic as possible and asked what you could do better. Well, with all due respect, funding holistically, break it down, break down the silos, include reimbursement silos across all agencies. If these funding silos are not broken down,

hepatitis and STIs, health disparities, and health equity will never come to fruition in our country. The \$40 million in funding is frankly something everyone at CDC should be ashamed of. One program highlighted yesterday gave 36 community-based organizations \$400,000 dollars in funding to address one part of HIV. The average funding each state receives in hepatitis funding is \$315,000 dollars. The last professional judgment from the CDC and 2016 called for closer to \$400 million in funding each year for 10 years. This is a finite number so we can reach our elimination goals. We have an elimination plan like HIV, but we have no implementation plan and we have no funding. In Oregon, we have 7600 people living with HIV. We have dozens of case managers and a room full of epidemiologists. We have 90,000 people living with hepatitis C, 1 case manager at 1 HIV organization, and 1 state epidemiologist that we just got after 15 years of no epi. Funding must be commensurate with the impact of the disease. Almost every presentation we've seen, and they've been great, has been a call to break down silos so programs can meet people where they are. We are missing too many opportunities to help people when they reach out for care to help them. There is a cost-savings when people are tested and treated for the disease they present with rather than sending them down the road to test for something else or go somewhere else for care. Every time someone is denied, we are telling them they are not worthy. Hepatitis care and treatment is cost-saving to our health system. I respectfully ask every member of CHAC to be bold. Consider asking the Administration and Congress for an expansion of Ryan White programs to fully integrate hepatitis care and treatment and STI care and treatment, and the CDC to fully integrate the Center with your programs and your funding. We're done PCSIs. We're done with demonstration projects. We know what works. We need the political will to change the policies that keep these funding and silos and place. Thank you very much. And one final comment. I never heard what the outcome was on the discussion of whether the CHAC should weigh in on the mental health of our children. I firmly believe that it is your duty to weigh in on that. I hope that you guys voted to do that and will be weighing in and helping our children to live fully as they grow. Thank you very much.

Daniel Raymond

Director of Policy

National Viral Hepatitis Roundtable

I'm Daniel Raymond. I'm the Director of Policy for the National Viral Hepatitis Roundtable (NVHR). You heard from my colleague yesterday, Adrienne Simmons, with our colleague from Harvard Law School, Julia Harvey, on the current state of Medicaid access to hepatitis C direct-acting antiviral. I just want to go back to their remarks and note that, John, when you asked for guidance that there was a recommendation that more guidance to state Medicaid programs would be enormously helpful. My colleague Adrienne specifically called out the value in recent years of the HHS Medicaid Affinity Working Group, which the Office of Infectious Disease Policies led, but wrapped up its work last year. That Affinity Working Group was really instrumental in aiding states, not only in removing barriers to coverage, but also serving as a catalyst and incubator for discussing innovative payment and financing models for comprehensive care, including elements like case management and peer patient navigation that can be especially vital for achieving health equity goals, but also for analyzing administrative data to construct care cascades for states' Medicaid beneficiaries. This kind of work has become even more important. As some of you may be familiar, the manufacturers of hepatitis C therapeutics have recently imposed greater restrictions on 340B-covered entities. The need for strategizing about ensuring access and scale-up of care is vital. I would encourage CHAC to consider opportunities for making recommendations to further that work through concerted efforts. And then secondarily, I wanted to note the release last week of the White House Office of National Drug Control Policy's "Drug Control Strategy," which included very strong discussion of harm reduction, including support for syringe services programs and

specifically in their performance measures, committed to increasing the number of counties with elevated overdose rates that had an operational SSP by 85% between a 2020 baseline and 2025. I would suggest that there's an opportunity here for CHAC to make recommendations that CDC and HRSA, as part of broader efforts, provide guidance, technical assistance, and policy development on accelerating SSP implementation. I would call attention particularly to opportunities through federally-funded facilities, including Ryan White-funded providers and clinics, STD clinics, and Federally Qualified Health Centers. As we heard earlier today in terms of, for example, the West Virginia experience with clusters and outbreaks, this work has taken on an increased urgency. With the leadership of the Biden/Harris Administration and the new drug control strategy, there is ample opportunity to dive in and make meaningful progress. Thank you.

Recap Day 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson emphasized that CHAC heard some incredible presentations and some very important topics covered. Reflecting on those and high-level messages, they started the morning with a special presentation from FDA and CDC about self-testing and self-collection of specimens in the diagnosis of HIV, HCV, and STIs. There was broad agreement on the needs and advantages of these tools now more than ever. The technology is available. Many of these are available globally. However, there are some barriers that they learned more about during the day in terms of meeting regulatory requirements. Some of the barriers identified include a possible need for additional validation for some tests, the high cost to seek regulatory approval, perhaps the lack of incentives for manufacturers regarding return-on-investment (ROI) in putting in the time, effort, and funding. The take-home message is that there needs to be concerted outreach, which to some degree already is being done, to key players and key stakeholders. It seems like the first step is to discuss with FDA avenues to reduce cost and consideration of where and when manufacturers can be incentivized to provide these critical tools. In the afternoon, CHAC heard about exemplary programs from New Mexico, North Dakota, and San Francisco. All of them exemplify a syndemic approach. They also heard a presentation on CDC cluster response and interventions. The take-home messages include the fact that in New Mexico, North Dakota, and San Francisco, the local or state policies enabled some of these programs and were able to breakdown silos and address things in a cross-cutting way. The issue of silos has been a recurring theme of this meeting and every CHAC meeting in which Dr. Anderson has been involved. The issue of the importance of meeting people where they are intersects with the discussion on self-testing and self-collection. There is a need to link to care and to pay attention to certain high-risk key populations, including incarcerated individuals and pregnant and post-partum women in terms of congenital syphilis, mental health disorders, and SDOH. There also was mention of some of the workflow issues that brought to mind some of the work that has been done in low- and middle-income countries on task-sharing and task-shifting and how the US could do a much better job of that.

Dr. Gayles indicated that in addition to Dr. Anderson's very thorough and comprehensive summary of the day, he had only a couple of points to add. Everything that Dr. Anderson mentioned was a reminder of the importance that all of this work takes into consideration the whole person and not just one aspect as they continue to think through access to testing, access to healthcare, and the full picture of what people face in terms of being able to access

and fully utilize all of the available resources needed to be successful. Regarding a comment raised during the public commentary about looking into the issue of children's mental health, particularly in the face of different legislative efforts occurring across the country specifically tied to sexual and gender identities, he assured everyone that CHAC is looking into that and would be addressing that as a group during the next day's Business Session. CHAC does believe this is an important issue, does take their role as a committee seriously, and hopefully will be able to utilize this role to raise further awareness to the relevant parties who may have an opportunity to fill some of the gaps or address some of the issues that are secondary to the various efforts underway.

Adjourn

Dr. Mermin thanked everyone for another day of outstanding presentations and discussions. He then officially adjourned the meeting for April 27, 2022 and CHAC stood in recess until 10:00 AM ET on April 28, 2022.

Day 3: Welcome and Roll Call

Jonathan Mermin, MD, MPH (RADM, USPHS)

Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

Dr. Mermin called the proceedings to order at 10:05 AM ET and welcomed participants to the third day of the CHAC meeting. He conducted roll call and asked members to disclose any new COIs. COIs did not differ from the previous day and are reflected in the table on page 8 of this document. He confirmed that 21 members were in attendance, which established quorum for the CHAC to conduct its business on April 28, 2022.

Recap of Days 1 and 2

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles provided some high-level highlights from the previous 2 days. The first day began with updates from colleagues at CDC at HRSA describing the fantastic work that they continue to do, including efforts to better understand the increased presence of mental health concerns among children, the increased work at CDC regarding health equity and infusing equity into all aspects of their work, and the great work underway at HRSA and introductions to new key staff members there. There is a lot of great innovation and it is important that CDC and HRSA continue to lead the way at the federal, state, and local levels. One of the key issues that arose during the morning session regarded the role CHAC might play in terms of commenting on or putting forward recommendations to offset some of the political efforts that are putting the great work at CDC and HRSA have invested in at risk, as well as creating obstacles and challenges for communities in being able to take advantage of the programs and opportunities that result from the work of these agencies. Programs from Mississippi, New York, and Minnesota highlighted innovative strategies they are implementing to increase utilization and access to testing, such as using the school space to increase access to young people and leveraging some of the technologies and strategies that were put in place during the COVID-19 response to modernize the public health infrastructure. These programs underscored the importance of using COVID-19 pandemic innovations as models for securing and sustaining funding to continue to support these efforts and codify that work moving forward in a post-COVID world.

During the second day, CHAC heard presentations highlighting how impactful self-collection kits could be in communities that have historically not utilized traditional brick-and-mortar structures. As a result, the availability of self-collection kits increased testing practices in a number of communities. It is known that when people are tested more frequently, the incidence of new cases is reduced. Self-testing also can be used as an opportunity to connect people to clinical care, social-emotional support, and other services such as those that address SDOH. There were discussions with colleagues from FDA regarding the pipeline and approval process for self-collection kits, given concerns that arose with regard to how FDA views HIV versus HCV self-collection kits. CHAC wondered if/how manufacturers producing self-testing kits could be incentivized to increase production in the variety and availability of self-test kits. There are authentication methods domestically and internationally that could serve as models to increase the self-test kit approval process. CHAC also engaged in discussion related to key topics in syndemic analysis, which continues to underscore the need for all work to take a whole person

approach with respect to the various issues that influence an individual's ability to access resources that are being put forward, utilize them effectively, and have successful health outcomes. Exciting and impressive syndemic approaches were presented, along with limitations many jurisdictions will have in moving those creative ideas forward due to financing challenges, particularly in under-resourced districts that do not have significant financing outside of the federal government. While this may not lend itself to a letter at this point, this topic deserves further discussion and consideration in future CHAC deliberations. The Telehealth WG put forth an excellent letter, which was approved and will be sent out following the meeting. Suggestions were made for potential development of 2 letters, one to the Secretary of Health regarding LGBTQ youth and one to FDA regarding the pipeline and approval process for self-collection kits.

Business Meeting

Adoption of November 2021 CHAC Minutes

Jean Anderson, MD

CHAC Co-Chair, HRSA Appointee

Dr. Anderson indicated that members had been provided with a copy of the November 2021 CHAC minutes for review. No errors or omissions were identified, no questions or concerns were raised, and no edits were suggested.

CHAC Action

Dr. Mehta made a motion to approve the November 2021 CHAC minutes, which Dr. Greene seconded. CHAC members unanimously approved the minutes with no changes or further discussion.

Update from the Presidential Advisory Council on HIV/AIDS (PACHA)

Ada Stewart, RPH, MD, FAAFP, AAHIVS, HMDC

PACHA Liaison Representative for CHAC

Dr. Stewart reported that PACHA last met virtually on March 14-15, 2022 for its 73rd full council meeting where they had an opportunity to bring back "PACHA-to-the-People." When PACHA was re-established in 2019, the goals of the Co-Chairs recognized the importance of reaching out to the people on the ground—the individuals working in, living with, or at risk for HIV and AIDS—to help guide the work of the PACHA. She expressed gratitude to PACHA's current Co-Chairs for allowing "PACHA-to-the-People" and thanked them for a very successful virtual meeting. The first day consisted of a welcome from Dr. Rachel Levine, Assistant Secretary for Health at HHS, and Harold Phillips, Director of the White House Office of National AIDS Policy regarding NHAS and their commitment to EHE. Reports were presented from PACHA's Stigma and Disparities, EHE, and Global Subcommittees and the Stigma and Disparity Subcommittee's WG that prioritizes molecular surveillance and cluster detection issues. PACHA took this on as a priority due to the growing number of responses they have heard from individuals living with HIV and others regarding the application of this response tool, especially in terms of criminalization of HIV and other social justices.

During the PACHA-to-the-People interactive community engagement session, community members provided feedback in breakout sessions focusing on 2 main topics. The first breakout session focused on HIV prevention in the context of EHE. This group focused on prevention of HIV in women and adolescent girls, those 55 years of age and over, persons living with substance use and mental health disorders, the LGBTQ+ community, and PrEP assistance programs. In the NHAS and EHE Initiative breakout, community folks provided input about how the strategy is working in their states, cities, and territories and how PACHA can help. During these community engagement sessions, there were passionate and robust discussions from communities highlighting the need for whole person care; addressing QOL issues; the need to address aging with HIV; the need to address persons with physical and/or mental health issues, and/or SUDs; the importance of elevating U=U and recognizing the needs of all women, cisgender and transgender; ensuring that there is a national comprehensive program to address barriers to prevention and making sure that rural communities are engaged; and the importance of advocacy in terms of funding.

There was an update on the President's Emergency Plan for AIDS Relief (PEPFAR). PACHA's Global Subcommittee has worked diligently to ensure that HIV/AIDS is elevated from a global perspective, making sure that future guidance is sought from global and domestic lessons learned. There was an important panel discussion related to HIV amongst women and adolescent girls and why representation matters in response to HIV in this population. There was an emphasis on the importance of women, especially women of color, being part of clinical trials and addressing the bias that exists in prescribing of PrEP to women. There was a call to action to shift the narrative to ensure that all women living with HIV need to have a seat at the table and that IPV and QOL must be addressed for both cisgender and transgender women.

There was a panel discussion regarding PrEP for the nation and how to get PrEP to everyone who wants and needs it. There was discussion and approval of a draft letter to the HHS Secretary with PACHA's recommendation on scaling up PrEP to the nation. There also was a panel discussion on strengthening the HIV workforce. Dr. Wendy Armstrong and Vincent Guillermo-Ramos presented as part of the panel about how this important goal can be accomplished. They discussed the importance of removing regulatory barriers that place restrictions on practice at the highest level of training and licensure to ensure that the talents of Advanced Practice Nurses (APN), Nurse Practitioners (NPs), and Social Workers can be leveraged to the fullest of their ability to increase the HIV workforce; ensuring that CMS offers reimbursement for decentralized, team-based, whole person, HIV prevention and care services; supporting a shift toward education and training for the future health workforce that emphasizes key competency of team-based, whole person, HIV care; providing training for those not only pursuing full-time HIV work, but also those who are intimately involved in that; having the knowledge to be able to address co-morbidities using training tracks, residency programs, access to experts, et cetera; investing in infrastructure; developing decentralized and differentiated HIV prevention and care such as telehealth and community-based services; and allocating funding toward HIV using specific demonstration projects.

CHAC Member Observations/Suggestions: PACHA Update

The following questions, observations, and suggestions were raised:

- Dr. Guilamo-Ramos noted that this speaks to the issue of meaningful engagement of people living with HIV in the workforce and expanding definitions of the workforce beyond the clinical to think about a range of important actors who could help to end the epidemic in the country.
- Mr. Lindsey pointed out that there is a community health worker apprenticeship program that came out of the broader HRSA environment.
- Dr. Armstrong indicated that HRSA established and put many resources behind a Community Health Worker Training Program (CHWTP). More programs such as this are needed, but do require additional resources for childcare, transportation, and other supports peers will need to take advantage of such opportunities.
- Dr. Driffin emphasized that it is important to be mindful of diversity, equity, and inclusion in the workforce so that there is racial and gender diversity in key health departments along HIV jurisdictions and such that the community sees more people who look like them in key leadership and executive decision-making roles.
- Dr. Gayles said that he was hearing that perhaps it would be beneficial to stand up a CHAC Workforce Development WG. There previously was a CHAC HIV and Aging WG. Perhaps it would be beneficial to hear an update on this WG and the status of its efforts.

Action Item #1: Potential Letter Regarding LGBTQ Children/Youth**Jean Anderson, MD**

CHAC Co-Chair, HRSA Appointee

Dr. Anderson reminded everyone that the work that CHAC does and the advice they can give to CDC and HRSA is somewhat limited between meetings. The reason they chose the 2 action items for this business meeting was because they felt that there was some sense of urgency for these topics and that some bullet points could be created that CHAC could vote on during this meeting, which could then be developed into a letter over the next few weeks. She then reviewed the proposed components for the letter:

- Background:
 - In December 2021, the Surgeon General warned of a “devastating mental health crisis among adolescents.”
 - There was a 60% increase in major depressive disorders from 2007 to 2019 (National Survey of Children’s Health. HRSA October 2020).
 - Suicide rates increased nearly 60% in youth 10-14 years of age from 2007-2018 (National Vital Statistics Reports September 2020).
 - These problems are magnified among LGBTQ youth (CDC Adolescent Behaviors and Experiences Survey (ABES) 2021).
 - More than 60% of LGBTQ students experiencing poor mental health during the pandemic, which is over twice that seen in heterosexual students.

- LGBQ students were more than 3 times as likely to have attempted suicide in the past year.
 - Three-quarters of LGBTQ students experienced emotional abuse at home during the pandemic.
- For youth to thrive in schools and communities, they need to feel socially, emotionally, and physically safe and supported.
- There are ample data showing that LGBTQ students experience more bullying, harassment, and physical assault as compared to heterosexual students (2015 National Youth Risk Behavior Survey).
 - Young gay/bisexual men are at increased risk for HIV infection (**need update**). In 2014, they accounted for 8 of 10 new HIV diagnoses among youth (HIV Surveillance Report 2014).
- LGBTQ-supportive school policies and practices support all youth with decreases in depressive symptoms, decreases in suicidal thoughts and behaviors, and decreases in suicide attempts—especially among LGBTQ students (National YRBS 2015 & 2017; CDC School Health Profiles 2014 & 2016).
- From 2015-2019, over 200 pieces of anti-LGBTQ legislation were proposed in 35 states. In 2022 alone, over 300 bills have been introduced in state legislatures, often focusing on restricting school curricula, access to books or other educational materials relating to gender identification/gender-affirming care, or sexual orientation (<https://childtrends.org/publications/anti-lgbtq-policy-proposals-can-harm-youth-mental-health>; NYT 4/27/22)
- Implications/Concerns:
 - These legislative efforts send a clear message to LGBTQ youth that they are not okay.
 - Legislative efforts at the state level likely will create significant gaps in access to health care and social support services critical to these youth, including mental health services.
 - These legislative actions also can cause significant anxiety and depression that can further impact adherence to and engagement in medical care.
 - These legislative efforts will put HRSA and CDC efforts (demonstration projects, funding mechanisms) at risk and will impair successful delivery of services.
 - These gaps in care introduce spaces for the federal government to step in and provide a connection to support services that fill that void.
 - Recommendations:
 - Develop and disseminate resources at the federal level for youth and their families, as well as teachers and school counselors, to try to mitigate the potential harmful effects of any LGBTQ legislation.
 - Develop and disseminate resources at the federal level targeted to healthcare providers to better educate them about LGBTQ health and mental health and risk reducing strategies, and to provide information about assistance when problems are identified.
 - Develop public service messages (PSAs) and social and other media to educate the public about these harms and the need to reduce/prevent stigma and discrimination for these vulnerable youth.
 - PSAs also should be developed to target social media and other electronic platforms most utilized by youth, including LGBTQ youth, to provide information and resources.

CHAC Member Observations/Suggestions: LGBTQ Letter

The following questions, observations, and suggestions were raised:

- Consider forming a CHAC WG around these issues.
- Be explicit about promoting ways to encourage healthy sexual behaviors.
- Be specific about risk reduction strategies for at-risk adolescents, such as availability and provision of PrEP.
- Recognize the importance of school counselors at the state and county levels, and support school connectedness in general.
- Thinking particularly about youth who are in the foster care system, target information to social service providers outside of the schools.
- Discuss the potential need for housing assistance, which often goes unnoticed as part of their lived experience.
- Discuss the lack of gender-affirming care and the lack of provision of services/information that involves gender identity, and be more explicit about the mental health challenges that entails. There are efforts to prohibit conversations about sexual or gender identity, some of which is legislative and is actively seeking to bring child abuse charges against anyone who provides gender-affirming services and/or information.
- Perhaps there should be something about starting earlier than the education system. For instance, Oklahoma wants to ban any markers of non-binary gender identities on birth certificates. This seems to be going even further in an effort to erase identities that have been long and hard fought for.
- Highlight the importance of safe spaces, including safe spaces in which families can receive high quality and accurate information. For youth who already feel isolated or for whom the online space or social media is exacerbating their mental health issues, perhaps there could be some opportunities for in-person convening or collective healing through safe spaces or similar avenues. Parental consent was raised during the presentations. Sometimes, parents may be the bullies. Youth need to have safe places where they can speak freely about bullying from one or both parents, as well as school and/or social bullying that is occurring.
- Willful disinformation campaigns should be mentioned in the background section.
- Discuss funding.
- Perhaps there could be a leading bullet point before getting specifically into LGBTQ youth to recommend enhanced effort across the board to increase access to mental health services for all children, particularly around connectedness, coping mechanisms, access to therapy in a timely manner that addresses their mental health needs. That could be the big take home since all youth are currently behind the metaphorical 8 ball. Then it could go on to say, because of everything Dr. Anderson laid out, there needs to be special attention to

LGBTQ youth given particular legislative efforts and include the data showing the implications and connections within all of that.

- Dr. Cheever noted that the topic pertains to LGBTQ issues. If the letter and recommendations are made more general, this topic could be swept into a more general set of discussions around mental health for children. While this is critical as well, it would not focus specifically on the needs of trans and LGBTQ youth who are in places where there have been specific political movements to make it more complicated for them.
- Dr. Mermin added that there are data that support the idea that not only is there a disproportionate effect on mental health among LGBTQ youth, but also there is a fairly large proportion of youth who identify as LGBTQ and, therefore, this has public health importance in this political and social environment that CHAC has been discussing. It is possible to make a difference and it seems like a very important issue, particularly because for STDs (though maybe less) and HIV, there is a highly disproportionate rate among gay and bisexual youth, males particularly. This is a strong rationale for the focus. Based on the discussions, it is very hard for parents, youth, and teachers to obtain information about how to deal with this. The idea for the first bullet to focus on dissemination and access to credible resources is the next generation. CDC/HRSA and other partner organizations have a responsibility to get information out that can be useful and there is also the legal/policy level.

CHAC Action

Dr. Anderson made a motion to approve the letter for LGBTQ youth, which will be developed and circulated for review by CHAC before sending it out, including the 4 original recommendations presented and the addition of the following 4 recommendations:

- Increase efforts across the board to develop and disseminate information and resources for youth and their families, as well as teachers/school counselors addressing the mental health crisis in adolescents.
- Develop and disseminate messages about healthy sexual behaviors and resources to improve access to PrEP and other preventive services to at-risk youth.
- Encourage development of safe spaces for youth in general and LGBTQ youth specifically to access accurate information and support.
- Ensure that resources for LGBTQ youth are available to address disparities in care related to social determinants of care (including homelessness, domestic violence, and racial/ethnic discrimination).

Dr. Dowler seconded the motion. CHAC unanimously approved the LGBTQ letter.

Action Item #2: Letter on Self-Collection and Self-Testing

Travis Gayles, MD, PhD

CHAC Co-Chair, CDC Appointee

Dr. Gayles noted that while this proposed letter to the FDA was not fully fleshed out, the CHAC discussions prompted them to put this forward, recognizing that data will need to be identified in order to further shape the letter before it is ready to move forward. Some of the highlighted

points discussed as key areas of concern pertaining to self-collection testing included the following:

- There is a differentiation in how HCV and HIV are viewed, particularly around the impact of results.
- Criteria required for the authentication process domestically versus internationally. One of the major issues was that there are similar tests that are utilized internationally that are not accessible in the US.
- There is a need for incentives and an increased sense of urgency to foster and facilitate a production pipeline. This may involve proactive outreach to manufacturers to encourage them to seek approval for tests, beginning with a discussion with FDA to explore how to decrease the costs associated with premarket approval (PMA). As raised the day before, the cost is just shy of \$400,000 for that process. Consideration needs to be given to how to remove barriers, as well as the existing data related to the impact of self-collection in terms of increased testing in certain groups. It is important to figure out ways to increase the pipeline and help foster a smoother process to move things forward in order to increase access to these testing modalities for certain groups.

CHAC Member Observations/Suggestions: FDA Letter on Self-Collection Testing

The following questions, observations, and suggestions were raised:

- This seems like a critical place for CHAC to focus its efforts to intervene.
- It is important to remember that payers cannot pay for self-collection tests without CPT HCPCS codes for home tests. This was done for COVID-19, which opened the door for other tests. Perhaps someone could reach out to the AMA to discuss this.
- There are some incentives already. Companies would like to market their products and have them widely used, which is why they develop them. Some companies have said the barrier is too high at the FDA level to get approval. FDA spoke about the risk-benefit comparison, but that does not align with the true risks and the true benefits of home testing. A high-level conversation is needed with FDA to come to an agreement that everyone needs to work together to make self-collection kits available to the people who need them. Regulatory barriers were put in place 10 or 20 years ago and need to be revisited.
- There are larger issues to consider when tests are brought to market pertaining to affordability, awareness of availability among communities who need the tests, linking people to services, payer issues, et cetera. With that in mind, perhaps CHAC should consider standing up a Self-Collecting Testing WG to further explore the issues.
- Dr. Mermin asked CHAC to consider whether a very specific, short-targeted, single-pointed letter could be more effective than one that tries to redress all of the comprehensive issues related to testing, which may be better suited for ongoing discussions. The first and part of the third bullets contain the major points. Based on the CHAC discussions throughout the meeting, FDA is aware that the marketing in Europe is different than in the US. While articles have been written about Europe's more efficient process, it is not going to change the US approach to approval processes. While it has been explicitly stated that HIV is exceptional in that it is much more dangerous for someone to have a false negative HIV test than it is to have a false negative hepatitis C test, there are theoretical arguments

against that view. Many years of HIV self-testing are already in place, so the rationale is unclear about the danger. High-quality thoughtful letters are more effective than ones that have not been thought out as well.

- Dr. Akolkar, FDA, clarified that the user fee is not determined by FDA. It is legislatively determined by the Congress. There are also regulations FDA has to abide by, even though they may want to do something for both HIV and HCV. HCV approval was basically done on the basis of persons with signs and symptoms, which is different than for HIV. It is not just a simple equation that HIV and HCV are the same—there are historical nuances. FDA has learned a lot from the self-test experience for HIV and is working with the sponsor, but it is important to remember that the sponsor must approach FDA before a process can begin. They are open to have preliminary discussions with sponsors who believe they have something of value and some data to support that.
- There was CHAC support for the idea of crafting a pointed letter that addresses and engages on the first bullet point specifically, plus/minus some language around asking for the deeper conversation to revisit the processes and how they can be updated to match current thinking versus the thinking of 20 some years ago when self-collection reviews were beginning.
- Some CHAC members wondered if perhaps they were rushing this and that it might be better to establish a WG rather than trying to litigate everything during this meeting. It was noted that an alternative to a WG would be to convene an interim business meeting, which would allow time to assemble the facts and develop a draft letter. Establishing a WG could prolong the process.
- Dr. Gayles recapped that they were hearing that there is still much to be clarified in terms of what would best fit into such a letter, which would take more time to flesh out into more detail. There are 2 mechanisms for moving forward that could work, which are to: 1) convene an interim business meeting that probably could not be scheduled until September; or 2) create a WG to study the key points, with specific tasks of differentiating the bullet points, determining whether the letter to FDA should focus on one point or be more general, and then reporting back to the full CHAC during its November meeting. Given the timeframe, the reality seemed that creating a WG would offer more time to further explore the issues and develop action items.

CHAC Action

Dr. Gayles made a motion to create a Self-Testing and Self-Collection WG to study this issue with the specific task of obtaining more information on: 1) differences in risk classification of HCV and HIV; 2) criteria required and data available for the FDA approval process; and 3) downregulation to Class II diagnostics. The WG will then propose messaging that should go into the letter related to self-collection, including the development of a set of recommendations to be presented during the November 2022 CHAC meeting. Dr. Dowler seconded the motion. CHAC unanimously approved the motion to create a Self-Testing and Self-Collection WG.

Action Item #3: Stand Up a Workforce Development WG

Dr. Anderson reminded everyone that a suggestion was made during the meeting to consider standing up a Workforce Development WG with several specific tasks.

CHAC Action

Dr. Gayles made a motion to create a Workforce Development WG to study this issue with the specific tasks of: 1) formulating a potential panel for the November CHAC meeting in order to have a larger discussion on this topic; 2) liaising with PACHA to ensure that CHAC is not duplicating and is supportive of their efforts that are already ongoing in this space; and 3) exploring the role of other health-related professionals and CHWs to enlarge the workforce and to task-share when appropriate. Dr. Guilamo-Ramos seconded the motion. CHAC unanimously approved the motion to create a Workforce Development WG.

Next Meeting / Proposed Agenda Items

The next CHAC meeting is scheduled for November 1-3, 2022. The following future agenda items were proposed:

- Gender-affirming care, coverage, and outcomes
- Barriers to providing PrEP for uninsured and under-insured individuals
- Lessons that can be learned from the global setting (e.g., task-sharing to enhance the workforce, availability of self-testing and self-collection of specimens, et cetera)
- Issues specific to pregnancy (e.g., perinatal transmission of HIV, HCV, HBV, and congenital syphilis; underuse of PrEP in at-risk pregnant women; mental health; intimate partner violence; breast and chest feeding; et cetera)
- The effects of COVID-19 in a variety of areas (e.g., healthcare overall, HIV, persons ≥50 years of age, disparities, and comorbidities post-COVID, et cetera)

Recap and Closing

Dr. Gayles expressed his personal gratitude to everyone for their thoughtful input, continued and consistent engagement across 3 days of Zoom meetings, and great input and work. He recognized that the work they all do on regular basis contributes to their expertise and membership on CHAC. He thanked Dr. Anderson for keeping the meeting moving along and for being the epitome of comprehensiveness and thoroughness.

Dr. Anderson echoed that this had been a tremendous meeting in terms of the topics covered, the work done, and the exciting future topics identified. She complimented Dr. Gayles on his amazing abilities not only to summarize, but also to draw out all of the implications. She also expressed gratitude to their CDC and HRSA support.

Adjournment

Dr. Cheever thanked everyone, recognizing that very good panels had been assembled with excellent presenters who brought forward important information. Secondly, she recognized the CHAC members for their ability to listen carefully and reflect on the information presented and engage amazing discussions. She expressed her gratitude for Drs. Gayle and Anderson for their leadership as Co-Chairs and their wonderful abilities to synthesize the information and discussions.

Dr. Mermin expressed his gratitude, emphasizing that he had learned a great deal. At its best, an advisory committee provides useful advice that can help influence the thought process on various topics. CHAC's did exactly that over the past 2.5 days with their thoughtful input, which raised important issues for CDC and HRSA to think about as they consider many issues of importance. He recognized that it is time-consuming and that everyone is very busy. Especially in the time of COVID-19 when site visits have been reduced, it is very difficult to understand what is occurring. It is great to have input from people who are thinking about the issues and want to make a positive difference in these areas of diseases that are of great public health importance and that experience a lot of inequity. He thanked everyone for their time and effort and emphasized that he was looking forward to the November 2022 CHAC meeting.

Certification

I hereby certify that, to the best of my knowledge, the foregoing minutes of the proceedings are accurate and complete.

Travis Gayles, MD, PhD
CHAC Co-Chair, CDC Appointee

Date

Jean R. Anderson, MD, Co-Chair
CHAC Co-Chair, HRSA Appointee,

Date

Attachment A: Participant List

CHAC Members Present

Dr. Jean Anderson (Chair)
Dr. Travis Gayles (Chair)
Dr. Wendy Armstrong
Dr. Jodie Dionne-Odem
Dr. Shannon Dowler
Mr. Daniel Driffin
Dr. Meredith Greene
Dr. Vincent Guilamo-Ramos
Mr. Kali Lindsey
Dr. Christine Markham
Dr. Shruti Mehta
Dr. Johanne Morne
Ms. Kneeshe Parkinson
Mr. Robert Riester
Mr. Leandro Rodriguez
Dr. Samuel So

CHAC Members Absent

Mr. Venton Hill-Jones
Ms. Gloria Searson

CHAC Ex-Officio Members Present

Dr. Pradip N. Akolkar
US Food and Drug Administration

Dr. Maureen Goodenow
National Institutes of Health

Dr. Neerja Gandotra
Substance Abuse and Mental Health
Services Administration

Mr. Richard Haverkate
Indian Health Service

Ms. Kaye Hayes
Office of Infectious Disease and
HIV/AIDS Policy
US Department of Health and Human
Services

Dr. Richard Wild
Centers for Medicare and Medicaid
Services

CHAC Ex-Officio Members Absent

Dr. Iris Mabry-Hernandez
Agency for Healthcare Research and Quality

CHAC Liaison Representatives Present

Dr. Ada Steward
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
Health Resources & Services Administration
HIV/AIDS Bureau Associate Administrator

Dr. Jonathan Mermin
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD
and TB Prevention Director

Attachment B: List of Acronyms

AAA	Area Agency on Aging
ABES	Adolescent Behaviors and Experiences Survey
ACA	Affordable Care Act
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living
ADAP	AIDS Drug Assistance Program
AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ANTHC	Alaska Native Tribal Health Consortium
APN	Advanced Practice Nurses
ART	Antiretroviral Therapy
ARV	Antiretroviral
BPHC	Bureau of Public Health Clinics
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBER	Center for Biologics Evaluation and Research
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CDRH	Center for Devices and Radiological Health
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHOW	Community Health Outreach Worker
CHW	Community Health Workers
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute
CMO	Committee Management Office
CMS	Centers for Medicare & Medicaid Services
COI	Conflicts of Interest
CPT	Common Procedural Terminology
CRUSH	Community, Restoring, Urban Youth, Sexual, Health
CVD	Cardiovascular Disease
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DBS	Dried Blood Spot
DC	District of Columbia
DDID	Deputy Director for Infectious Diseases
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DHP	Division of HIV Prevention
DIS	Disease Intervention Specialists

DOCR	Department of Corrections and Rehabilitation
DSTDP	Division of STD Prevention
DTC	Direct-to-Consumer Test
DVH	Division of Viral Hepatitis
EHE	Ending the HIV Epidemic
EIS	Epidemic Intelligence Service
ELEVATE	Engage Leadership through Employment, Validation, and Advancing Transformation & Equity
EMR	Electronic Medical Record
EMR	Electronic Medical Record
EOB	Explanation of Benefits
EPT	Expedited Partner Therapy
ET	Eastern Time
FACA	Federal Advisory Committee Act
FD&C Act	Food, Drug & Cosmetic Act
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Center
GS	General Schedule
HAB	HIV/AIDS Bureau
HCP	Health Care Provider/Practitioner
HCPCS	Healthcare Common Procedure Coding System
HCV	Hepatitis C Virus
HHS	(United States Department of) Health and Human Services
HIV	Human Immunodeficiency Virus
HIVST	HIV Self-Tests
HOPWA	Housing Opportunities for People with AIDS
HPV	Human Papillomavirus
HR	Human Resources
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
IHS	Indian Health Service
IPV	Intimate Partner Violence
ITCA	Inter Tribal Council of Arizona, Inc.
IVD	In Vitro Diagnostic Devices
LARC	Long-Acting Reversible Contraception
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Questioning
MCH	Maternal and Child Health
MCO	Managed Care Organization
MFPP	Minnesota Family Planning Program
MIEP	Medicaid Inmate Exclusion Policy
MMP	Medical Monitoring Project
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MOUD	Medicated Opioid Use Disorder
MSM	Men Who Have Sex With Men

MSW	Men Who Have Sex With Women
NAAT	Nucleic Acid Amplification Testing
NAAT	Nucleic Acid Amplification Test
NACCHO	National Association of County and City Health Officials
NACCHO	National Association of County and City Health Officials
NASTAD	National Alliance of State and Territorial AIDS Directors
NATO	National AIDS Treatment Advocacy Project
NCHHSTP	National Center for HIV, Viral Hepatitis, STD and TB Prevention
NCIPC	National Center for Injury Prevention and Control
NDDOH	North Dakota Department of Health
NHAS	National HIV/AIDS Strategy
NHBS	National HIV Behavioral Surveillance
NHRC	National Harm Reduction Coalition
NHRTAC	National Harm Reduction Technical Assistance Center
NIH	National Institutes of Health
NMCD	New Mexico Corrections Department
NMMIP	Mexico Medical Insurance Pool
NOFO	Notice of Funding Opportunity
NP	Nurse Practitioner
NRWC	National Ryan White Conference
NVHR	National Viral Hepatitis Roundtable
NWPC	National Working Positive Coalition
NYC	New York City
NYC Health	NYC Department of Health and Mental Hygiene
OAA	Older Americans Act
OIDP	HHS Office of HIV/AIDS and Infections Disease Policy
OMB	Office of Management and Budget
OMB	Office of Management and Budget
ONAP	Office of National AIDS Policy
ONAP	Office of National AIDS Policy
OTC	Over-The-Counter
ODU	Opioid Use Disorder
PACHA	Presidential Advisory Council on HIV/AIDS
PACHA	Presidential Advisory Council on HIV/AIDS
PCSI	Program Coordination and Service Integration
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PMA	Premarket Approval
PN	Peer Navigators
POC	Point-of-Care
PrEP	Pre-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
PWID	People Who Inject Drugs

QOL	Quality of Life
RCT	Randomized Controlled Trial
RNA	Ribonucleic Acid
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SB	Senate Bill
SDOH	Social Determinants of Health
SFUSD	San Francisco Unified School District
SHCs	Sexual Health Clinics
SNS	Social Network Strategies
SPPS	St. Paul Public Schools
SPTHB	Southern Plains Tribal Health Board
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
SUD	Substance Use Disorder
SVR	Sustained Virologic Response
TA	Technical Assistance
TAP	Technical Assistance
TB	Tuberculosis
US	United States
US PLHIV Caucus	US People Living with HIV Caucus
USPSTF	United States Preventive Services Task Force
VH	Viral Hepatitis
WG	Working Group
WGS	Whole Genome Sequencing
WHO	World Health Organization
WIC	Women, Infants, and Children
YAB	Youth Advisory Board
YRBS	Youth Risk Behavior Survey

Attachment C: Public Comment Letters

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April 18, 2022

CDC/HRSA Advisory Committee on HIV, Viral
Hepatitis and STD Prevention and Treatment
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop US8-6
Atlanta, GA 30329-4027

Submitted by email to nchhstppolicy@cdc.gov

Subject: Spring CHAC Public Comment Registration

Dear Advisory Committee Members:

Thank you for the opportunity to submit written comments to the upcoming meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). Founded in 2015, Everly Health is an Austin, TX based company offering modern, diagnostics-driven care. Our goal is to meet the consumer where they are by leveraging our national clinical network composed of hundreds of physicians, nurses, genetic counselors, pharmacists, and member care specialists along with our digital platform and fully-owned CLIA certified, CAP accredited laboratories. We provide services both directly to the consumer through Everlywell as well as complete solutions for diagnostics-driven virtual care at scale to health plans and enterprises through Everly Health Solutions.

Everly Health is an industry leader in facilitating telehealth and at-home services for laboratory testing. In total, we offer over 2500 tests with our partner laboratories in addition to the thirty tests across six key categories within our own diagnostic laboratories. Our demonstrated success in at-home collection and testing enabled us to mobilize quickly and early in the pandemic to provide nationwide access to testing for COVID-19. We were the second company to receive emergency use authorization (EUA) from the Food and Drug Administration for our at-home collection kit and since March 2020, we have provided clinical oversight, care coordination, and physician services for tens of millions of tests for COVID-19. Everly Health Solutions' 50 state provider network can facilitate test ordering, follow up with patients who test positive, and offer assistance with accessing treatment.

Just released this month, the Centers for Disease Control (CDC) preliminary report on 2021 surveillance of sexually transmitted diseases (STDs) shows that rates of syphilis continue to increase, with a 34% increase among women.¹ The agency also reported that the pandemic led to underreporting of infections and increased transmission in 2020 due to reduced screening as healthcare clinics either closed or restricted in-person visits to limit spread of COVID-19.² Additionally, public health departments are already facing limited resources needed to move

¹ <https://www.cdc.gov/std/statistics/2020/preliminary2021.htm>

² <https://www.cdc.gov/std/statistics/2020/impact.htm>

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personnel from STD prevention and control efforts to the pandemic.³ Recognizing this shift in access to STD prevention, in its 2021 update to its Sexually Transmitted Infections Treatment Guidelines, the CDC identified an opportunity to build upon the lessons learned from the response to COVID-19 including the use of at-home collection for STDs.⁴ The pandemic clearly illustrated the critical role at-home testing plays in responding to and controlling infectious disease outbreaks and for these reasons, we were very pleased to see that the agenda for the upcoming CHACHSPT meeting included a focus on self-testing and self-sample collection for STDs.

We currently offer a direct-to-consumer testing channel for men and women to self-sample within the comfort of their own home to test for chlamydia, gonorrhea, hepatitis C, HIV, syphilis, trichomoniasis and herpes simplex virus type 2. For those who test positive, we provide access to providers who can initiate access to appropriate treatment. We have found that patients prefer privacy when testing for sensitive conditions and the seamless access to treatment to quickly resolve their infection and symptoms. In 2021, we had 77,800 sexual health kits ordered and registered to 47,400 unique users. Of those, 6202 tested positive for one or more STD, and 8,604 consults were scheduled. We have surveyed our customers about their at-home testing experience and they consistently report high levels of satisfaction.

We hope that our experience in providing access to laboratory testing directly to consumers will help inform future policy recommendations that support self-testing and self-sample collection for testing for STDs. Our own experience has proven that the sampling technology and digital platforms exist to successfully enable at-home collection and testing for STDs. Not only will it remove major barriers to access, including during public health emergencies, but our data show that people prefer and desire this testing option. Now we just need proactive policy to support the delivery of these critical and innovative prevention and treatment tools directly to those at greatest risk.

Thank you for your consideration of our comments and we hope that you will look to Everly Health as a resource and partner as you consider the role of self-testing and self-sample collection in preventing STDs. Please do not hesitate to contact me at marisa@everlyhealth.com if I may be of further assistance.

Sincerely,

Marisa L. Cruz, MD

Marisa L. Cruz, MD
EVP Regulatory and Clinical Affairs
Everly Health

³ Ibid.

⁴ https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm?s_cid=rr7004a1_w

April 4, 2022

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & Human Services
200 Independence Avenue, S.W. Washington, DC 20201

Dear Secretary Becerra:

We, the undersigned national, local, and state-based health, education, and civil rights organizations, outline our support for a national program to finance and distribute medications that prevent HIV infection, known as pre-exposure prophylaxis, or PrEP. A key goal of a national program is to scale up access to PrEP substantially in order to help end the HIV epidemic. A national PrEP program should be guided by these principles: accessibility, equity, simplicity, affordability, sustainability, and adaptability. We were pleased to see the historic investment in a national PrEP program included in the President's 2023 budget. We believe systems-wide reforms and innovative policies are needed to end the HIV epidemic in the U.S., and we look forward to working with the Administration to help make this ambitious proposal a reality.

HIV in the United States (U.S.)

In 2019, nearly 37,000 people in the U.S. were diagnosed with HIV. Black and Latinx/Hispanic individuals comprised 42 percent and 29 percent of new diagnoses, respectively. Every person living with HIV requires a lifetime of treatment at an estimated individual cost of about \$501,000, with potential adverse effects that include liver toxicity and insulin resistance. HIV was the underlying cause of death for more than 5,000 people in 2019 in the U.S.

A major gap in U.S. efforts to address HIV is the under-utilization of medications that can virtually eliminate the acquisition of HIV. Fewer than 25 percent of people who could benefit from PrEP actually receive it, with large and growing disparities by race, ethnicity, gender, and geography. In 2019, the CDC found that 63 percent of White Americans recommended for PrEP received a prescription, compared to 14 percent of Latinx/Hispanic Americans and just 8 percent of Black Americans.

The current role of the federal government in HIV prevention

In 2019, the federal government launched a major new initiative called *Ending the HIV Epidemic*, investing more than \$500 million in HIV prevention, treatment, and research programs. The goal is to reduce new HIV infections in the United States by 90 percent by the year 2030. Though achievable, success will require substantial improvement over the modest 9 percent decline in new infections from 2015 to 2019.

The recently updated National HIV/AIDS Strategy for 2022-2025 recognizes the need for much greater use of PrEP. The major reasons for poor access include high prices, expensive and inaccessible laboratory tests, complex and confusing eligibility requirements to access PrEP services, limited provider availability in many parts of the country, and stigma. The Department of Health and Human Services (HHS)'s *Ready, Set, PrEP* Program, launched in 2019, aimed to reduce this gap by providing free PrEP medication for those without prescription drug coverage; however, the program does not cover the required associated clinic and lab costs for PrEP. The program also relies on high-cost, brand-name oral medications from a single manufacturer, despite the fact there are currently 12 manufacturers marketing generic PrEP in the U.S as well as a new long-acting injectable form of PrEP approved in December 2021.

Benefits of a national PrEP program

To scale up PrEP as part of an effective, sustainable strategy to end the HIV epidemic, a national PrEP infrastructure must move away from the current reliance on high-cost, brand-name drugs that have resulted in overly complex, difficult-to-navigate programs for the un- and under-insured and a relatively small number of access points in the Medicaid program. The [proposal from Killelea and colleagues](#) provides one potential path for a national PrEP program focused on these populations. A call for a national PrEP program builds off of recent efforts to secure congressional and Administration support for expanded access to PrEP. Any new funding must be strategically invested to ensure that scarce dollars are stretched to help the most amount of people and focused on reversing growing inequities in PrEP access. A multi-pronged approach will be needed to create a system in which individuals and providers can equitably and sustainably access PrEP.

To reduce the growing inequities enabled by our fragmented PrEP financing system, we seek your support for a national PrEP program which:

- Expands access to PrEP medications and lab services for people who are uninsured and on Medicaid
- Allows the federal government to negotiate with manufacturers and labs for fair public health prices
- Scales-up access to generic PrEP medication as a safe, effective, and cost-effective option for the majority of those indicated for PrEP and provides access to other PrEP options when indicated
- Creates an expansive provider network of non-clinical community-based PrEP providers and local health departments serving the uninsured and Medicaid that are paired with clinical providers via telehealth partnerships
- Works in tandem with existing PrEP funding and programs to supplement, not supplant programs and activities that are working
- Creates a platform for the effective and rapid deployment of novel PrEP medications

- Provides new opportunities to effectively raise awareness and combat stigma by enrolling and educating a new, broad network of providers and building community-led campaigns that connect key populations to this new PrEP infrastructure

A national PrEP program would help put the U.S. on track to end the HIV epidemic.

If you have any questions, do not hesitate to reach out to Jeremiah@prep4all.org

Sincerely,

Advocates for Youth
AIDS Alabama
AIDS Foundation of Chicago (AFC)
AIDS United
Amida Care
AVAC
Black AIDS Institute
Callen-Lorde Community Health Center
Center for Health Law and Policy Innovation, Harvard Law School
Community Education Group
COVID Clinic, Inc.
Equality California
Fenway Health
Friends For Life Corp - Memphis, TN
Georgia AIDS Coalition.
Georgia Equality
HealthHIV
HIV Medicine Association (HIVMA)
Housing Works
International Association of Providers of AIDS Care (IAPAC)
John Snow, Inc. (JSI)
Latino Commission on AIDS
NASTAD
National AIDS Housing Coalition (NAHC)
National Association of City and County Health Officials (NACCHO)
National Coalition for LGBTQ Health
NMAC
PrEP4All
San Francisco AIDS Foundation
Silver State Equality-Nevada
Southern AIDS Coalition
The AIDS Institute
The Aliveness Project, Inc.
The Reunion Project
Treatment Action Group
Vivent Health



3010 North First Street
San Jose, CA 95134

(650) 257-7587
www.visbymedical.com

National Center for HIV, Viral Hepatitis, STD, and TB Prevention
U.S. Centers for Disease Prevention and Health Promotion
[1600 Clifton Road NE](#), Mailstop US8-6
Atlanta, Georgia 30329-4027
Attention: Marah Condit, MS, Committee Management Lead

Re: Written Comments for the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT)

Dear Members of the CHACHSPT:

On behalf of Visby Medical, Inc. (Visby), a medical diagnostics technology company headquartered in San Jose California, and the patients and providers we seek to support with our point-of-care (POC) testing, we appreciate this opportunity to submit comments for consideration during the spring meeting. Our mission is to "empower anyone to test for any infection anywhere with near-100% accuracy." As such, we very much support the CHACHSPT's focus on activities related to the prevention and control of sexually transmitted infections (STI) and stand ready to be a resource and partner with you in your important work.

About Visby

Visby Medical is transforming the order of diagnosis and treatment for infectious diseases so clinicians can test, talk with, and treat the patient in a single visit. The Company's proprietary technology development program culminated in the world's first instrument-free, single-use PCR platform that fits in the palm of your hand and rapidly tests for serious infections. Originally developed for sexually transmitted infections, the Company's FDA-cleared, CLIA-waived Sexual Health Click Test for women returns accurate results within 28 minutes. The Visby Medical technology is also helping to fight the global pandemic via the Visby Medical COVID-19 Test, and its robust pipeline includes tests for other infectious diseases. Visby Medical is accelerating the delivery of fast and accurate, palm-sized PCR diagnostics to the point of care, and eventually for use at home. Visby Medical has received Federal funding from NIH and BARDA to support the development and validation of the PCR platform. For more information, visit www.visbymedical.com.

Accurate POC Tests Can Promote and Protect Public Health

The nation is in the sixth year-over-year increase in chlamydia and gonorrhea cases and this silent – and neglected – epidemic will not wane unless we become more intentional as a nation in how we deploy accurate, rapid test modalities. The Centers for Disease Control and Prevention's (CDC) 2021 Sexually Transmitted Disease (STD) Treatment Guidelines recommends Nucleic Acid Amplification Tests (NAATs) for detecting chlamydia and gonorrhea. The 2021 STI National Strategic plan includes a recurring theme of the need for "innovative solutions and approaches to address the ongoing and emerging challenges to STI prevention and control" and specifically calls out the need to develop "point of care diagnostic tools."

Visby has developed and introduced such a test to the market. We have the first FDA-cleared and CLIA-waived instrument-free PCR platform that can detect and distinguish

April 19, 2022

between three of the most common and curable STIs – chlamydia, gonorrhea, and trichomonas. This test provides lab-accurate results in less than 30 minutes without the need for trained laboratory technicians to operate or interpret test results. These tests can be used in any POC setting that has a CLIA-waiver, including STI clinics, OBGYN offices, emergency departments (EDs), urgent care settings (UC), and mobile vans. Because this platform does not require an extra instrument, it lends itself well for use in resource-constrained and remote settings. Many tests can be run in parallel to meet surge capacity.

The standard of care (SOC) practice is to send-out STI test samples for PCR testing, which typically does not return results for at least 24 hours, oftentimes longer. In the absence of real-time test results, patients are presumptively treated based on symptoms and sexual history. While this generally no longer happens in any other disease-state, it is common practice for STIs. Often the initial diagnosis is incorrect, meaning that the patient will need to be contacted with the right diagnosis and a new prescription for treatment or the patient may have to return for a second appointment to get the appropriate treatment. Women bear the greatest burden of this delay in accurate treatment, where untreated STIs can result in pelvic inflammatory disease (PID), ectopic pregnancies, and infertility. Moreover, STI infection increases the risk of HIV transmission. In sum, the current SOC practice delays accurate treatment, inconveniences the patient, can burden providers, and increases costs – and decreases efficiency – within the health care system.

The reality is that we are treating patients before test results are available. The rates of overtreatment (e.g., patient is treated for chlamydia, but laboratory results show she is not infected with chlamydia) can be as high as 80%, especially in settings such as EDs and UCs where staff fear patients will be lost to care. The Visby STI test can prevent overtreatment thus reducing the unnecessary use of antibiotics and promoting antibiotic stewardship. Conversely, undertreatment (e.g., patients are not given treatment, but laboratory results show they are infected with chlamydia) are also high. The consequences of undertreatment are detrimental to both individual and public health as untreated STIs can lead to PID and other severe sequelae, and patients can continue to spread disease. Importantly, clinic staff spend time calling the patient back with their test results and, in many settings, can never get in contact with the patient. The patients lost to care can be as high as 40%, posing a risk to public health by continuing to spread untreated disease.

Because Visby test results are available during the span of a patient's clinic visit, this enables:

- Accurate treatment informed by real-time PCR results
- Patient education (treatment and how to avoid future infections)
- Expedited Partner Therapy (EPT) (this is permitted in most states)

POC STI testing is better for the patient because:

- Patients are accurately treated based on what they have. This in turn improves their outcomes directly and helps reduce the spread of STIs.
- Treatment in a timely fashion means chlamydia infection does not progress to pelvic inflammatory disease (PID), which if left untreated can result in infertility and

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ectopic pregnancies, which can be devastating for patients and expensive for the health care system.

- Accurate treatment means the patient does not receive an unnecessary antibiotic (and not subject to unnecessary side effects from the antibiotic).
- Unnecessary additional clinic visits are avoided and clinician effort spent trying to reach patients for follow-up is eliminated.

Taken together, these advantages reduce costs and decrease the burden on the health care system.

Visby's STI Test Helps Advance the 2021 STI National Strategic Plan

Deploying a test like the Visby sexual health test supports all of the goals in the STI National Strategic Plan that was released in 2021.

Goal 1: Prevent new STIs

- By treating patients with the right drug in the initial clinic visit patients are not at risk of transmitting disease to other sexual partners; this provides timely, appropriate care to the patient directly and results in a better outcome for public health
- The provider has an opportunity to educate the patient face-to-face in real time. This will help increase awareness of STI prevention and sexual health.

Goal 2: Improve health of people by reducing adverse outcomes of STIs

- By providing test results within a patient's clinic visit, morbidity is reduced:
 - Patients are accurately treated based on what they have, not the best guess of the physician.
 - Timely treatment will reduce morbidity and in turn, improve outcomes and reduce costs. As noted above, timely treatment means chlamydia, gonorrhea, or trichomonas infections do not progress to PID, which, if left untreated, can result in infertility and ectopic pregnancies. Because infection with these STIs can increase the risk of HIV transmission, it is important to test, educate, and treat patients quickly.
 - Accurate treatment means the patient does not receive an unnecessary antibiotic and is not subject to unnecessary side effects from the antibiotic: Antibiotic Stewardship.

Goal 3: Accelerate progress in STI research, technology, and innovation

- By using an innovative diagnostic like the Visby Sexual Health STI test, the government can support shifting the paradigm from syndromic treatment to 'test, talk, treat'. Evidence-based treatment and decision-making is strengthened by POC accurate testing.

Goal 4: Reduce STI-related health disparities and health inequities

- Making a POC test like this available as standard of care can help advance equity, reduce health disparities, and decrease implicit bias that may be a component in syndromic treatment and diagnosis.

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- Innovations in diagnostic testing, like that of the Visby STI test, can fundamentally transform the patient experience, making it more patient-centered and convenient, which in turn can address access and equity concerns.
- STIs disproportionately affect women, and particularly minorities. For example, even though the population/clinic-based prevalence for trichomonas is 0.2%, black women bear the highest burden of disease (9%).
- The newly released 2020 STD Surveillance Report showed that while STDs are increasing across many groups, some racial and ethnic minority groups, gay and bisexual men, and our nation's youth continue to experience higher rates of STDs.

Goal 5: Achieve integrated, coordinated efforts that address the STI epidemic

- A key attribute of the Visby test is that it does not rely on a separate instrument, meaning that it is deployable almost anywhere, and lends itself well for surge capacity; as many people as possible can be treated contemporaneously.
- These tests can easily be deployed in the community and utilized in mobile clinic vans. For example, Visby is supporting a study to assess how this test can be used when deployed into a harm reduction mobile van that reaches rural individuals with substance use disorders.
- As a POC test the Visby test facilitates the delivery of integrated, coordinated care; all within one visit, the patient will be tested, diagnosed, educated about their infection, and prescribed a treatment pathway.

Call to Action

The potential for innovative, game changing POC STI tests to have a significant, positive impact on the STI epidemic is enormous. However, a number of barriers preclude the test becoming available to all who need it. As such, we respectfully call upon the CHACHSPT to support and recommend to Department of Health and Human Services (HHS), CDC, and the Health Resource and Services Administration (HRSA) the following:

1. *Implementation science studies* to assess clinical adoption in various settings, especially those settings where health inequities can be improved, such as with underrepresented groups, rural populations, novel health care delivery settings (e.g, mobile vans), and others.
2. *Policies, programs, and funding for equitable access to innovative technologies.* Access to innovative technologies should not be limited to those with means; innovation, especially that funded with taxpayer dollars, should be available to everyone. HHS should advance policies, programs, and funding that facilitate equitable access to technologies that can improve individual and public health.
3. *Efforts to uncover the true prevalence of Trichomonas* in all geographies and demographics. Trichomonas, as with other STIs, is a silent epidemic. Currently, Trichomonas is not required to be reported, so the true prevalence is unknown. Some clinics in the South report 30% prevalence in women and 10% in men, but in other geographies it appears to be less prevalent; however, this could be

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because people are not being routinely tested for *Trichomonas*. Knowing the true prevalence will help guide CDC treatment and reporting guidelines.

4. *Adequate coverage and payment policies for breakthrough innovative technologies that can make a difference to patient outcomes.* Patients and providers want, need, and deserve access to accurate, POC testing. However, reimbursement for such tests can be so low that it thwarts utilization of the technology when and where it is needed most. Moreover, the current federal coverage and payment system – as operationalized by the Centers for Medicare and Medicaid Services (CMS) – is built around laboratory-based testing and not POC. As many commercial payors and Medicaid often follow CMS, the adverse impact on the adoption rate for new diagnostic technology can be significant. The Visby test was built intentionally to engineer out the need for highly trained laboratory personnel to operate and interpret the test results so that it could be used nimbly in a variety of care settings to have the maximum positive impact on public health. Unfortunately, without improved coverage and payment policies, the test will not be adopted, and its promise will not come to fruition.

Conclusion

Again, on behalf of Visby and the patients and providers we seek to support with our POC testing, we thank you for your consideration of our views and recommendations. With sufficient reimbursement and intentional deployment, we feel strongly that our POC STI test has the potential to make a significant difference in addressing the STI epidemic. We are eager to serve as a resource to you, CDC, HRSA, and HHS to reduce and prevent STIs.

Sincerely,



Christopher J. Jowett
Chief Commercial Officer

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EXHIBIT M

Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2027- 2031

Division of HIV Prevention

**National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention**

HIV/AIDS Bureau

Health Resources and Services Administration

February 2025



Executive Summary

The Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) developed this guidance to support the submission of the Integrated HIV Prevention and Care Plan (hereafter referred to as Integrated Plan), including the Statewide Coordinated Statement of Need (SCSN) for calendar year (CY) 2027-2031 (hereafter referred to as Integrated Plan Guidance). This guidance builds upon the previous guidance issued in 2015 and 2021, for the submission of the Plan for CYs 2017-2021 and 2023-2026, respectively. That guidance allowed funded health departments and planning groups to submit one integrated HIV plan to lead the implementation of both HIV prevention and care services. As in 2021, the Integrated Plan Guidance for CY 2027-2031 meets all programmatic and legislative requirements associated with both CDC and HRSA funding. It reduces grant recipient burden and duplicative planning efforts and promotes collaboration and coordination around data analysis. The Integrated Plan Guidance necessitates engagement from a wide range of collaborators and partners including communities disproportionately affected by the HIV epidemic and people with HIV. The Integrated Plan Guidance intends to accelerate progress towards meeting national goals while allowing each jurisdiction to design a HIV services delivery system that reflects local vision, values, and needs.

CDC and HRSA funded recipients will notice several key changes in the Integrated Plan Guidance for CY 2027-2031. These changes reflect feedback from internal and external collaborators, which include recipients and people with HIV as well as priorities detailed in national HIV goals and the implementation strategies outlined in the [Ending the HIV Epidemic in the U.S. \(EHE\) initiative](#). Specifically, recipients who have already conducted extensive planning processes in response to the CDC's *High-Impact HIV Prevention and Surveillance Programs for Health Departments (PS24-0047)* program or through other jurisdictional efforts (e.g., Getting to Zero plans, Fast Track Cities, HIV Cluster Detection and Response plans) may submit portions of those plans to satisfy this Integrated Plan Guidance as long as the Integrated Plan submission addresses the broader needs of the geographic jurisdiction and applies to the entire HRSA and CDC HIV funding portfolio. To that end, additional details on key changes can be found in the *CY 2027– 2031 CDC DHP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist (See Appendix I)*. This checklist details submission requirements and allows each jurisdiction to determine which elements may require new content and which elements were developed as part of another jurisdictional plan.

Integrated Plan submissions address the broader needs of the geographic jurisdiction and apply to the entire HRSA and CDC HIV funding portfolio. Additionally, jurisdictions should submit plans that follow national HIV goals and priorities and use data to devise strategies that reduce new HIV infections by 90% by 2030. Proposed strategies should include the implementation of activities that will diagnose all people with HIV as early as possible, treat all people with HIV rapidly and effectively to reach sustained viral suppression, prevent new HIV transmissions by using proven interventions, and respond quickly to potential outbreaks to get appropriate prevention and treatment services to people who need them.

Section I: Introduction

In the United States, we have the tools to end the HIV epidemic and continue to make progress toward that goal. From 2018 to 2022, estimated HIV infections in the U.S. decreased by 12 percent largely attributed to the decrease in new HIV infections among people aged 13 to 24.¹ The work of dedicated individuals across HIV prevention and care delivery systems have contributed to this decrease in HIV diagnoses and the increase in viral suppression rates for clients in the Ryan White HIV/AIDS Program (RWHAP) from 69.5 percent in 2010 to 90.6 percent in 2023.

Although rates of new HIV incidence have decreased overall and viral suppression continue to increase, racial and ethnic differences in diagnoses and treatment outcomes of HIV persist. To reach the national goal of reducing new HIV infections, our systems of HIV prevention and care must work together in unprecedented ways. This includes providing access to all available tools so that people and communities disproportionately impacted by HIV are not left behind and efforts to end the HIV epidemic are accelerated.

The Integrated Plan Guidance for CY 2027-2031 is the third five-year planning guidance developed by CDC and HRSA. This Integrated Plan Guidance builds on the previous iterations of the Integrated Plan Guidance by allowing each jurisdiction to develop new goals and objectives that align public and private sectors to leverage strengths from the last five years and to add or revise services to address local HIV care and prevention needs that may remain. The Integrated Plan Guidance speaks to the need for aggressive actions necessary to achieve national HIV goals and targeted efforts to end the HIV epidemic in the U.S. by the year 2030.

Specifically, the Integrated Plan Guidance was designed to:

1. Coordinate HIV prevention and care activities by assessing resources and service delivery gaps and needs across HIV prevention and care systems to ensure the allocation of resources based on data (e.g., other payors, number of ADAP-eligible clients on health insurance coverage, in-depth analysis of needs assessment of people with HIV and people who can benefit from HIV prevention services or are vulnerable to HIV acquisition);
2. Address requirements for planning, community engagement, and coordination established by the RWHAP legislation as well as programmatic planning and community engagement requirements established by both HRSA and CDC through guidance;
3. Improve health outcomes along the HIV care continuum by using data to prioritize people and communities who have been disproportionately impacted by HIV where systems of care are not adequately addressing high HIV morbidity and/or lower overall viral suppression rates;

¹ [HIV Surveillance Supplemental Report: Estimated HIV Incidence and Prevalence in the United States, 2018–2022](#)

4. Promote a whole-person approach² to improve the health of people with HIV and people who can benefit from prevention services;
5. Reduce recipient burden by allowing jurisdictions to submit portions of other significant planning documents (e.g., EHE Plans, Fast Track Cities, Getting to Zero, or HIV Cluster Detection and Response plans) to meet Integrated Plan requirements and by aligning submission requirements and dates across HIV prevention and care funding;
6. Advance health by ensuring that government programs promote effective delivery of services and engage people with lived experience in service delivery system design and implementation; and,
7. Leverage strategic partnerships to prioritize efforts, and focus resources and evidence informed interventions, to reach those who are diagnosed, but not engaged in care.

Relationship to other National Plans and Initiatives

HRSA and CDC recognize that many jurisdictions have established and implemented extended planning processes as part of other local initiatives including but not limited to EHE funding, Fast Track Cities, locally funded Getting to Zero initiatives, or Cluster Detection and Response Plans. To minimize burden and align planning processes, the jurisdiction may submit portions of these plans to satisfy the Integrated Plan Guidance requirements. Jurisdictions should review national HIV goals or subsequent updates by visiting www.hiv.gov and [subscribing to receive updates](#).

National Framework for Ending the HIV Epidemic

It is important to think about this Integrated Plan Guidance within the framework of national objectives and strategic plans that detail the principles, priorities, and actions that direct the national public health response and provide a blueprint for collective action across the federal government and other sectors (see *Appendix 5*). HRSA and CDC support the implementation of these strategies.

Each jurisdiction should create Integrated Plans that address national HIV goals³:

- Prevent new HIV infections
- Improve HIV-related health outcomes of people with HIV
- Reduce HIV-related disparities
- Achieve integrated, coordinated efforts that address the HIV epidemic among all partners and collaborators

² A whole-person approach to HIV prevention and treatment considers the multitude of factors affecting a person's health. Source: <https://www.cdc.gov/hiv/policies/strategic-priorities/hiv-and-whole-person-care/index.html#:~:text=A%20whole%2Dperson%20approach%20can,expand%20flexible%20and%20tailored%20interventions.>

In 2020, HHS began implementation of the Ending the HIV Epidemic in the United States initiative coordinated around four strategies – diagnose, treat, prevent, and respond – that leverage highly successful programs, resources, and infrastructure. The EHE initiative aligns with national HIV goals to reduce new HIV diagnoses in the United States, decreasing the number of new HIV infections to fewer than 3,000 per year. The EHE initiative focuses resources, expertise and technology in jurisdictions hardest hit by the HIV epidemic. For more information on the EHE initiative, visit: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

The Integrated Plan Guidance utilizes the HIV care continuum model and the whole-person approach. The HIV care continuum depicts the stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication to reach viral suppression. Supporting people with HIV to reach viral suppression not only increases their own quality of life and lifespan, it also prevents sexual transmission to an HIV-negative partner, thus providing an additional strategy to prevent new HIV infections. Effective strategies to address barriers within HIV prevention, care, and treatment systems are needed to increase the number of people with HIV that reach and maintain viral suppression.

The adoption of a whole-person approach can improve HIV prevention and care service delivery and outcomes. Persons with positive test results should be linked to HIV care, treatment, and other social support services; and persons testing negative should be linked, as needed, to biomedical HIV prevention services, such as PrEP, and other social support services.

The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively. HRSA and CDC encourage jurisdictions to use the HIV care continuum to identify people and communities who have been disproportionately impacted by HIV and for whom the service system may not be adequately engaging in HIV prevention services or may not support improved HIV health outcomes. Additionally, all jurisdictions should include performance measures in their Integrated Plan submission including the core performance measures that measure progress along the HIV care continuum for all people and communities who have been disproportionately impacted by HIV. Please see *Appendix 4* for links to suggested CDC and HRSA data sources, performance measures, and indicators.

Section II: Planning Requirements and Submission Guidelines

Integrated planning is a vehicle for jurisdictions to identify HIV prevention and care needs, existing resources, barriers and gaps, and outline local strategies to address them. The Integrated Plan submission should articulate existing and needed collaborations among people with HIV, service providers, funded program implementers, and other collaborators, including but not limited to other programs funded by the federal government, such as the Housing Opportunity for Persons with AIDS (HOPWA) program and providers from other service systems such as substance use prevention and treatment providers. The Integrated Plan submission should reflect

current approaches and use the most recent data available. To ensure coordinated implementation of their Integrated Plan submission, each jurisdiction should include information on the persons or agencies responsible for developing the plan, implementing the plan, coordinating activities and funding streams, and monitoring the plan.

HIV Planning Requirements

All CDC DHP and HRSA HAB funded jurisdictions (the 50 states, RWHAP Part A-funded Eligible Metropolitan Areas and Transitional Grant Areas, directly-funded CDC HIV prevention cities, Puerto Rico, the United States Virgin Islands, and the United States Affiliated Pacific Island jurisdictions) are required to have a planning process that includes the development of a system-wide plan for the delivery of HIV prevention and care services and the establishment of an HIV planning group, planning council, or advisory group, also known as a planning body.

By design, the HIV planning body must engage people with different interests, responsibilities, and involvement with HIV to inform and support the development and implementation of an Integrated Plan submission that guides the delivery of HIV prevention and care services. CDC and HRSA recognize and understand the value of individuals who receive services actively participating in the planning process for HIV service delivery, as this drives services that are tailored to the needs of clients in the jurisdiction, and these individuals must be engaged in the development and implementation process.

For the development of the Integrated Plan, jurisdictions should include and use their existing local prevention and care HIV planning bodies, as consistent with CDC and HRSA planning group requirements, and engage traditional collaborators and community members (e.g., people with HIV, people with certain risk factors for acquiring HIV, AIDS Education and Training Centers (AETCs), state Medicaid agencies, STI/sexually transmitted disease (STD) clinics and local education agencies (LEAs)) to get input. In addition, recipients should broaden their existing group of partners and collaborators to include other federal, state, and local HIV programs, local organizations, and community groups not previously engaged for the purposes of improving data sources, leveraging services, and assisting with key portions of the plan, such as the HIV prevention and care inventories.

When developing the Integrated Plan submission, the planning body should collaborate with the recipient to review and analyze data (e.g., resource inventory, needs assessments, satisfaction surveys, listening sessions) for program action and decisions, prioritize resources to those jurisdictions at highest risk for HIV transmission and acquisition, and improve HIV health outcomes in those jurisdictions for both people and communities disproportionately impacted by HIV. Through strategic collaborations among collaborators, HIV planning is based on the principle that local planning is the best way to respond to local HIV prevention and care service delivery needs and priorities. Please refer to CDC's most recent [HIV Planning Guidance \(HPG\)](#) and the [RWHAP Part A](#) and [Part B Manual](#) for more details about HIV planning processes.

Integrated Plan Components

The Integrated Plan submission should demonstrate an understanding of and considerations for all funding sources, service delivery, and system integration (entire system of HIV prevention and care). It should include the following sections:

1. Introduction
2. Community Engagement and description of Jurisdictional Planning Process
3. Contributing Data Sets and Assessments, including:
 - a. Epidemiologic Snapshot
 - b. HIV Prevention, Care and Treatment Resource Inventory
 - c. Needs Assessment
4. Situational Analysis Overview, including people and communities disproportionately impacted by HIV
5. CY 2027-2031 Goals and Objectives to be organized by national HIV goals and inclusive of the strategies: Diagnose, Treat, Prevent, and Respond. See *Appendix 2* for examples.
6. Integrated Plan Workplan

In addition to these sections, please use the checklist attached, as *Appendix 1*, to ensure the jurisdiction submits all of the documents needed to meet submission requirements, including existing materials and newly developed materials needed for each required section.

As part of a complete Integrated Plan submission, jurisdictions must provide a signed letter from the planning body(ies) documenting concurrence, non-concurrence, or concurrence with reservations with the Integrated Plan submission. In RWHAP Part A jurisdictions that cross state lines, the Part A Planning Councils/Planning Bodies need to submit signed letters to all RWHAP Part B jurisdictions included in the Part A jurisdiction. As part of the Integrated Plan submission, jurisdictions will need to outline the communities and collaborators represented in the planning and concurrence process (e.g., community members, people with HIV, service providers, governmental entities). Submissions that do not contain the required letters of concurrence will be deemed incomplete and returned for revisions.

See the table below for the required letters of concurrence depending upon the plan submission type. If there are additional planning bodies in the state/territory or jurisdiction, additional letters of concurrence should be submitted. Please see *Appendix 6* for a sample letter of concurrence.

Required Letters of Concurrence			
	Type of Plan		
Planning Body	Integrated State/City Prevention and Care Plan	Integrated State-Only Prevention and Care Plan	Integrated City-Only Prevention and Care Plan
RWHAP Part A Planning Council	✓ ⁴	✓ ⁵	✓
RWHAP Part B Planning Group	✓	✓	
CDC Prevention Planning Group	✓	✓	✓

⁴ RWHAP Part A recipients need to submit letters of concurrence to all states where 10% or more of the HIV cases in their jurisdiction reside.

Submission

The Integrated Plan submission must include all the components outlined in this guidance and include a completed *CY 2027- 2031 CDC DHP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist*. Plans must be comprehensive to ensure that all HIV prevention and care funding work together to reduce new HIV diagnoses and to increase viral suppression among all people with HIV. The new plan should use existing documents such as an epidemiologic profile, if documents are current. Existing versions of documents may be updated or modified if needed during the current integrated planning process.

Each HRSA and CDC-funded jurisdiction needs to participate in the completion and submission of an Integrated Plan and must include the following:

- Detailed information of who is responsible for developing the Integrated Plan within the jurisdiction (i.e., RWHAP Part A planning councils/body(ies), RWHAP Part B advisory groups, Integrated Planning Bodies and CDC HIV planning bodies).
- Well defined goals and objectives. Each jurisdiction should provide a descriptive detail and process for how it will address HIV prevention, care, and treatment needs in its service areas and accomplish national HIV goals.

All funded jurisdictions (funded by both CDC DHP and HRSA HAB) must submit an Integrated Plan and address all sections as outlined in the guidance. State and/or local jurisdictions (municipalities) have the option to submit to CDC and HRSA:

- Integrated state/city prevention and care plan,
- Integrated state-only prevention and care plan, and/or
- Integrated city-only prevention and care plan.

NOTE: All submissions should demonstrate an integrated prevention and care plan as a method to better coordinate a response to HIV among all partners and collaborators. Per legislative and programmatic requirements, CDC and HRSA expect coordination among funded entities and community collaborators in the development of the Integrated Plan.

The Integrated Plan submission may include several jurisdictions (e.g., the state, the RWHAP Part A jurisdiction(s) in that state, CDC directly funded cities in that state). Each HRSA and CDC-funded jurisdiction must participate in the completion and submission of the Integrated Plan.

- For jurisdictions submitting city-only plan, the city Integrated Plan should complement the state Integrated Plan, including the SCSN.
- Both the city-only and state-only Integrated Plans should describe how the jurisdictions will coordinate actions to prevent duplication.
- Both city-only and state-only plans should include and address the HIV epidemic within its jurisdiction.

The jurisdiction's Integrated Plan submission is due to CDC DHP and HRSA HAB **no later than 11:59 PM ET on June 30, 2026**. Submissions should be no longer than 100 pages, not including the completed checklist, and no smaller than 11 pt. font.

The submission package must contain the following documents:

- A CY 2027 – 2031 Integrated Plan that includes all components outlined in this guidance;
- A completed *CY 2027 – 2031 CDC DHP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist* detailing where CDC and HRSA may find each of the required elements; and
- A signed letter from all jurisdictional HIV planning groups/bodies indicating concurrence, concurrence with reservations, or non-concurrence with the plan.

Further detailed instructions on how to submit your jurisdiction's Integrated Plan will be addressed during the upcoming webinar. You may also reach out to your CDC and HRSA project officers for questions or concerns regarding your Integrated Plan.

While there is not a standard template for the Integrated Plan submission, the plan submitted must include all the components outlined in this guidance and include a completed *CY 2027 – 2031 CDC DHP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist*. Plans must be broad enough to ensure that all HIV prevention and care funding work together to reduce new HIV diagnoses and to increase viral suppression among all people with HIV. The new written plan should not redevelop existing products such as epidemiologic profiles, if these products are current and up-to-date. Existing versions of these documents may be updated or modified if needed for the current integrated planning process.

Workplan Monitoring

The Integrated Plan Workplan provides an overarching vehicle to coordinate approaches for addressing HIV prevention and care needs at the state and local levels. The Integrated Plan Workplan must contain goals, SMART (specific, measurable, achievable, relevant and time-bound) objectives, specific activities, responsible parties, key partners, and performance measures that address both HIV prevention and care needs.

In addition, the goals and objectives must be in alignment with national HIV goals and the four EHE strategies, listed below:

- Diagnose all people with HIV as early as possible
- Treat people with HIV rapidly and effectively to reach sustained viral suppression
- Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and syringe services programs (SSPs)
- Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

Monitoring the Integrated Plan Workplan will assist recipients and planning bodies with identifying ways to measure progress toward goals and objectives; selecting strategies for

collecting information; and analyzing information to inform decision-making and improve HIV prevention, care, and treatment efforts within the jurisdiction. Jurisdictions must identify how they will provide regular updates to the planning bodies and collaborators on the progress of plan implementation, solicit feedback, and use the feedback from collaborators for plan improvements. Each jurisdiction also will need to use surveillance and program data to assess and improve health outcomes, health disparities, and the quality of the HIV service delivery systems, including strategic long-range planning.

The Integrated Plan, including the Integrated Plan Workplan, is a “living document” and must be reviewed and updated at least annually or as needed. The process for annual review should include the identification of relevant data and data systems, analysis of data on performance measures, the inclusion of planning bodies in the ongoing evaluation of activities and strategies, a mechanism to revise goals and objectives as needed based on data, and an evaluation of the planning process.

To ensure progress on Integrated Plan activities and the Integrated Plan’s alignment with funding strategies, CDC and HRSA will engage in monitoring workplan activities both independently and jointly. Recipients will use established reporting requirements (i.e., applications, annual progress reports) to document progress on achieving the objectives presented in the Integrated Plan. These reporting updates should include the jurisdiction’s plan to monitor and evaluate implementation of the goals, strategies, and objectives included in the Integrated Plan. Project officers will also utilize the Integrated Plan Workplan as a tool in monitoring and supporting the jurisdiction’s progress. Additionally, CDC and HRSA project officers will continue to monitor progress during regularly scheduled calls and will conduct periodic joint monitoring calls with recipients.

CDC DHP and HRSA HAB remain committed to our ongoing partnership and the provision of technical assistance (TA) services. For TA services around integrated planning, please contact your respective project officers.

Appendix 1

CY 2027 – 2031 CDC DHP and HRSA HAB Integrated Prevention and Care Plan Guidance Checklist

Section I: Introduction of Integrated Plan and SCSN			
Purpose: To provide a description of the Integrated Plan, including the SCSN and the approach the jurisdiction used to prepare and package requirements for submission • Write a detailed summary: Ensure it shows how you have met the Integrated Plan requirements. • Combining materials: Explain how new and existing materials relate.			
Requirements	Materials	Title/File Name of materials	Page(s) for this section
1. Introduction Describe the Integrated Plan • Include SCSN • Explain how past plans/SCSNs inform this plan/SCSN. • Or provide an overall description of an existing plan/SCSN that meets all requirements and includes the information below.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
a. Approach Describe your approach to preparing the Integrated Plan submission. • Update existing plan: Modify and enhance previously submitted plan. • Integrate Existing Documents: Combine sections from current plans and documents. • Develop a New Plan: Create an entirely new plan from scratch.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
b. Documents submitted to meet requirements. Fill out for each requirement per column provided: • New or existing material • Title/File Name for materials • Page numbers within the section	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
Section II: Community Engagement and Planning Process			

Purpose: To describe how the jurisdiction’s planning approach engaged community members and collaborators, fulfilled legislative and programmatic requirements, and addresses the HIV care and prevention needs of people with HIV and people vulnerable to HIV.

Tips for meeting this requirement

1. This requirement may include submission of portions of other submitted plans including the EHE plans, and other jurisdictional plans (e.g., Getting to Zero plans, Fast Track Cities, Cluster Detection and Response plans).
2. Be sure to provide adequate detail to confirm compliance with legislative and programmatic planning requirements, including:
 - a. SCSN,
 - b. RWHAP Part A and B planning requirements including those requiring feedback from key collaborators and people with HIV, and
 - c. CDC planning requirements.
3. The community engagement process should reflect the local demographics.
4. The planning process should include key collaborators and broad-based communities that include but are not limited to:
 - a. People with HIV,
 - b. People and communities disproportionately impacted by HIV,
 - c. Funded-service providers, and
 - d. Collaborators, especially new collaborators, from disproportionately affected communities. See *Appendix 3* for required and suggested examples of collaborators to be included.
5. Explain how the jurisdiction will build collaborations including sharing of data and establishing/maintaining services agreements, among:
 - a. Systems of prevention and care, and
 - b. Other service systems relevant to HIV in the jurisdictions (e.g., behavioral health and housing services).
6. Include community engagement related to “Respond” and support of cluster detection activities. Describe what happens when a potential cluster is detected and how community partners and affected communities are engaged.

Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. Jurisdiction Planning Process Describe Jurisdiction’s approach to planning • Planning Steps: explain steps in planning process. • Groups Involved: list involved groups for needs assessment and goal setting. • Usage of Data Sources: detail data sources used. • Representation from People and Communities Disproportionately Impacted by HIV: how were they included?	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

Consider sections from other plans, like the EHE plan. Ensure you cover these points.			
a. Entities involved in the process. List and describe the types of entities involved in the planning process. Be sure to include: • CDC and HRSA-funded programs, • New collaborators (e.g., new partner organizations, people with HIV, people and communities disproportionately impacted by HIV), and • Other entities such as HOPWA-funded housing service providers or the state Medicaid agency that met as part of the process. See Appendix 3 for list of required and suggested collaborators	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
b. Role of the RWHAP Part A Planning Council/Planning Body Describe the role of the RWHAP Part A Planning Council(s)/Planning Body(s) in developing the Integrated Plan. Note: Jurisdictions submitting a State-Only Plan are not required to complete this narrative section; however, letters of concurrence must be submitted.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
c. Role of Planning Bodies and Other Entities <u>Describe how programs and planning bodies contributed to:</u> • CDC Prevention Program, • RWHAP Part B, • State/territory or jurisdiction prevention and care, • EHE, and • Community members and other entities. <u>Describe collaboration efforts.</u> • How did prevention and care bodies work together? Provide documentation of the type of engagement that occurred. EHE planning may be submitted as long as it includes updates that describe ongoing activities.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
d. Collaboration with RWHAP Parts – SCSN requirement Describe how jurisdictions incorporate RWHAP Parts A-D providers and Part F recipients in the planning process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

Describe how RWHAP Part A or Part B only plan: • Aligns with other Integrated Plans, • Avoids service duplication, and • Prevents gaps in service delivery systems.			
e. Engagement of people with HIV – SCSN requirement Describe how jurisdictions engaged people with HIV in all stages of the process including: • Needs assessment, • Priority setting, and • Development of goals/objectives. Describe how people with HIV will be involved in implementing the plan including: • Implementation, • Monitoring, • Evaluation, and • Improvement process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
f. Priorities List key priorities that arose out of the planning and community engagement process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
g. Updates to Other Strategic Plans Used to Meet Requirements If the jurisdiction is using portions of another local strategic plan (e.g., EHE, Ending the Epidemic, Getting to Zero) to satisfy this requirement, please describe: 1. How the jurisdiction uses annual needs assessment data to adjust that plan's priorities. 2. How the jurisdiction incorporates the ongoing feedback of people with HIV, people and communities disproportionately impacted by HIV, and collaborators in that plan. 3. Any changes due to updated assessments and community input. 4. Any changes made to that planning process as a result of evaluating the planning process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

Section III: Contributing Data Sets and Assessments

Purpose: To analyze the qualitative and quantitative data used by the jurisdiction to describe how HIV impacts the jurisdiction; to determine the services needed by clients to access and maintain HIV prevention, care and treatment services; to identify barriers for clients accessing those services; and to assess gaps across the HIV Prevention and HIV Care Continuums of Care. This section fulfills several legislative requirements including:

1. SCSN,
2. RWHAP Part A and B planning requirements including those requiring feedback from key collaborators and people with HIV, and
3. CDC planning requirements including those requiring feedback from key collaborators and people and communities disproportionately impacted by HIV acquisition.

Tips for meeting this requirement

1. This requirement may include submission of portions of other submitted plans including the EHE plan submitted as a deliverable for PS24-0047. *Please ensure that if using a previously developed plan that the data included describes the entire jurisdiction and not just a subsection of the jurisdiction such as an EHE priority county.*
2. Be sure to provide adequate detail to confirm compliance with legislative and programmatic planning requirements.
3. Include both narrative and graphic depictions of the health disparities in the area for people with HIV and people and communities disproportionately impacted by HIV including information about HIV outbreaks and clusters.
4. The data used in this section should inform both the situational analysis and the goals established by the jurisdiction.
5. Please refer to the [Integrated Guidance for Developing Epidemiologic Profiles \(cdc.gov\)](https://www.cdc.gov/eid/content/ed010104.htm) for HIV Prevention and Ryan White HIV/AIDS Program Planning.
6. *Appendix 4* includes suggested data resources to assist with this submission including the Epidemiologic Snapshot.

Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. Data Sharing and Use Provide an overview of data available to the jurisdiction and how data were used to support planning. Identify with whom the jurisdiction has data sharing agreements and for what purpose.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
2. Epidemiologic Snapshot Provide a snapshot summary using: • Current data: by using both narrative and graphic depictions display trends using the most recent 5 years (most available data). • Key descriptors: people diagnosed with HIV (including newly diagnosed), people vulnerable to HIV, and those with HIV who do not know their HIV	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

status. Highlight populations for prevention and care and align with national HIV goals. • Types of data: demographic, geographic, socioeconomic, behavioral, and clinical characteristics. • HIV clusters: outline key characteristics of HIV clusters and cases linked to these clusters. Note: Use the HIV prevention and care continuum in your graphic depiction showing burden of HIV in the jurisdiction.			
3. HIV Prevention, Care and Treatment Resource Inventory Develop an inventory that includes a table and/or narrative but must address <u>all</u> of the following information: Providers: • Agencies providing HIV care and prevention services in the jurisdiction. • Agencies providing substance use prevention and treatment services: describe the coordination strategy with HIV prevention and care services. Funding Sources: • HRSA (all RWHAP parts) and CDC funding sources. Funding amounts not needed. • Additional funding sources: HRSA's Community Health Center Program, HUD's HOPWA program, Indian Health Service (IHS) HIV/AIDS Program, Substance Abuse and Mental Health Services Administration programs, and foundations. <u>Provided Services:</u> • Services and activities by organizations • People and communities disproportionately impacted by HIV served • How services maximize the quality of health and support for those with certain risk factors of acquiring or with HIV	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
a. Assessment of Strengths and Gaps across the HIV Prevention and Care Continuum Assessment of Strengths and Gaps Inventory should include: • Geographic landscape	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

• Occurrences of HIV clusters/outbreaks • Underuse of new HIV prevention tools (e.g., injectable antiretrovirals, environmental impacts) This analysis should include areas where the jurisdiction may need to build capacity for service delivery based on the items listed.			
b. Approaches and partnerships Please describe the approaches the jurisdiction used to complete the HIV prevention, care and treatment inventory. Be sure to include partners, especially new partners, used to assess service capacity in the area.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
4. Needs Assessment Identify and describe all needs assessment activities or other activities/data/information used to inform goals and objectives in this submission. Include a summary of needs assessment data including: HIV Testing Services: 1. Services needed for HIV testing access. 2. Services for staying HIV negative (e.g., PrEP, Syringe Services Programs) 3. Rapid linkage to HIV care after positive diagnosis. HIV Care and Treatment: 4. Services for maintaining HIV care and reaching and sustaining viral suppression. Barriers to access: 1. HIV testing barriers. 2. Challenges with state laws and regulations. 3. HIV prevention, care, and treatment service access issues.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
a. Priorities List the key priorities arising from the needs assessment process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

b. Action Taken List any key activities undertaken by the jurisdiction to address needs and barriers identified during the needs assessment process.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
c. Approach Please describe the approach the jurisdiction used to complete the needs assessment. Be sure to include how the jurisdiction incorporated people with HIV and people and communities disproportionately impacted by HIV in the process and how the jurisdiction included entities listed in Appendix 3.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
Section IV: Situational Analysis <u>Purpose:</u> To provide a snapshot summary that synthesizes information from the Community Engagement and Planning Process in Section II and the Contributing Data sets and Assessments detailed in Section III that in turn informs the goals and objectives of the Integrated Plan. The situational analysis provides an overview of strengths, challenges, and identified needs across the HIV prevention and care continuum. Tips 1. New or existing material may be used; however, if existing material is used, it needs to be updated to reflect the most current information. 2. This section not only provides a snapshot of the data and environment for goal-setting but meets the RWHAP legislative requirement for the SCSN. 3. Jurisdictions may submit the Situational Analysis requirement. <i>However, it must include information for the entire HIV prevention and care system and not just the EHE priority area or service system.</i> If using an updated or current version of your EHE plan to fulfill this requirement, be sure to include updates as noted below.			
Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. Situational Analysis Based on the Community Engagement and Planning Process in Section II and the Contributing Data Sets and Assessments detailed in Section III. Provide a short overview across the HIV prevention and care continuum to include: • Strengths • Challenges • Identified needs.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

• Analysis of structural and systemic issues impacting people and communities disproportionately impacted by HIV. Analysis should include each of the following areas: <u>Diagnose</u> all people with HIV as early as possible. <u>Treat</u> people with HIV rapidly and effectively to reach sustained viral suppression. <u>Prevent</u> new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs) <u>Respond</u> quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them. Note: Jurisdictions may submit other plans to satisfy this requirement, if they are current and applicable to the entire HIV prevention and care service system across the jurisdiction.			
a. People and Communities Disproportionately Impacted by HIV Based on the Community Engagement and Planning Process in Section II and the Contributing Data Sets and Assessments detailed in Section III, describe how the goals and objectives address the needs of people and communities disproportionately impacted by HIV for the jurisdiction	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
Section V: 2027-2031 Goals and Objectives <u>Purpose:</u> To detail goals and objectives for the next 5 years. Goals and objectives should reflect strategies that ensure a comprehensive, coordinated approach for all HIV prevention and care funding. Tips for meeting this requirement: 2. Recipients may submit plans (e.g., EHE, Getting to Zero, HIV Cluster Detection and Response plan) for this requirement as long as it sets goals for the entire HIV prevention and care continuum and geographic area. 3. Goals and objectives should be in SMART format and structured to include strategies that accomplish the following: a. Diagnose all people with HIV as early as possible b. Treat people with HIV rapidly and effectively to reach sustained viral suppression c. Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP) and syringe services programs (SSPs) d. Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.			

4. The plan should include goals that address both HIV prevention and care needs.			
Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. Goals and Objectives Description List and describe goals and objectives for the jurisdiction. Include 3 goals/objectives for each area: • Diagnose • Treat • Prevent • Respond to HIV Ensure goals address any barriers or needs identified during the planning process. See Appendix 2 for examples. Note: Jurisdictions may submit other updated plans to satisfy this requirement as long as they include goals that cover the entire HIV prevention and care service delivery system and geographic area.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
a. Updates to Other Strategic Plans Used to Meet Requirements If the jurisdiction is using portions of another local strategic plan to satisfy this requirement, please describe any changes made as a result of analysis of data.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
Section VI: 2027-2031 Integrated Planning Implementation, Monitoring, and Jurisdictional Follow-Up <u>Purpose:</u> To describe the infrastructure, procedures, systems, and/or tools that will be used to support the key phases of integrated planning. In this section jurisdictions will detail how best to ensure the success of Integrated Plan goals and objectives through the following 5 key phases: 1. Implementation 2. Monitoring 3. Evaluation 4. Improvement 5. Reporting and Dissemination Tips for meeting this requirement 1. This requirement may require the recipient to create some new material or expand upon existing materials. 2. Include sufficient descriptive detail for each of the 5 key phases to ensure that all entities understand their roles and responsibilities, and concur with the process.			

3. If you are submitting portions of a different jurisdictional plan to meet this requirement, you should include updates that describe steps the jurisdiction has taken to accomplish each of the 5 phases.

Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. 2027-2031 Integrated Planning Implementation Approach 1. Describe the infrastructure, procedures, systems and/or tools that will be used to support the 5 key phases (see phases above) of integrated planning to ensure goals and objectives are met	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
a. Implementation 2. To achieve the jurisdictions Integrated Plan goals and objectives. Describe the process for coordinating partners: • New partners • People with HIV • People and communities disproportionately impacted by HIV • Providers and administrators from different funding streams Include how the plan will influence, leverage, and coordinate funding streams including but not limited to HAB and CDC funding.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
b. Monitoring 3. Describe the process for monitoring progress on the Integrated Plan goals and objectives. Include how the jurisdiction will: • Coordinate different collaborators. • Use different funding streams to implement plan goals. • Collaborate/coordinate monitoring of multiple different plans (e.g., city-only, state-only) to avoid duplication of effort and potential gaps in service provision. • Coordinate activities and timelines.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

Note: Recipients will be asked to provide updates to both CDC and HRSA as part of routine monitoring of all awards.			
c. Evaluation 4. Describe performance measures and methodology used to evaluate progress on goals and objectives. Include how often the jurisdiction: • Conducts analysis of the performance measures • Presents data to the planning group.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
d. Improvement 5. Describe how the jurisdiction will: • Continue to use data. • Use community input to make revisions and improvements to the plan. • How revision decisions will be made and how often.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
e. Reporting and Dissemination 6. Describe the process for informing collaborators, including people with HIV, about progress made to the plan. (implementation, monitoring, evaluation and improvements).	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

f. Updates to Other Strategic Plans to Meet Requirements If using portions of another local strategic plan to satisfy this requirement, please describe: - Steps the jurisdiction has already taken to: - Implement - Monitor - Evaluate - Improve - Report/disseminate plan activities. - Describe Achievements/challenges in implementing: - Strategies to resolve challenges. - Plan to replicate successes. - Revisions made based on work completed.	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
Section VII: Letters of Concurrence Provide letters of concurrence or concurrence with reservation. Each letter should specify how the planning body was involved in the Integrated Plan development. Include a letter of concurrence for each planning body in the state/territory or jurisdiction. Please note, a letter of concurrence is required from Planning Councils regardless of the type of plan submitted. See <i>Appendix 6</i> for a sample Letter of Concurrence.			
Requirements	New/existing Materials	Title/File Name of materials	Page(s) for this section
1. CDC Prevention Program Planning Body Chair(s) or Representative(s) Required letter of concurrence	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
2. RWHAP Part A Planning Council/Planning Body(s) Chair(s) or Representative(s) Required letter of concurrence	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
3. RWHAP Part B Planning Body Chair or Representative Required letter of concurrence unless City-Only Plan is submitted	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
4. Integrated Planning Body Optional letter of concurrence	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.

5. EHE Planning Body Optional letter of concurrence	Choose an item.	Click or tap here to enter text.	Click or tap here to enter text.
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Appendix 2

Examples of Workplan Components

Note: *A workplan template is available on TargetHIV under the Integrated HIV/AIDS Planning & Technical Assistance Center (IHAP TAC) as a part of the Integrated Plan Toolkit.*

Diagnose (EXAMPLE)

Goal 1: Diagnose all people with HIV as early as possible.

Objective: To increase the number of HIV tests conducted by XX% within the jurisdiction by 2031.

Key Activities/Strategies:

- 1) Increase capacity of health care delivery systems to offer routine testing in XX ERs, acute care settings, etc.
- 2) Plan and develop a wide dissemination of self-testing kits through system partners across the jurisdiction to improve access for testing.

Responsible Parties: RWHAP Part A recipient, RWHAP Part B recipient, EHE recipient, CDC recipient

Key Partners: Health departments, community-based organizations, FQHCs, correctional facilities, school-based clinics, people and communities disproportionately impacted by HIV, STI/sexually transmitted disease clinics, women's health services/prenatal services providers, hospitals, etc.

Performance Measures:

- # of HIV tests
- # of newly identified persons with HIV

Progress towards national HIV goals: Increase the number of people who know their HIV diagnosis by XX% to prevent new HIV infections.

Treat (EXAMPLE)

Goal 1: Treat HIV timely and effectively.

Objective: To engage and provide access to care for XX people with HIV by 2028.

Key Activities/Strategies:

- 1) Identify and address mental health barriers for people who have never engaged in care or who have fallen out of care by partnering with mental health providers
- 2) Develop and implement at least one effective, evidence-based, or evidence-informed interventions that improve retention in care

Responsible Parties: RWHAP Part A recipient, RWHAP Part B recipient, EHE recipient

Key Partners: FQHCs, medical care providers, hospitals, people and communities disproportionately impacted by HIV, community-based organizations, mental health providers, various professional health care associations, etc.

Performance Measures:

- # of newly identified persons with HIV linked to care within 30 days
- # of persons with HIV identified as not in care linked to care within 30 days

Progress towards national HIV goals: Increase the number of people receiving care by XX% to improve HIV-related health outcomes.

Prevent (EXAMPLE)

Goal 1: Prevent new HIV transmissions.

Objective: To increase access to PrEP by X% for people and communities disproportionately impacted by HIV by 2031.

Key Activities/Strategies:

- 1) Increase number of providers trained each year by X% to prescribe PrEP
- 2) Increase PrEP prescriptions among people and communities disproportionately impacted by HIV to reduce health disparities

Responsible Parties: RWHAP Part A recipient, RWHAP Part B recipient, EHE recipient, CDC recipient

Key Partners: Community-based organizations, people and communities disproportionately impacted by HIV, FQHCs, STI/sexually transmitted disease clinics, hospitals, private providers, social service providers, primary care providers, etc.

Performance Measures:

- # of providers trained
- # of prescriptions for PrEP

Progress towards national HIV goals: Reduce HIV-related disparities

Respond (EXAMPLE)

Goal 1: Respond quickly to potential HIV clusters and/or outbreaks.

Objective: To develop a Cluster Detection and Response (CDR) Plan that can be implemented effectively by 2028.

Key Activities/Strategies:

- 1) Identify and engage all key collaborators in the plan development process, including people and communities disproportionately impacted by HIV
- 2) Convene existing communities of practice to share outbreak best response practices and known gaps to guide development and key strategies in the plan

Responsible Parties: CDC Recipient

Key Partners: Community members, community-based organizations, HIV care providers, FQHCs, correctional facilities, hospitals, social services providers, people with HIV, health departments, public health professionals, etc.

Performance Measures: Completion of CDR plan

Progress towards national HIV goals: Achieve integrated and coordinated efforts that address the HIV epidemic

Appendix 3

Examples of Key Collaborators and Community Members

Community engagement is a key requirement of the Integrated Planning Guidance. Community engagement involves the collaboration of key collaborators and broad-based communities who work together to identify strategies to increase coordination of HIV programs throughout the state, local health jurisdictions, or tribal areas. Each community should select collaborators including people and communities disproportionately impacted by HIV and can best help align resources and set goals that promote HIV prevention and health outcomes. This should include not only traditional collaborators but engagement with new partners and non-traditional organizations. While the Integrated Plan submission should be done in collaboration with identified Integrated Planning body(s), community engagement may also include assessment processes (e.g., focus groups) that take place outside of or in conjunction with the Integrated HIV Care and Prevention body(s) and to inform the Integrated Plan submission.

Please Note: Persons or groups with a “*” must be included in the planning process to meet HRSA and/or CDC’s legislative or programmatic requirements.

Key Collaborators to Consider for Planning Group Membership

- Health department staff*
- Community- based organizations serving populations affected by HIV as well as HIV services providers*
- People with HIV, including members of a Federally recognized Indian tribe as represented in the population, and individuals co-infected with hepatitis B or C*
- People and communities disproportionately impacted by HIV
- Behavioral or social scientists
- Epidemiologists
- HIV clinical care providers including (RWHAP Parts C and D) *
- STD clinics and programs
- Non-elected community leaders including faith community members and business/labor representatives*
- Community health care center representatives including FQHCs*
- Substance use treatment providers*
- Hospital planning agencies and health care planning agencies*
- Intervention specialists
- Jurisdictions with CDC- funded local education agencies/academic institutions (strongly encouraged to participate).
- Mental health providers*
- Individuals (or representatives) with an HIV diagnosis during a period of incarceration (within the last three years) at a federal, state, or local correctional facility*
- Representatives from state or local law enforcement and/or correctional facilities
- Social services providers including housing and homeless services representatives*
- Local, regional, and school-based clinics; healthcare facilities; clinicians; and other medical providers

- Medicaid/Medicare partners
- Area Agencies on Aging and other aging oriented organizations

Examples of Key Collaborators to Consider for Community Engagement

- Existing community advisory boards
- Community members resulting from new outreach efforts
- Community members that represent the demographics of the local epidemic (e.g., race, ethnicity, sex, age, etc.)
- Community members unaligned or unaffiliated with agencies currently funded through HRSA and/or CDC
- STD clinics and programs
- Other key informants
- City, county, tribal, and other state public health department partners
- Local, regional clinics, and school-based healthcare facilities; clinicians; and other medical providers
- Medicaid/Medicare partners and private payors
- Correctional facilities, juvenile justice, local law enforcement and related service providers
- Community- and faith-based organizations, including civic and social groups
- Professional associations
- Local businesses
- Local academic institutions
- Area Agencies on Aging and other aging oriented organizations
- Other key informants

Examples of Community Engagement Activities

- Focus groups or interviews
- Town hall meetings
- Topic-focused community discussions
- Community advisory group or ad hoc committees or panels
- Collaboration building meetings with new partners
- Public planning body(s) meetings or increased membership
- Meetings between state and local health departments
- Social media events

Appendix 4

Suggested Data Sources

Suggested Data Sources:

- Behavioral surveillance data, including databases such as National HIV Behavioral Surveillance System (NHBS), Youth Risk Behavioral Surveillance System (YRBSS), Behavioral Risk Factor Surveillance System (BRFSS) (e.g., patterns of, or deterrents to, HIV testing, substance use and needle sharing, healthcare-seeking behavior, and adherence to prescribed antiretroviral therapies)
- HIV surveillance data, including clinical data (e.g., CD4 and viral load results) and HIV cluster detection and response data. HIV Surveillance Report, Supplemental Reports, and Data Tables
- STI surveillance data
- HIV testing program data (e.g., data from Early Identification of Individuals with HIV/AIDS for RWHAP Parts A and B Grantees; CDC HIV testing data)
- NCHHSTP AtlasPlus (HIV, STD, Hepatitis, TB, and Social Determinants): https://www.cdc.gov/nchhstp/about/atlasplus.html?CDC_AAref_Val=https://www.cdc.gov/nchhstp/atlas/index.htm?s_cid=ss_AtlasPlusUpdate001
- Medical Monitoring Project: https://www.cdc.gov/hiv-data/mmp/?CDC_AAref_Val=https://www.cdc.gov/hiv/statistics/systems/mmp/index.html
- AHEAD: America's HIV Epidemic Analysis Dashboard: <https://ahead.hiv.gov/>
- Other relevant demographic data (i.e., Hepatitis B or C surveillance, tuberculosis surveillance, and substance use data)
- Qualitative data (e.g., observations, interviews, discussion groups, focus groups, and analysis of social networks)
- Vital statistics data (e.g., state office of vital statistics, National Death Index, Social Security Death Master File)
- Other Federal Data Sources (e.g., Medicaid Data, HOPWA Data, VA Data)
- Local Data Sources (e.g., Department of Corrections, Behavioral Health services data including information on substance use and mental health services)
- Other Relevant Program Data: (e.g. Community Health Center program data).

Appendix 5

Federal Strategic Plans and Resources

Federal Strategic Planning Documents

- [Healthy People 2030](#): Sets data-driven national objectives to improve health and well-being over the next decade.
- [Sexually Transmitted Infections National Strategic Plan for the United States \(2021 - 2025\)](#): Groundbreaking, first ever five-year plan that aims to reverse the recent dramatic rise in STIs in the United States
- [Viral Hepatitis National Strategic Plan: A Roadmap to Elimination \(2021 - 2025\)](#): Provides a framework to eliminate viral hepatitis as a public health threat in the United States by 2030.
- [HHS Ending the HIV Epidemic \(EHE\): A Plan for America Initiative](#): EHE aims to reduce the number of new HIV infections in the United States to fewer than 3,000 per year.

Centers for Disease Control and Prevention (CDC)

- [Ending the Epidemic \(EHE\): Scaling Up HIV Prevention Services in STD Specialty Clinics](#)

U.S. Department of Housing and Urban Development (HUD)

- [HUD Community Planning and Development Program Listing](#)
- [HUD Community Planning and Development – Cross-Program Funding Matrix and Dashboard Reports](#)

Substance Abuse and Mental Health Services Administration (SAMHSA)

- [SAMHSA Grant Awards by State](#)
- [SAMHSA's Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders](#)

National Institutes of Health

- [Centers for AIDS Research \(CFAR\) program](#)

Appendix 6

Sample Letter of Concurrence or Concurrence with Reservations between Planning Body and State or Local Health Department or Funded Agency

Dear (Name):

The [insert name of Planning Body, e.g. planning council, advisory council, HIV planning group, planning body] [insert ***concurs or concurs with reservations***] with the following submission by the [insert name of State/Local Health Department/ Funded Agency] in response to the guidance set forth for health departments and HIV planning groups funded by the CDC's Division of HIV Prevention (DHP) and HRSA's HIV/AIDS Bureau (HAB) for the development of an Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN) for calendar year (CY) 2027-2031.

The planning body (e.g. planning council, advisory council, HIV planning group, planning body) has reviewed the Integrated HIV Prevention and Care Plan submission to the CDC and HRSA to verify that it describes how programmatic activities and resources are being allocated to the most disproportionately affected people and communities and geographical areas with high rates of HIV. The planning body [insert ***concurs or concurs with reservations***] that the Integrated HIV Prevention and Care Plan submission fulfills the requirements put forth by the CDC's Notice of Funding Opportunity for Integrated HIV Surveillance and Prevention Programs for Health Departments and the Ryan White HIV/AIDS Program legislation and program guidance.

[Insert the process used by the planning body to provide input or review the jurisdiction's plan.]

[If applicable, insert how jurisdictions with directly funded states and cities plan to coordinate their HIV Planning process.]

The signature(s) below confirms the [insert ***concurrence or concurrence with reservations***] of the planning body with the Integrated HIV Prevention and Care Plan.

Signature:

Date:

Planning Body Chair(s)

EXHIBIT N

NATIONAL HIV/AIDS STRATEGY



for the **United States**
2022–2025





Acknowledgments: The National HIV/AIDS Strategy (NHAS or Strategy) was developed by the White House Office of National AIDS Policy (ONAP) in collaboration with federal partners and with input from the HIV community across the country. Interested parties and organizations throughout the federal government and those engaged in work in many different communities have helped shape the goals, objectives, and strategies in the Strategy. ONAP extends the gratitude and appreciation of the White House to everyone who made thoughtful recommendations and recommitted to the Strategy’s vision and goals. ONAP also offers thanks to the team at the Office of Infectious Disease and HIV/AIDS Policy in the U.S. Department of Health and Human Services for its many contributions to developing the Strategy.

Language used in the National HIV/AIDS Strategy: The Strategy honors the lived experiences and choices of all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance. To reflect this, authors made a concerted effort to use inclusive and person-first language throughout the strategy. Evidence-based, contemporary terminology is also used to convey respect and to reduce stigma faced by communities and populations disproportionately impacted by HIV. This approach is intended to reflect the administration’s vision for a collective, inclusive, and respectful national response. Despite these efforts, in certain instances, for example to accurately convey scientific meaning, specific terminology or language may be unintentionally offensive or stigmatizing to some individuals or populations.

Additional information regarding the Strategy and associated activities may be accessed at the [White House website](#).

Suggested citation: The White House. 2021. *National HIV/AIDS Strategy for the United States 2022–2025*. Washington, DC.

The National HIV/AIDS Strategy is not a budget document and does not imply approval for any specific action under Executive Order 12866 or the Paperwork Reduction Act. The Strategy will inform the Federal budget and regulatory development processes within the context of the goals articulated in the President’s Budget. All activities included in the Strategy are subject to budgetary constraints and other approvals, including the weighing of priorities and available resources by the Administration in formulating its annual budget and by Congress in legislating appropriations.

VISION ★ ★ ★ ★ ★

The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

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EXECUTIVE SUMMARY

Building on lessons learned and progress made in the past 40 years, the United States now has the opportunity to end the HIV epidemic. This opportunity has been made possible by tireless advocacy, determined research, and dedicated delivery of diagnostic, prevention, care, treatment, and supportive services.

The nation's annual new HIV infections have declined from their peak in the mid-1980s, and people with HIV in care and treatment are living longer, healthier lives. In 2019, the estimated number of new HIV infections was 34,800 and 1.2 million people were living with HIV in the United States. However, not all groups have experienced decreases in HIV infections or improvements in health outcomes. Centers for Disease Control and Prevention data show that new HIV infections fell 8% from 2015 to 2019, after a period of general stability in new infections in the United States. This trend represents a hopeful sign of progress. But gains remain uneven, illuminating opportunities for geographic- and population-focused efforts to make more effective use of the powerful HIV prevention, care, and treatment tools now available.

This National HIV/AIDS Strategy (the Strategy), the nation's third national HIV strategy, updates the HIV National Strategic Plan (2021). The Strategy sets forth bold targets for ending the HIV epidemic in the United States by 2030, including a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. For interested parties and organizations across the nation, the Strategy articulates goals, objectives, and strategies to prevent new infections, treat people with HIV to improve health outcomes, reduce HIV-related disparities, and better integrate and coordinate the efforts of all partners to achieve the bold targets for ending the epidemic. The Strategy also establishes evidence-based indicators to measure progress, with quantitative targets for each indicator, and designates priority populations.

The Strategy establishes the following vision:

The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

The vision, goals, objectives, and other components of the Strategy were developed and approved by a dedicated Steering Committee, composed of subject matter experts from across the federal government, with input from numerous and varied interested parties and organizations in the field. The Strategy is designed to be accessible to and useful for a broad audience, including people working in public health, health care, government, community-based organizations, research, private industry, and academia. It serves as a roadmap for all sectors of society to guide development of policies, services, programs, initiatives, and other actions to achieve the nation's goal of ending the HIV epidemic by 2030.

The Strategy is designed to facilitate a whole-of-society national response to the HIV epidemic in the United States that accelerates efforts to end the HIV epidemic in the United States by 2030 while supporting people with HIV and reducing HIV-associated morbidity and mortality. While not every objective or strategy will speak to or be actionable by all readers, the intent is that individuals and organizations from all sectors of society can find opportunities

where they can support necessary scale-up, expansion, and refinement efforts. All communities, regardless of HIV prevalence, are vital to ending the HIV epidemic in this country and private- and public-sector partners must work together with community-based, faith-focused, and advocacy organizations; governmental public health; mental health and substance use disorder treatment services; the criminal justice system; and providers of housing, food and nutrition, education, and employment services because we all have a role in reducing new HIV infections, improving outcomes and quality of life for people with HIV, and eliminating HIV disparities.

Interwoven throughout the Strategy are approaches to address the individual, community, and structural factors and inequities that contribute to the spread of HIV, such as stigma and social determinants of health. The Strategy highlights opportunities to integrate HIV prevention, care, and treatment into prevention and treatment for sexually transmitted infections, viral hepatitis, mental health and substance use disorders, and other public health efforts by leveraging capacity and infrastructure across the domains and breaking down operational and funding silos. A recurring theme is the need to bring to scale innovative solutions and data-driven approaches to address the ongoing and emerging challenges to HIV prevention, care, and treatment, including expanding the types of community and clinical sites that address HIV to help reach and engage people in need of services; supporting retention in HIV prevention and care services; continuing research into development of better prevention tools, therapeutics, and vaccines; and understanding how to make best use of available tools in real-world settings. Throughout this document, the term “care” is used as an umbrella term meant to encompass holistic services including treatment and supportive services.

To ensure implementation and accountability, a Federal Implementation Plan that documents the specific actions that federal partners will take to achieve the Strategy’s goals and objectives will be developed in early 2022. Progress toward meeting the Strategy’s goals will be monitored and reported annually.

The Strategy and the [*Ending the HIV Epidemic in the U.S.*](#) (EHE) initiative are closely aligned and complementary, with EHE serving as a leading component of the work by the U.S. Department of Health and Human Services (HHS), in collaboration with local, state, tribal, federal, and community partners, to achieve the Strategy’s goals. The EHE initiative focuses on scaling up four strategies in the communities most affected by HIV. The Strategy covers the entire country, has a broader focus across federal departments and agencies beyond HHS and all sectors of society, and addresses the integration of several key components that are vital to our collective work, including stigma, discrimination, and social determinants of health.

NHAS AT-A-GLANCE

This At-A-Glance section briefly summarizes the Goals, Objectives, and Strategies that are discussed in detail in the narrative that follows.



Goal 1: Prevent New HIV Infections

1.1 Increase awareness of HIV

- 1.1.1 Develop and implement campaigns, interventions, and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.
- 1.1.2 Increase knowledge of HIV among people, communities, and the health workforce in geographic areas disproportionately affected.
- 1.1.3 Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders, as well as in primary care and general wellness, and as part of annual reproductive health visits and wellness visits.

1.2 Increase knowledge of HIV status

- 1.2.1 Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.
- 1.2.2 Develop new and expand implementation of effective, evidence-based, or evidence-informed models for HIV testing that improve convenience and access.
- 1.2.3 Incorporate a status-neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.
- 1.2.4 Provide partner services to people diagnosed with HIV or other STIs and their sexual and/or syringe-sharing partners.

1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options

- 1.3.1 Engage people who experience risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.
- 1.3.2 Scale up treatment as prevention (i.e., U=U) by diagnosing all people with HIV, as early as possible, and engaging them in care and treatment to achieve and maintain viral suppression.
- 1.3.3 Make HIV prevention services, including condoms, PrEP, PEP, and SSPs, easier to access and support continued use.
- 1.3.4 Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.
- 1.3.5 Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.

- 1.3.6 Expand implementation research to successfully adapt evidence-based interventions to local environments to maximize potential for uptake and sustainability.

1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

- 1.4.1 Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 1.4.2 Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.
- 1.4.3 Increase the inclusion of paraprofessionals on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.
- 1.4.4 Include comprehensive sexual health and substance use prevention and treatment information in curricula of medical and other health workforce education and training programs.



Goal 2: Improve HIV-Related Health Outcomes of People with HIV

2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment

- 2.1.1 Provide same-day or rapid (within 7 days) start of antiretroviral therapy for persons who are able to take it; increase linkage to HIV health care within 30 days for all persons who test positive for HIV.
- 2.1.2 Increase the number of schools providing on-site sexual health services through school-based health centers and school nurses, and linkages to HIV testing and medical care through youth-friendly providers in the community.

2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

- 2.2.1 Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.
- 2.2.2 Identify and address barriers for people who have never engaged in care or who have fallen out of care.

2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs

- 2.3.1 Support the transition of health care systems, organizations, and patients/clients to become more health literate in the provision of HIV prevention, care, and treatment services.
- 2.3.2 Develop and implement effective, evidence-based, or evidence-informed interventions and supportive services that improve retention in care.
- 2.3.3 Expand implementation research to successfully adapt effective evidence-based interventions, such as HIV telehealth, patient and peer navigators, accessible pharmacy services, community health workers, and others, to local environments to facilitate uptake and retention to priority populations.
- 2.3.4 Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence, and durable viral suppression.

2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

- 2.4.1 Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 2.4.2 Increase the diversity of the workforce of providers who deliver HIV care and supportive services.
- 2.4.3 Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.

2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

- 2.5.1 Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.
- 2.5.2 Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.
- 2.5.3 Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.
- 2.5.4 Promote research, cross-agency collaborations, and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.
- 2.5.5 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.

2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure

- 2.6.1 Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.
- 2.6.2 Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ART-free remission, reduce and eliminate viral reservoirs, and achieve HIV cure.



Goal 3: Reduce HIV-Related Disparities and Health Inequities

3.1 Reduce HIV-related stigma and discrimination

- 3.1.1 Strengthen enforcement of civil rights laws (including language access services and disability rights), promote reform of state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, substance use, and sexism.
- 3.1.2 Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work.
- 3.1.3 Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.
- 3.1.4 Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.
- 3.1.5 Create funding opportunities that specifically address social and structural drivers of health as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.

3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

- 3.2.1 Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.
- 3.2.2 Develop new and scale up effective, evidence-based or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.

3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

- 3.3.1 Create and promote public leadership opportunities for people with or who experience risk for HIV.
- 3.3.2 Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors.

3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities

- 3.4.1 Develop whole-person systems of care and wellness that address co-occurring conditions for people with or who experience risk for HIV.
- 3.4.2 Adopt policies that reduce cost, payment, coverage, and/or access barriers to improve the delivery and receipt of services for people with or who experience risk for HIV.
- 3.4.3 Improve screening and linkage to services for people with or who experience risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.

- 3.4.4 Develop and implement effective, evidence-based and evidence-informed interventions that address social and structural determinants of health among people with or who experience risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.
- 3.4.5 Increase the number of schools that have implemented LGBTQ-supportive policies and practices, including (1) having a Gay/Straight Alliance (GSA), Gender Sexuality Alliance, or similar clubs, (2) identifying safe spaces, (3) adopting policies expressly prohibiting discrimination and harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development, (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- 3.4.6 Develop new and scale up effective, evidence-based or evidence-informed interventions that address intersecting factors of HIV, homelessness or housing instability, mental health and violence, substance use, and gender especially among cis- and transgender women and gay and bisexual men.

3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations

- 3.5.1 Promote the expansion of existing programs and initiatives designed to increase the numbers of non-White research and health professionals.
- 3.5.2 Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.
- 3.5.3 Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.

3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust

- 3.6.1 Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
- 3.6.2 Increase diversity and cultural competence in health communication research, training, and policy.
- 3.6.3 Expand community engagement in health communication initiatives and research.
- 3.6.4 Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.
- 3.6.5 Expand effective communication strategies between providers and consumers to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.



Goal 4: Achieve Integrated, Coordinated Efforts That Address the HIV Epidemic among All Partners and Interested Parties

4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence

- 4.1.1 Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness or housing instability, STIs, viral hepatitis, and substance use and mental health disorders.
- 4.1.2 Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.
- 4.1.3 Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.
- 4.1.4 Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, and local partners.
- 4.1.5 Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.

4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community

- 4.2.1 Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.
- 4.2.2 Enhance collaboration among local, state, tribal, territorial, national, and federal partners and the community to address policy and structural barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.
- 4.2.3 Coordinate across partners to quickly detect and respond to HIV outbreaks.
- 4.2.4 Support collaborations between community-based organizations, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.

4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

- 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.
- 4.3.2 Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator's Health IT Certification Program, and health information exchange networks, to improve HIV prevention efforts and care outcomes.

- 4.3.3 Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy supportive manner.

4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances

- 4.4.1 Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, community-based organizations, allied health professionals, people with HIV and their advocates, the private sector, and other partners.
- 4.4.2 Expand opportunities and mechanisms for information sharing and peer technical assistance within and across jurisdictions to move effective interventions into practice more swiftly.
- 4.4.3 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing persons of all ages living with HIV.

4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals

- 4.5.1 Streamline and harmonize reporting and data systems to reduce burden and improve the timeliness, availability, and usefulness of data.
- 4.5.2 Monitor, review, evaluate, and regularly communicate progress on the National HIV/AIDS Strategy.
- 4.5.3 Ensure that the National HIV/AIDS Strategy's goals and priorities are included in cross-sector federal funding requirements.
- 4.5.4 Strengthen monitoring and accountability for adherence to requirements, targets, and goals by funded partners.
- 4.5.5 Identify and address barriers and challenges that hinder achievement of goals by funded partners and other interested parties.

INDICATORS AT-A-GLANCE

- Indicator 1:** Increase knowledge of status to 95% from a 2017 baseline of 85.8%.
- Indicator 2:** Reduce new HIV infections by 75% from a 2017 baseline of 37,000.
- Indicator 3:** Reduce new HIV diagnoses by 75% from a 2017 baseline of 38,351.
- Indicator 4:** Increase PrEP coverage to 50% from a 2017 baseline of 13.2%.
- Indicator 5:** Increase linkage to care within 1 month of diagnosis to 95% from a 2017 baseline of 77.8%.
- Indicator 6:** Increase viral suppression among people with diagnosed HIV to 95% from a 2017 baseline of 63.1%.
 - Indicator 6a:** Increase viral suppression among MSM diagnosed with HIV to 95% from a 2017 baseline of 66.1%.
 - Indicator 6b:** Increase viral suppression among Black MSM diagnosed with HIV to 95% from a 2017 baseline of 58.4%.
 - Indicator 6c:** Increase viral suppression among Latino MSM diagnosed with HIV to 95% from a 2017 baseline of 64.9%.
 - Indicator 6d:** Increase viral suppression among American Indian/Alaska Native MSM diagnosed with HIV to 95% from a 2017 baseline of 67.3%.
 - Indicator 6e:** Increase viral suppression among Black women diagnosed with HIV to 95% from a 2017 baseline of 59.3%.
 - Indicator 6f:** Increase viral suppression among transgender women in HIV medical care to 95% from a 2017 baseline of 80.5%.
 - Indicator 6g:** Increase viral suppression among people who inject drugs diagnosed with HIV to 95% from a 2017 baseline of 54.9%.
 - Indicator 6h:** Increase viral suppression among youth aged 13-24 diagnosed with HIV to 95% from a 2017 baseline of 57.1%.
- Indicator 7:** Decrease stigma among people with diagnosed HIV by 50% from a 2018 baseline median score of 31.2 on a 10-item questionnaire.
- Indicator 8:** Reduce homelessness among people with diagnosed HIV by 50% from a 2017 baseline of 9.1%.
- Indicator 9:** Increase the median percentage of secondary schools that implement at least 4 out of 7 LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%.

In addition, quality of life for people with HIV was designated as the subject for a developmental indicator, meaning that data sources, measures, and targets will be identified and progress monitored thereafter.

INTRODUCTION

HIV EPIDEMIC: PROGRESS TO DATE

After nearly 40 years of tireless advocacy, determined research, and dedicated delivery of diagnostic, prevention, care, treatment, and supportive services, the United States now has the opportunity to end the HIV epidemic. Since it was first discovered in 1981, HIV has affected the lives of millions of people across the nation. Today, through the ongoing commitment of interested parties and organizations from many sectors, as well as landmark biomedical and scientific research advances, the nation has many effective HIV diagnostics, prevention strategies, and improved care and treatment models. New laboratory and epidemiological approaches enable us to identify where HIV is spreading most rapidly and to respond swiftly to stop the further spread of new HIV transmissions.

Over the past decade, the HIV response in the United States has been guided by the National HIV/AIDS Strategy (NHAS or Strategy), first released in 2010 and updated in 2015. The Strategy has changed the way that Americans talk about HIV, prioritize and coordinate resources, and deliver prevention and care services along with other clinical and nonclinical services that support people with or who experience risk for HIV. It has also led to increased collaboration among federal agencies; people with or who experience risk for HIV; state, local, tribal, and territorial governments; health care providers; researchers; faith communities; and many other community partners. Since the release of those first national strategies, several important achievements have bolstered the nation's HIV response:

- **Population-level viral suppression has increased.** After the NHAS was released, the Centers for Disease Control and Prevention (CDC) published its first national estimates of the share of all people with HIV who have achieved viral suppression, finding that only about one in four people with HIV (27.9%) in the United States was virally suppressed in 2010.¹ By 2019, however, viral suppression rates in the United States had doubled to 57%.² Although still too low, these rates represent real progress.
- **HIV diagnoses have declined, especially in key groups.** HIV diagnosis rates were relatively stable for many years prior to the release of the NHAS. CDC data suggest that annual new diagnoses declined by 14.3% from 2010 (42,938) when the Strategy was released to 2019 (36,337).^{3, 4} Large declines occurred in some groups, including women. Deaths declined by 7.6% from 2010 (16,726) to 2019 (15,463).^{3, 4}
- **Outcome disparities within the Ryan White HIV/AIDS Program have decreased.** Nearly 9 in 10 clients of the Health Resources and Services Administration's (HRSA's) Ryan White HIV/AIDS Program (RWHAP) were virally suppressed in 2019, and the program continues to show progress at reducing disparities across groups.⁵ From 2010 to 2019, the gap between male and female clients decreased from nearly 5 percentage points to <1 percentage point. Similarly, the difference between viral suppression rates in Black clients and White clients was 13 percentage points in 2010 but 7 percentage points in 2019.^{5, 6}
- **Policy changes ensure that federal money follows the epidemic.** Earlier in the epidemic, federal HIV resources to states and local governments were either allocated via a discretionary manner or via a formula that relied on cumulative AIDS cases, skewing resources toward early epicenters of the epidemic and not reflecting the current burden of HIV across the country. Prior to release of the Strategy, Congress changed the formulas used by the RWHAP to be based on living HIV/AIDS cases. The Strategy's call for federal money to follow the epidemic spurred further action. In fiscal year 2012, CDC changed the formula for its major HIV prevention program for state and local health departments to be based on living HIV/AIDS cases, and, in 2016, Congress modernized the law that authorized the Housing Opportunities for Persons With AIDS (HOPWA) program to be based on living HIV/AIDS cases.
- **The advent of pre-exposure prophylaxis (PrEP) has increased options for HIV prevention.** The first randomized controlled trial of PrEP reported results in 2010, and the U.S. Food and Drug Administration (FDA) approved the first PrEP medication in 2012. Several federal actions embraced this new biomedical

tool as an important part of comprehensive HIV prevention: for example, CDC issued interim and then final prescriber guidance; the expansion of PrEP access was a central component of the 2015 update to the NHAS; and the *Ending the HIV Epidemic in the U.S.* (EHE) initiative further sought to remove barriers to PrEP uptake, including through the establishment of the Ready, Set, PrEP program, which makes PrEP available at no cost to individuals without prescription drug coverage. Although uptake remains too low and disparities are large, the adoption of new medical technologies often takes decades, and the goal is to expedite widespread adoption of PrEP for people who can benefit from it.

- **Health insurance coverage rates for people with HIV have increased to match the general population.** In 2018, just 1 in 10 (11%) nonelderly people with HIV were uninsured, a rate on par with that of the general population (10%).⁷ An estimated 42% of the adult population with HIV is covered by Medicaid, compared to 13% of the overall adult population.⁸ Medicaid is the largest source of insurance coverage for people with HIV, covering a broad range of services from inpatient and outpatient care, to prescription medications, to preventive services.⁹
- **Strategic investments by the National Institutes of Health (NIH) in research have advanced efforts toward new prevention tools, next-generation therapies, a vaccine, and a cure.** NIH discovery science has been newly complemented by a suite of NIH implementation science projects designed to meet EHE initiative goals through improved use of proven HIV strategies.
- **States, cities, tribes, and local communities have developed their own HIV strategies.** These strategies (e.g., plans to end the HIV epidemic or achieve zero new infections) aligned with the NHAS and resulted in increased coordination across government agencies, nongovernmental organizations, and the private sector.
- **Interested parties and organizations have enhanced the focus on supports and support services such as housing and employment, which play key roles in enabling economic self-sufficiency and improving health outcomes.** With the effectiveness of early antiretroviral treatment (ART), many people with HIV can (and do) participate in the country's workforce. Employment is associated with improved HIV health outcomes, notably testing, linkage to care, and adherence to medication.¹⁰ Coordination and collaboration at all levels of government and across the public and private sectors have led to an increased awareness of these supports. Moreover, the COVID-19 pandemic has led communities across the nation to employ new strategies in providing support services, improving access to food, housing, and employment services.
- **The *Ending the HIV Epidemic in the U.S.* initiative was launched in 2019.** This bold plan aims to end the HIV epidemic in the United States by 2030. EHE is the operational plan developed by agencies across the U.S. Department of Health and Human Services (HHS) to pursue that goal. The initiative leverages critical scientific advances in HIV prevention, diagnosis, treatment, and outbreak response by coordinating the highly successful programs, resources, and infrastructure of many HHS agencies and offices. The initiative is focused on areas where data show the highest numbers of new HIV infections, providing 57 geographic focus areas with a rapid infusion of additional resources, expertise, and technology to develop and implement locally tailored EHE plans.
- **President Biden issued an Executive Order on preventing and combating discrimination on the basis of gender identity or sexual orientation.** This Executive Order aims to prevent and combat discrimination on the basis of gender identity or sexual orientation, and to fully enforce Title VII and other laws that prohibit discrimination on the basis of gender identity or sexual orientation.

HIV IN THE UNITED STATES TODAY

HIV persists as a serious public health challenge in the United States. An estimated 1.2 million people in the United States had HIV at the end of 2019, the most recent year for which this information is available.¹¹ National HIV prevention and care efforts have taken the nation from a peak of 130,000 HIV infections annually in the mid-1980s¹² to approximately 34,800 in 2019.¹⁰ Although HIV infection rates have decreased in the United States, new infections continue in every U.S. state with 34,800 new infections occurring in 2019.

HOPEFUL SIGNS OF PROGRESS EXIST.

The nation has seen hopeful signs of progress in recent years, but not everyone is benefiting equally from advances in HIV prevention and treatment. The latest CDC data show that new HIV infections declined by 8% from 2015 to 2019, after a period of general stability in new infections in the United States (see Figure 1). Much of this progress was due to larger declines among young gay and bisexual men in recent years.¹³

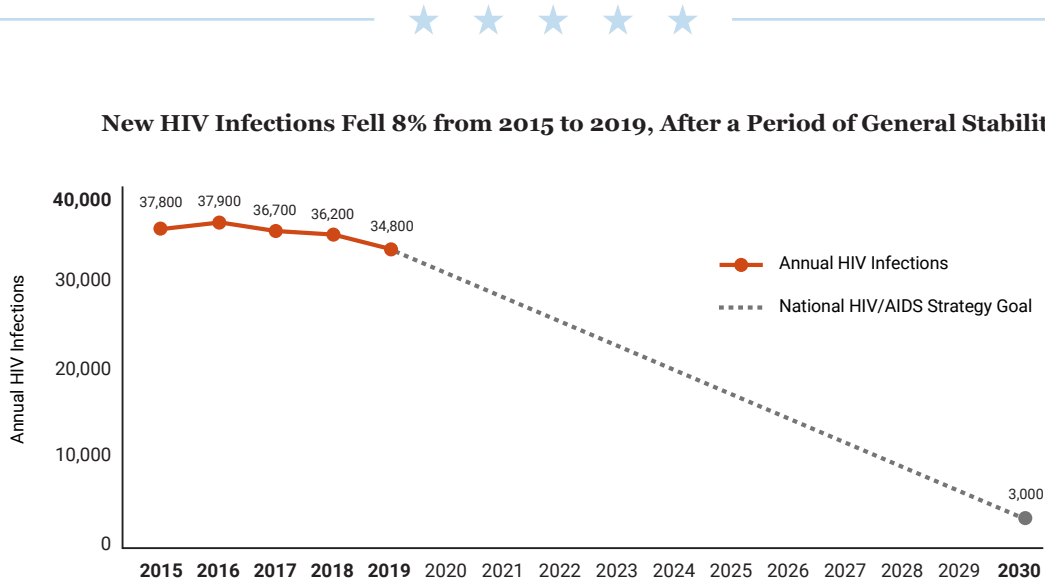


Figure 1. Annual HIV infections in the United States, 2015–2019

Despite this progress, important disparities persist. During this period, Black, Latino, and White gay and bisexual men and Black heterosexual women bore the greatest burden of new HIV infections.¹¹ (See Figure 2.)

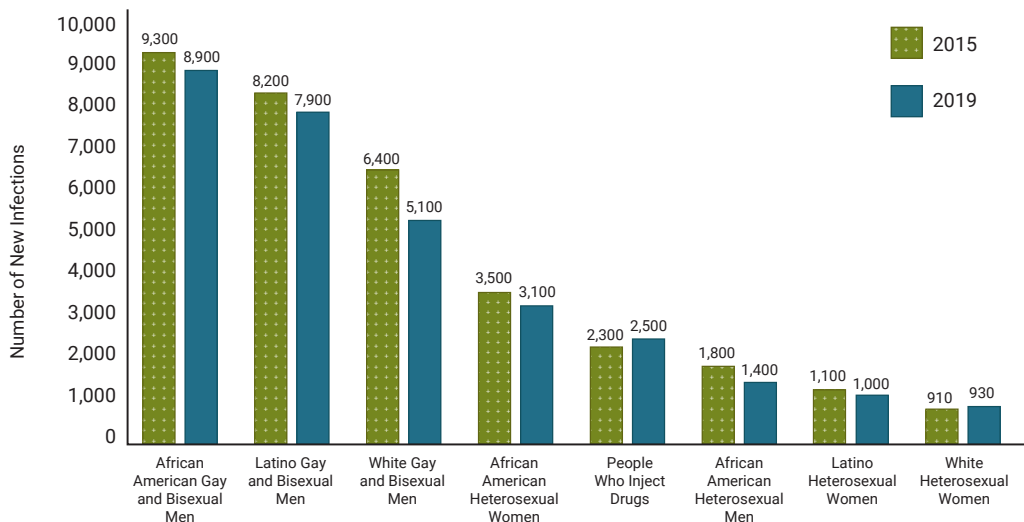


Figure 2. New HIV infections by most impacted populations, United States, 2015 vs. 2019¹¹

EFFECTIVE TREATMENT AND PREVENTION ARE NOT ADEQUATELY REACHING PEOPLE WHO COULD BENEFIT MOST.

Although HIV remains a threat in every part of the United States, certain populations—and parts of the country—bear most of the burden, signaling where HIV prevention, care, and treatment efforts must be focused.

HIV by Population

Black and Latino communities are disproportionately affected by HIV compared to other racial/ethnic groups (see Table 1).

Table 1. Proportion of People with HIV by Race/Ethnicity Compared to Proportion of U.S. Population, 2019

Race/Ethnicity	% of People with HIV, 2019 ¹¹	% of U.S. Population, 2019 ¹⁴
Black/African American	40.3%	13.4%
White	28.5%	60.1%
Hispanic/Latino	24.7%	18.5%
Asian	1.5%	5.9%
American Indian/Alaska Native	0.3%	1.3%
Native Hawaiian and Other Pacific Islander	0.09%	0.2%

The disproportionate impact of HIV among Black and Latino communities is also evident in incidence (new infections). (See Figure 3.)

The latest incidence estimates indicate that effective **prevention and treatment are not adequately reaching people who could benefit most.**

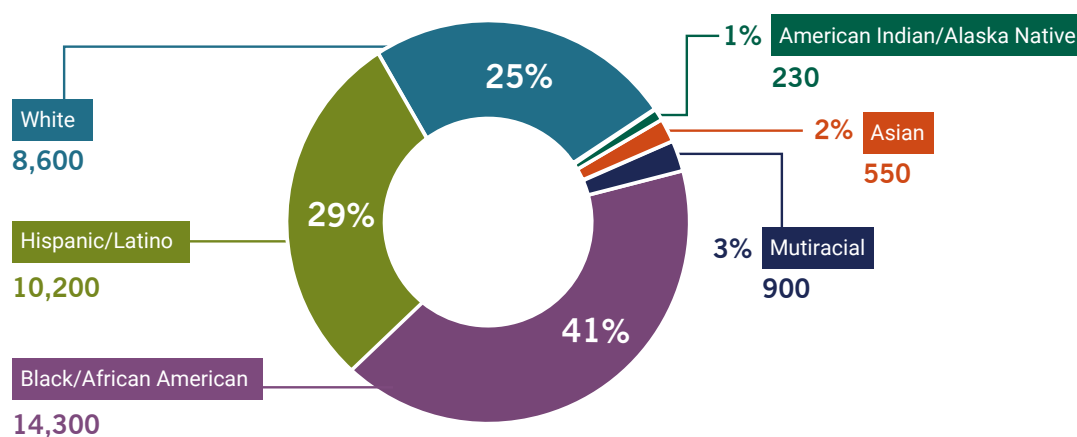


Figure 3. HIV incidence by race/ethnicity, 2019¹¹

In all regions of the United States, gay and bisexual men are the most disproportionately affected group. They account for about 66% of new HIV infections each year, even though they account for only 2% of the population, with the highest burden among Black and Latino gay and bisexual men and young men.^{11, 15} In 2019, 26% of new HIV infections were among Black gay and bisexual men, 23% among Latino gay and bisexual men, and 45% among gay and bisexual men under the age of 35.

Disparities persist among women. Black women are disproportionately affected compared to women of other races/ethnicities. Although annual HIV infections remained stable among Black women from 2015 to 2019, the rate of new HIV infections among Black women was 11 times that of White women and 4 times that of Latina women.¹¹

Over 1 million people identify as transgender in the United States.¹⁶ Adult and adolescent transgender people composed 2% (669) of new HIV diagnoses in the United States and dependent areas in 2019. Most of those new HIV diagnoses were among Black/African American people. Compared to all adults and adolescents with diagnosed HIV in 2019, transgender women had almost equal viral suppression rates, while transgender men had higher viral suppression rates.^{2, 17, 18}

In 2019, youth aged 13–24 years composed 21% of the 36,398 new HIV diagnoses in the United States. Youth with HIV are the least likely of any age group to be retained in care and have a suppressed viral load.³ However, in a national survey of students in grades 9–12 in the United States, significantly fewer students reported being tested for HIV in 2019 (9.4%) than in 2009 (12.4%). In addition, trends over the past 10 years (from 2009 to 2019) indicate significant decreases in the percentage of sexually active high school students who used condoms during last sexual intercourse (61.1% vs. 54.3%), and only 8.6% of sexually active students reported being tested for sexually transmitted infections (STIs) during the past year.¹⁹ This despite the fact that almost half of the 26 million new STIs were estimated to occur in youth ages 15–24 in the United States in 2018.

In 2019, 7% of new HIV infections in the United States were among people who inject drugs (PWID). Men who inject drugs accounted for 4% of new HIV infections, and women who inject drugs accounted for 3%. Long-term declining trends in HIV incidence among people who inject drugs have stalled. For example, from 2015 to 2019, the number of new HIV infections remained stable among people who inject drugs.¹¹ Localized outbreaks have contributed to this trend. People who inject drugs are at high risk for acquiring hepatitis C virus infection, and, in fact, 62–80% of people who inject drugs and have HIV experience coinfection with HIV and hepatitis C.

HIV by Geography

Most of the nation's HIV diagnoses are concentrated in certain geographic areas, that is, urban areas and southern states. In 2016 and 2017, more than half of new HIV diagnoses were concentrated in geographic hotspots across the United States: 48 counties plus Washington, DC, and San Juan, Puerto Rico.⁴ Seven states also have a substantial number of HIV diagnoses in rural areas.²⁰ These 57 jurisdictions are prioritized for the EHE initiative. Southern states account for 38% of the U.S. population but bear the highest burden of HIV infection with 53% of annual HIV infections, 46% of people with HIV, and 52% of people with undiagnosed infections.¹¹ (See Figure 4.)

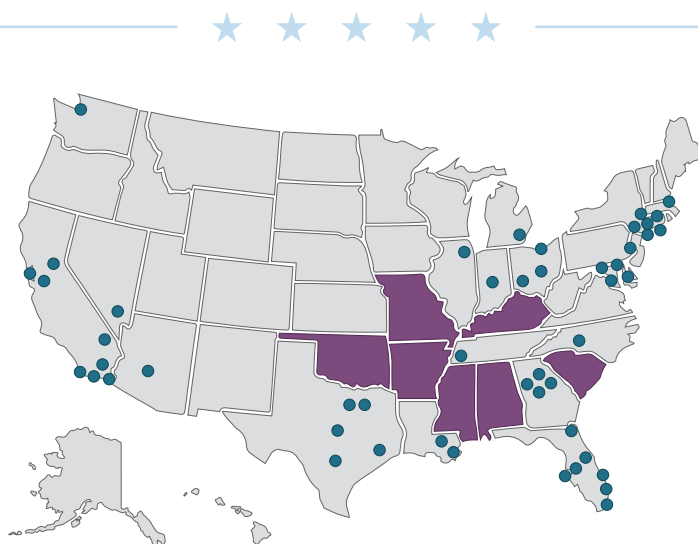


Figure 4. 57 jurisdictions prioritized in the *Ending the HIV Epidemic* initiative

This current landscape of HIV prevention, care, and treatment presents several opportunities and challenges that shape this 5-year Strategy.

OPPORTUNITIES

More tools than ever before are available to end the HIV epidemic in the United States. People who initiate ART soon after diagnosis and remain adherent can live long, healthy lives.²¹ In addition, people with HIV who take ART and achieve and maintain an undetectable viral load have effectively no risk of transmitting HIV through sex.²²⁻²⁵ Thanks to a robust toolbox that includes syringe services programs (SSPs), PrEP, and post-exposure prophylaxis (PEP), and treatment as prevention, an individual's risk of acquiring HIV is significantly lower than ever (see Figure 5).

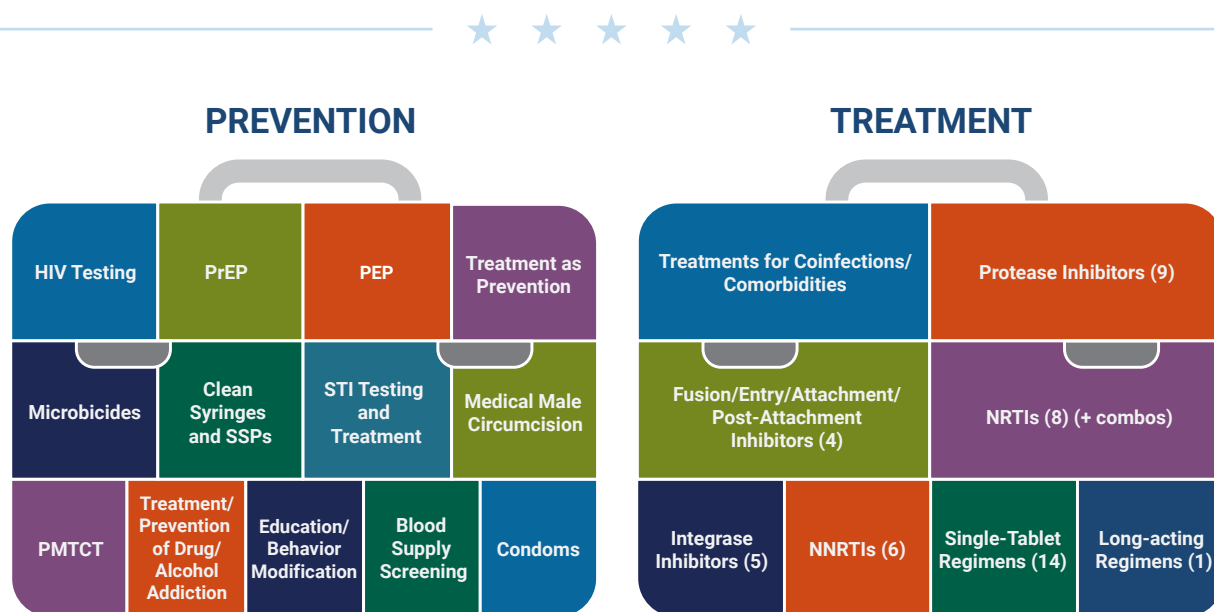


Figure 5. HIV prevention and treatment toolkits. Source: Eisinger et al.²⁶ Published by Oxford University Press for the Infectious Diseases Society of America 2019. This work is written by (a) U.S. Government employee(s) and is in the public domain in the U.S. Image modified with permission of authors.

To realize the full potential of these tools, several opportunities exist to expand the capacity of existing public health infrastructure, health care systems, and the health care and social service workforce. Engaging the diverse communities of people with and affected by HIV in planning for and delivery of HIV prevention and care services is essential. Further, expanding partnerships and training among traditional settings and parties, as well as identifying and working with nontraditional partners that are likely to engage people with or who experience risk for HIV, will better leverage the capacities of more interested parties and organizations to facilitate access to HIV diagnostics, prevention, care, treatment, and supportive services.

Importantly, the availability and use of data from a variety of sources, along with national, state, tribal, territorial, and local (and even clinic-level) indicators and targets, can help guide decision-making, service planning, and resource allocation.

Along with better use of data, ensuring that community-driven planning and decision-making include more diverse voices, expertise, and experiences can enhance how programs and services are tailored, implemented, and assessed to reach the populations that need them.

During the lifespan of this Strategy, other long-acting therapeutics and other simplified HIV drug regimens may become available. The overall value, potential impact, and cost-effectiveness of each new HIV testing, prevention, care, or treatment intervention must be demonstrated. Policy and program development should occur in parallel with the review and approval process for any new prevention or treatment options, such as long-acting injectable or implantable medications. These efforts should incorporate formative research and conversations with all relevant interested parties and organizations, especially patients, providers, and payers to identify challenges and opportunities to prevent gaps between the approval, implementation, and uptake stages.

Ongoing HIV research will facilitate progress toward HIV prevention and treatment, addressing of comorbid health conditions, and better understanding and addressing of HIV disparities and inequities, while advancing novel approaches toward long-term HIV remission and the ultimate goal of an HIV cure. Incorporating a strong implementation science framework in that research will support successful adaption and utilization of effective interventions that are acceptable to target communities.

These opportunities and developments, among others, will continue to transform and help guide the nation's approach to HIV through 2025.

BIOMEDICAL HIV PREVENTION TOOLS

PrEP is medicine that people who experience risk for HIV take to prevent getting HIV from sex or injection drug use.

PEP is HIV medicine used in emergency cases for people who have possibly been exposed to HIV. People must start taking the pill within 72 hours of exposure.

Treatment as Prevention is a highly effective prevention method in which people with HIV take HIV medication daily as prescribed and get and keep an undetectable viral load. As a result, they have effectively no risk of sexually transmitting HIV to their HIV-negative partners. This is often referred to as U=U or "undetectable = untransmittable."

CHALLENGES

Although the United States is making significant progress in improving HIV outcomes, significant challenges remain. Gaps in the HIV care continuum (see Figure 6) are driving HIV transmission. By ensuring that everyone with HIV is aware of their status, receives the treatment they need, and achieves and maintains viral suppression—key steps in the HIV care continuum—we can preserve the health of people with HIV, improve the quality of their lives, and drive down new HIV infections.

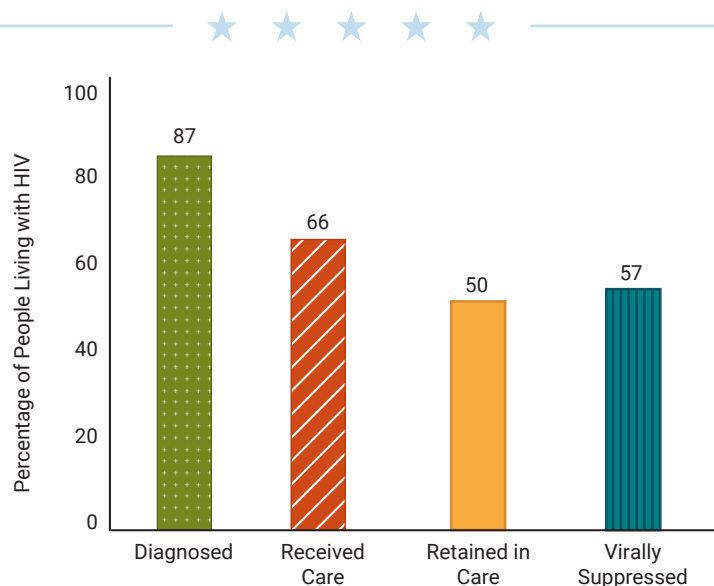


Figure 6. Prevalence-based HIV care continuum, United States, 2019²

The most recent data available (2019) show the following:

- Less than one-half (39%) of the U.S. population has ever been tested for HIV.²⁷ Of people with HIV, an estimated 158,500 (13%) were unaware of their status,¹¹ meaning they are not receiving the care they need to stay healthy and prevent transmission to others. The number unaware is especially high in the South, likely contributing to the high burden of HIV in the region.
- One in three people with HIV (34%) is not receiving needed HIV care.²
- Only 57% of people with HIV were virally suppressed, meaning that 43% are not receiving the benefits of HIV treatment.²

These gaps in the care continuum are challenges to be addressed because, according to a CDC transmission model based on 2016 data, approximately 80% of new HIV infections were transmitted from the nearly 40% of people with HIV who either do not know they have HIV or who received a diagnosis but are not receiving regular care (see Table 2).²⁸

Table 2. HIV Transmissions in the United States, 2016

% of People with HIV	Status of Care	Accounted for X% of New Transmissions ^a
15%	Didn't know they had HIV	38%
23%	Knew they had HIV but weren't in care	43%
11%	In care but not virally suppressed	20%
51%	Taking HIV medicine and virally suppressed	0%

^a Total does not equal 100% because of rounding. Source: CDC.²⁹

In addition to these gaps in HIV diagnoses, care, and treatment, there are HIV prevention challenges. Only 23% of the approximately 1.2 million people indicated for PrEP are receiving it; in other words, about 3 in 4 people who could benefit from PrEP are not receiving it.³⁰ Further, significant disparities in PrEP coverage persist based on race/ethnicity, sex at birth, and age.^{31, 32} Among those who initiate PrEP, daily pill adherence and long-term maintenance can be a challenge.^{33, 34}

Although anyone can acquire HIV, the epidemic disproportionately affects specific populations, communities, and geographic areas across the United States. These disparities exist among gay, bisexual, and other men who have sex with men (MSM), especially Black, Latino,* and American Indian/Alaska Native men. They also exist among Black women, transgender women, youth (particularly gay and bisexual young men and transgender youth), and people who inject drugs. These gaps remain particularly troublesome not only among disproportionately affected populations, but also in some rural areas and the South. In 2019, it was estimated that more than one-half of new HIV infections occurred in the South.¹¹

Inequities in the social determinants of health are significant drivers and contributors to health disparities and highlight the need to focus not only on HIV prevention and care efforts, but also on the ways that programs, practices, and policies affect communities of color and other populations that experience HIV disparities.

Persons from racial and ethnic minority groups are more likely to be uninsured compared to non-Hispanic Whites,³⁵ limiting their access to health care. Barriers to health care access include lack of transportation and childcare, inability to take time off work, experiences with housing instability or homelessness, communication and language barriers, racism, discrimination, and lack of trust in health care providers.

*For this Strategy, Black is defined as African American or Black, and Latino is defined as Latino or Hispanic.

Sexual and gender minorities also face health disparities.³⁶⁻⁴⁰ Barriers to health care include stigma, discrimination, medical mistrust, safety, and lack of access to affirming mental health care.⁴¹ Sexual and gender minorities face greater health challenges than heterosexual and cisgender people due in part to inequities such as stigma and discrimination.³⁷ Sexual and gender minority populations have lower levels of health insurance and access to regular health care compared to heterosexual/cisgender people.^{42, 43}

Another threat to achieving national HIV prevention and care goals is the increase in drug use resulting from both the nation's opioid crisis and resurgent availability and use of methamphetamine and other stimulants among gay men and others who experience higher risk for HIV. Increases in drug use are linked to rising rates, and clusters, of several infectious diseases including hepatitis A, hepatitis B, hepatitis C, and HIV,⁴⁴ which threaten the progress to date to reduce HIV transmission, particularly among people who inject drugs. Recognizing this threat, in 2016 CDC identified 220 counties in 26 states that are vulnerable to HIV and viral hepatitis because of the opioid epidemic.⁴⁵ Many of those counties have taken steps to implement harm reduction services and strengthen their capacity to detect and respond to a potential outbreak. Half of the vulnerable counties were in the Appalachian region, where—along with other areas of the country—there have been multiple recent clusters and outbreaks of new HIV infections among people who inject drugs. Tailored technical assistance and support is needed to help these communities address the syndemic of HIV and hepatitis C virus fueled by substance use disorders. A particular focus should be on supporting them in resolving the local and state structural and systemic issues that get in the way of implementing evidence-based harm reduction and other services for the prevention of HIV and other infectious diseases and making best use of all available substance use disorder and infectious disease funding.

Using drugs or alcohol may lead to sexual behaviors (e.g., having sex without a condom, having multiple partners) that increase the risk of getting or transmitting HIV. In a recent large study of HIV-negative sexual and gender minorities who have sex with men, of whom a substantial proportion used crystal methamphetamine (crystal meth), this highly addictive drug emerged as the dominant risk factor associated with HIV seroconversion, with persistent methamphetamine users accounting for one-third of all observed HIV seroconversions in the study.⁴⁶ Further, a 2018 analysis of the National Notifiable Diseases Surveillance System found substantial overlap in reported substance use and sexual risk behaviors among primary and secondary syphilis cases.⁴⁷ For people with HIV, substance use can hasten disease progression and negatively affect care retention and treatment adherence.⁴⁸

Rising rates of STIs also threaten efforts to reduce new HIV infections.⁴⁹ STIs are associated with a higher risk of transmitting or acquiring HIV.⁵⁰ A recent modeling analysis estimated that 7% of HIV infections were attributed to chlamydia, gonorrhea, syphilis, and trichomoniasis.^{51, 52} Siloed program delivery leads to missed opportunities to screen, link, and provide navigation, care management, and treatment for people with HIV, STIs, viral hepatitis, and substance use and/or mental health disorders.

HIV, STIs, VIRAL HEPATITIS, AND SUBSTANCE USE DISORDERS—A HOLISTIC APPROACH TO THE SYNDEMIC

A syndemic is a set of linked health conditions—such as HIV, viral hepatitis, STIs, and alcohol and substance use and mental health disorders—that adversely interact with one another and contribute to an excess burden of disease in a population. Addressing a syndemic can be challenging because it requires the implementation of integrated and sometimes simultaneous prevention, screening, diagnosis, and treatment efforts, as well as the rapid application of new scientific advances. To be successful, these efforts must go beyond disease-specific responses to identifying and

Stigma is an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable.

Discrimination is often a consequence of stigma, occurring when unfair and often unlawful actions are taken against people based on their belonging to a particular stigmatized group.

addressing root causes, with greater disease risk and poorer health outcomes often closely tied to employment, stable housing, access to health care and food, and other social determinants of health.

A holistic approach to addressing the syndemic of HIV, viral hepatitis, STIs, and substance use and mental health disorders can only be effective if we also continue to explore the connection between mental health, experience of violence and other types of traumas, substance use, and infectious diseases. Past and present trauma, including experience of violence, homo- and transphobia, discrimination, and racism, contribute to the excess burden of disease in many communities at risk for or diagnosed with these health conditions. This burden challenges our collective efforts to provide prevention and care services because models of trauma-informed care are often not fully developed within many health care settings. In addition, ready access to substance use and mental health care, or health care in general, is lacking in many communities, exacerbating existing health disparities in communities of color.

A **syndemic** is a set of linked health problems that interact synergistically and contribute to excess burden of disease in a population.

Social determinants of health and stigma also play a significant role in this syndemic.

The syndemic does not just appear in adulthood; the inter-relationship between sexual health, trauma, mental health, and substance use may have precursors in early childhood and coalesce in adolescence. Adverse childhood experiences have substantial effects on health and well-being through adolescence and into adulthood. In adolescence, sexual risk, substance use, experience of violence, and mental health problems co-occur and represent significant risk for STIs and HIV, particularly among sexual minority youth. The opportunity exists, however, to adopt trauma-informed approaches and bolster the coordination, capacity, and delivery of services to populations with and experiencing risk for these linked conditions.

To help drive a coordinated response to the syndemic, the Strategy complements the Viral Hepatitis National Strategic Plan (Viral Hepatitis Plan) and the Sexually Transmitted Infections National Strategic Plan (STI Plan), both released in early 2021. These plans mutually recognize that both the specific health conditions and the syndemic itself present opportunities to conduct relevant research and analyses, develop evidence-based interventions and policy options, and allocate resources to respond efficiently and effectively. The Strategy aligns with the Administration's statement of first-year drug control priorities and will also align with the comprehensive 2022 National Drug Control Strategy being developed by the White House Office of National Drug Control Policy.

COVID-19 and the Syndemic

This Strategy is being released during the unprecedented COVID-19 pandemic. Since early 2020, SARS-CoV-2, the coronavirus that causes COVID-19 disease, has spread rapidly across the globe, causing more than 200 million confirmed cases worldwide and claiming the lives of more than 4 million individuals to date. The pandemic has caused great uncertainty, including for people with and who experience risk for HIV, STIs, viral hepatitis, and substance use and mental health disorders.

In the United States, the pandemic has exacerbated existing challenges in public health and health care systems, exposing longstanding and pervasive structural inequities. Many clinical and public health services focused on people with or who experience risk for HIV, viral hepatitis, STIs, and substance use and mental health disorders have been forced to reduce hours or close temporarily, with staff redeployed to address the public health emergency. These actions have particularly affected populations who are already disproportionately affected by these health conditions and who are most vulnerable to the economic and societal consequences of the pandemic, including loss of employment and insurance, the necessity to work in unsafe environments, housing and food insecurity, cutbacks to public transportation, lack of access to credible health information in multiple languages, and obstacles to practicing safe social distancing. Faced with these challenges, many individuals have not received necessary medical care or related services. Implementation of the Strategy should consider the potential long-term effects caused by these circumstances.

The Strategy accounts for the many lifesaving program innovations and policy changes that were developed to counteract the curtailment of in-person visits and other challenges posed by the COVID-19 pandemic. Examples include the use of telephone- and video-based telehealth visits to ensure that people who experience risk for HIV can access PrEP and that people with HIV can access ongoing care and treatment; exploration and implementation of tele-harm reduction approaches to substance use disorder treatment and HIV treatment; distribution of HIV self-tests and home specimen collection kits; multi-month dispensation of ART; condom delivery; and modification of policies to support mail order, home delivery, or curbside pick-up of medication. Further, community-based programs expanded their roles to ensure the safety of health care workers, clients, and community members by distributing timely and accurate information about COVID-19 testing and vaccinations; facilitating interactions with public health authorities; and serving as testing and vaccination sites.

These innovations in HIV prevention and care delivery prove that the nation can innovate and adapt to ensure that access to HIV prevention and treatment services continues uninterrupted—even in the presence of unprecedented circumstances. Although their outcomes must be studied, many of these innovations may prove worth sustaining as effective tools in our work to achieve our national HIV goals. Our tasks ahead are to carefully determine how to preserve these innovations over the long term for people who can benefit from them, adapt these innovations to achieve success with other populations, and leverage resources to deliver these innovations to larger audiences.

NATIONAL HIV/AIDS STRATEGY 2022–2025

This Strategy, updated for 2022–2025, builds on the lessons learned and progress of previous iterations and seeks to leverage opportunities and address the challenges that remain. It provides a national roadmap for continuing the coordinated response to HIV and puts the country on the path to end the HIV epidemic in the United States by 2030. The Strategy is guided by this vision statement:

The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment, lives free from stigma and discrimination, and can achieve their full potential for health and well-being across the lifespan.

This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.

OVERVIEW

This Strategy includes the following:

- Four goals to achieve this vision, specific objectives for each goal, and strategies for each objective.
- Priority populations, identified by national-level data as being disproportionately affected by HIV, to help focus stakeholder efforts and resource allocation.
- Nine core indicators, one disparities indicator stratified for each priority population with quantitative targets to track progress toward achieving national HIV goals, and one developmental indicator to be established.

OBJECTIVES AND STRATEGIES

The Strategy sets forth four goals, objectives for each goal, and strategies for each objective (see Table 3 for definitions). These objectives and strategies are designed to guide federal partners as well as nonfederal parties in achieving the Strategy’s vision and goals. The objectives provide direction for the attainment of each goal. The strategies recommend approaches to achieve the objectives. Numerous objectives and strategies could fit under more than one goal. However, each one has been placed under the goal with which it most closely aligns.

Table 3. Definitions of Elements of the Strategy

National HIV/AIDS Strategy	Federal Implementation Plan
Goals: Broad aspirations that enable a plan’s vision to be realized Objectives: Changes, outcomes, and impact a plan is trying to achieve Strategies: Choices about how best to accomplish objectives	Action Steps: Specific activities that will be performed to implement the strategies and achieve the goals of the plan Progress Reports: Reports on progress, successes, and challenges

^a Adapted from the HHS Office of the Assistant Secretary for Planning and Evaluation.

The Strategy’s objectives and strategies are intended to be implemented by a broad mix of interested parties and organizations at all levels and across many sectors, both public and private. They also serve as a tool to foster a shared focus, enhance coordination of efforts across agencies and programs, and identify areas of synergy and new opportunities to sharpen collective efforts. The strategies are intended to be scalable by implementer type and size of population to be served.

INDICATORS

The Strategy adopts bold targets for ending the HIV epidemic in the United States by 2030, calling for a 75% reduction in new HIV infections by 2025 and a 90% reduction by 2030. The Strategy’s goals, objectives, and strategies focus on achieving national targets set for 2025, setting the stage to ultimately end the HIV epidemic by 2030. As such, the Strategy’s vision, goals, objectives, strategies, indicators, and quantitative targets align with the EHE initiative, which complements and will serve as one of many important implementation elements of the Strategy (see Box 1).

The Strategy includes indicators for measuring progress and quantitative targets for each indicator. There are nine core indicators, one of which is stratified to measure progress in addressing HIV disparities in the priority populations (i.e., disparities indicators). In addition, one key issue, quality of life for people with HIV, was designated as the subject for a “developmental indicator,” meaning that data sources, measures, and targets will be identified, and progress monitored thereafter. The Strategy’s indicators and quantitative targets also align with *Healthy People 2030*. A detailed discussion of the indicators, including methodology, and specifications is found in Appendix A.



BOX 1 THE NATIONAL HIV/AIDS STRATEGY AND THE *ENDING THE HIV EPIDEMIC IN THE U.S.* INITIATIVE

The Strategy and *Ending the HIV Epidemic in the U.S.* (EHE) initiative are complementary, with EHE serving as a leading component of the work by the U.S. Department of Health and Human Services (HHS), in collaboration with federal, state, tribal, territorial, and local partners, to end the HIV epidemic in the United States by 2030. Both the Strategy and the EHE initiative aim to reduce new HIV transmissions in the United States by 75% by 2025 and by 90% by 2030, which would mean fewer than 3,000 new HIV infections per year.

EHE efforts focus on 57 priority jurisdictions, including 48 counties, Washington, DC, and San Juan, Puerto Rico, where greater than 50% of new HIV diagnoses occurred in 2016 and 2017, as well as 7 states with a disproportionate occurrence of HIV in rural areas. With additional funding appropriated by Congress, HHS is providing the 57 geographic focus areas with an infusion of additional resources, expertise, and technology to develop and implement locally tailored EHE plans. Those plans, developed and being implemented with significant community involvement, focus on four pillars:

- Diagnose all people with HIV as early as possible.
- Treat people with HIV rapidly and effectively to reach sustained viral suppression.
- Prevent new HIV transmissions by using proven interventions, including preexposure prophylaxis (PrEP) and syringe services programs (SSPs).
- Respond quickly to potential HIV outbreaks to get prevention and treatment services to people who need them.

The scope of the Strategy extends to agencies beyond HHS and encompasses the entire nation. The Strategy presents a holistic approach to engaging a broad range of interested parties and organizations across many sectors of society to not only end the HIV epidemic by 2030, but also address other components of the syndemic, stigma, discrimination, and social determinants of health.

PRIORITY POPULATIONS

Although HIV affects people from all social, economic, and racial and ethnic groups, and from all parts of the United States, it disproportionately affects certain populations. The disproportionate prevalence of HIV in specific populations increases the risk for HIV transmission with each sexual or injection drug use encounter within those populations. In addition, a range of social, economic, and demographic factors—such as stigma, discrimination, socioeconomic status, income, education, age, and geographic region—affect people’s risk for HIV or their ability to access or remain engaged in prevention or care services.

To focus effort and resources for the greatest impact, the Strategy uses national-level HIV surveillance data to identify populations disproportionately affected by HIV. The following factors were considered: (1) incidence of new HIV infections and trends; (2) prevalence of HIV; (3) HIV diagnoses; (4) outcomes along the HIV care continuum; and (5) potential impact of other major public health threats (e.g., opioid epidemic). Based upon this analysis, the Strategy prioritizes efforts to reduce disparities and improve HIV outcomes among

- gay, bisexual, and other men who have sex with men, in particular Black, Latino, and American Indian/Alaska Native men;

- Black women;
- transgender women;
- youth aged 13–24 years; and
- people who inject drugs.

Focusing efforts on these five priority populations will reduce the HIV-related disparities they experience, which is essential if the nation is to succeed on the path toward ending the HIV epidemic by 2030.

To drive action and measure progress toward reducing health inequities and disparities among the priority populations, the Strategy uses viral suppression, stratified by population, as an indicator. Viral suppression was selected as the disparities indicator because increasing and maintaining viral suppression among priority populations will improve health outcomes, reduce HIV-related deaths, and prevent new HIV transmissions. Monitoring progress on these disparities indicators also helps ensure that the nation is making progress with all populations, leaving no groups behind.

This Strategy acknowledges that other populations with unique circumstances warrant specific attention, such as sex workers, immigrants, older adults, people experiencing housing instability or homelessness, individuals with disabilities, and justice-involved individuals. For example, the risk of HIV among people who exchange sex for money, drugs, food, or shelter is high; however, little data exist for this population. The illegal—and often criminalized—nature of exchange sex complicates the collection of population-wide data on HIV risk among this population. Nevertheless, the high prevalence of HIV and STIs among people who participate in exchange sex warrants attention. Sex work is largely performed by transgender women, cisgender women, and men who have sex with men, and is also heavily concentrated among Black and African Americans. The convergence of gender, poverty, and racial and ethnic discrimination as social determinants of health within exchange sex must be examined further to fully understand the HIV epidemic.

Similarly, some non-U.S.-born people with or experiencing risk for HIV face unique challenges when accessing prevention, care, and treatment services. Discrimination, lack of culturally and linguistically competent service providers, and fear of interacting with health care systems and other authorities are often barriers to accessing needed services.

People involved in the justice system face a confusing/disparate system of prevention and care services, often for short time periods. These individuals experience a disproportionately high risk of HIV, as well as risk factors associated with under-utilization of prevention and treatment options, including substance use, mental health issues, and poor access to care.⁵³ Improving HIV prevention and management among justice-involved people requires innovative approaches to integrating care. HIV programs must work with state and local facilities to ensure that care services are provided throughout the justice system, particularly to people upon release back to their communities; pre- and post-transition planning is critical to decreasing barriers to care.

More than one-half of people diagnosed with HIV in the United States today are over age 50. Although an indicator of the success of modern HIV treatment, this statistic signals the need to tailor services to individuals within this population not only to continue their engagement in care and viral suppression but also to address the comorbidities and psycho-social needs often associated with aging.

Evidence suggests that some people with disabilities may experience higher risk of acquiring HIV than people who are not disabled. Some of the factors associated with this risk include poverty, vulnerability to sexual violence and abuse, limited access to education and health care, and social marginalization. Some people with disabilities may experience barriers to accessing the HIV prevention, testing, or care and treatment services they need.

People with HIV often have other disabilities, and people with disabilities can be at higher risk for acquiring HIV than the general population. Adopting syndemic approaches that place HIV in the context of multiply marginalized

communities and that seek to comprehensively leverage a variety of health care, social services, and other community supports to improve overall community health offers an important opportunity to strengthen health care outcomes and improve the quality of life.

Local partners and interested parties should use local surveillance and program data on HIV—as well as on STIs, viral hepatitis, and social determinants of health—to identify the populations most affected in their communities and to understand the outcomes for each population along the continuums of HIV prevention and care. Each state, tribe, community, program, or clinic will make its own assessment of relevant priority populations so that programs and services can be tailored and focused accordingly. In some jurisdictions, local surveillance and program data may indicate that additional populations not mentioned here are experiencing persistent HIV disparities that require focus from local efforts.

In addition, some partners and organizations may work with specific populations or communities in a limited area with data that vary somewhat from the national data. For example, on a federal level, agencies such as the Indian Health Service, CDC’s Division of Adolescent and School Health, Department of Veterans Affairs, Federal Bureau of Prisons, and Administration for Community Living serve distinct populations with or who experience risk for HIV. Likewise, state, tribal, territorial, and local jurisdictions, as well as schools and other institutions, may serve distinct populations. For these and other interested parties, efforts should be guided by an assessment of health disparities within their purview and/or jurisdiction to determine how best to focus available resources to achieve results with the greatest impact.

IMPLEMENTATION

A separate NHAS Federal Implementation Plan will be developed in early 2022 and will detail federal partners’ plans and activities to implement the strategies set forth in this document. During development of that plan, the federal partners involved will explore opportunities to engage other federal departments or agencies that could expand services or that administer programs or support delivery of services that address social determinants of health and reduce health disparities and, as such, could make vital contributions to national efforts to end the HIV epidemic.



GOAL 1: PREVENT NEW HIV INFECTIONS

THE OPPORTUNITY

The most effective ways to reduce new HIV infections are to ensure timely diagnosis and engagement in care and treatment for people with HIV so that they achieve and maintain viral suppression and therefore cannot transmit the virus; target prevention resources to the places with the largest disease burden and the populations experiencing greatest risk; and ensure that the most effective prevention strategies are prioritized and widely implemented. An array of HIV prevention options, for use in combination or on their own, is available to people with or experiencing risk for HIV.

- **HIV treatment as prevention.** Evidence has definitively shown that people with HIV who achieve and maintain an undetectable viral load by taking HIV medication as directed will not sexually transmit the virus to an HIV-negative partner.
- **HIV testing and engagement in care.** Nearly 40% of people with HIV are unaware of their status or are diagnosed but not receiving care. In 2016, people unaware or not receiving care accounted for nearly 80% of new HIV infections in the United States.²⁸
- **PrEP.** Because of the 2019 USPSTF recommendation that clinicians offer PrEP with effective ART to persons who are at high risk of HIV acquisition, as of January 2021 HHS requires most insurance plans to cover PrEP without copay or cost-sharing as a result of the preventive care provisions of the ACA. Implementation guidance issued in July 2021 clarified that this coverage also includes a range of clinical services as part of PrEP clinical care.^{54, 55} In addition, in 2019 FDA approved a second PrEP drug for people assigned male at birth. A generic version of the original drug became available, increasing options for people who wish to use PrEP. Researchers are investigating a variety of non-vaccine HIV prevention products including long-acting injectable antiretrovirals, long-acting oral pills, vaginal rings, vaginal and rectal gels, and more. If found safe and effective and approved by FDA, these products would further expand the options in the prevention toolbox.
- **SSPs, medication for treatment of opioid use disorder, and other harm reduction services.** Nearly 30 years of research shows that comprehensive SSPs are safe, effective, and cost-saving; do not increase illegal drug use or crime; and play an important role in reducing the transmission of HIV, viral hepatitis, and other infections.⁵⁶ FDA has approved several different medications to treat alcohol and opioid use disorders. Certain medications for opioid use disorder relieve the withdrawal symptoms and psychological cravings resulting from opioid dependence. Research also shows that these medications and certain behavioral therapies can contribute to lowering a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse. Appropriations language from Congress permits the use of funds from HHS, under certain circumstances, to support SSPs with the exception that funds may not be used to purchase needles or syringes. [Multi-agency guidance](#) was issued on this opportunity, and in 2020 CDC published a [technical package](#) on effective strategies and approaches for planning, design, and implementation of SSPs. The White



GOAL 1: PREVENT NEW HIV INFECTIONS

Objectives

- 1.1 Increase awareness of HIV
- 1.2 Increase knowledge of HIV status
- 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options
- 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

House Office of National Drug Control Policy also included several actions related to increasing access to SSPs in its first-year policy priorities, including authorizing the use of federal funds to purchase syringes and other supplies.⁵⁷ In addition, in October 2021, the HHS released the new HHS Overdose Prevention Strategy in which evidence-based harm reduction services, including SSPs, are prioritized as a key target area of action.⁵⁸

- **PEP, condoms, and other effective prevention interventions.** PEP is a short course of HIV medicines taken very soon after a possible exposure to HIV to prevent the virus from taking hold in the body. PEP should be used only in emergency situations and must be started within 72 hours after a recent possible exposure to HIV. Correct condom use remains one of the most effective methods to reduce the risk of HIV transmission during sexual activity. The CDC and USPSTF recommend intensive behavioral counseling on ways to prevent STIs (including HIV) in all adolescents and adults at increased risk for STIs.

In addition, a range of HIV prevention or multipurpose prevention products are under development or regulatory review, which could result in even more HIV prevention tools becoming available within the 5-year span of this Strategy.

CHALLENGES

The following challenges hinder efforts to reduce new infections:

- HIV awareness remains too low.^{59, 60}
- HIV testing and diagnosis opportunities are being missed (see Box 2).⁶¹
- STIs are surging in the United States (see Box 3).⁶²
- A significant number of people with HIV are unaware of their status or are diagnosed in the later stages of their HIV disease.^{3, 11}
- Retention in HIV care is suboptimal.²
- Uptake of PrEP is too low.^{30, 63, 64}
- There are a range of policy, legal, and resource barriers that limit full implementation of SSPs, especially in the most needed areas.^{65, 66}



BOX 2 MISSED OPPORTUNITIES FOR HIV DIAGNOSIS

Substantial numbers of people who are diagnosed with HIV and who had experienced high risk for HIV experienced missed opportunities for earlier diagnosis. For example, in one study, approximately one-half of newly diagnosed gay and bisexual men and people who inject drugs had been unaware of their infection until diagnosed during the study. They reported not being offered HIV testing by any health care provider despite having seen one within the past year.⁶¹ Further, a retrospective study at an urban adolescent HIV clinic found that many youth recently diagnosed with HIV had prior primary and acute care encounters within the health care system but did not receive an HIV test.⁶⁷

Other studies have highlighted missed opportunities by setting. For example, STI clinic patients experience increased risk for HIV, yet data from nine STI clinics across the United States revealed that three-quarters of STI clinic patients were not tested for HIV despite visiting the clinic within the past year.⁶⁸



BOX 2 MISSED OPPORTUNITIES FOR HIV DIAGNOSIS (CONTINUED)

Similarly, more than two-thirds of missed opportunities for HIV diagnoses in a Louisiana health care system occurred at health care visits outside the primary care setting, including inpatient care, specialty care clinics, surgical specialties, ob-gyn visits, and emergency care facilities.⁶⁹ In addition, an infectious disease practice in New Jersey found that hospital emergency departments and subspecialty clinics were the two most common settings for missed testing opportunities, with between 37% and 45% of patients presenting with a new HIV diagnosis with an encounter in the institution in the year prior.⁷⁰ Dental facilities present another opportunity to provide point-of-care HIV screening and testing.⁷¹ Pharmacies and retail clinics represent a vast, largely untapped potential for the delivery of HIV testing in settings that are more accessible and, for some people, less stigmatizing than traditional settings.⁷² Finally, the Centers for Disease Control and Prevention recommends that HIV screening be provided upon entry into and before release from correctional settings and that voluntary (opt-out) HIV testing be offered periodically during incarceration.⁷³ Studies have shown that opportunities for HIV diagnosis and linking HIV-positive individuals with justice system involvement to community care after release are being missed in the majority of prison systems and jails.^{74, 75}

COVID-19 testing and vaccinations also present an opportunity to diagnose people who are unaware of their HIV status. One hospital in an urban setting saw a “considerable increase in acute HIV diagnoses” when it linked HIV screening with COVID testing in emergency departments.⁷⁶

Missed opportunities for HIV testing result in diagnosis delays, disease progression, and lack of access to HIV care and treatment. They also prolong the time a person is unaware of their infection, increasing the potential for HIV transmission. For care and treatment to effectively reduce HIV incidence, improved testing coverage and frequency are needed to ensure that a large proportion of cases are diagnosed and treated soon after infection occurs.



BOX 3 OPPORTUNITIES FOR ENHANCED HIV PREVENTION SERVICES IN STI SPECIALTY CLINICS

STI specialty clinics have been an important health care setting for people who may not otherwise have access to health care services, including those who are uninsured, and for people seeking low-barrier (e.g., nontraditional hours, walk-in or express appointments, low or no cost), expert, and confidential services. STI clinics serve people who may not be engaged in HIV prevention programs or the primary health care system for their STI and HIV prevention, care, and treatment.⁷⁷⁻⁷⁹ As such, they are suitable settings to (1) reach people who could benefit from HIV pre-exposure prophylaxis (PrEP) and nonoccupational post-exposure prophylaxis (PEP), including people diagnosed with an STI; and (2) identify people with HIV who are either unaware of their status or are not virally suppressed and could benefit from linkage to or reengagement in care.⁸⁰

An evaluation of HIV testing events funded by the Centers for Disease Control and Prevention provided further evidence of STI clinics' important role in identifying people who experience increased risk for HIV. In 2019, STI clinics provided almost one-third of all CDC-funded HIV tests conducted among health care settings, and approximately 20% of all newly identified HIV-positive persons were diagnosed in STI clinics.⁸¹

SUMMARY OF OBJECTIVES

The following objectives are critical to achieving the goal of preventing new HIV infections:

- 1.1 Increase awareness of HIV
- 1.2 Increase knowledge of HIV status
- 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options
- 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

OBJECTIVES AND STRATEGIES

Objective 1.1 Increase awareness of HIV

Nearly four decades into the HIV epidemic, too many people still lack essential information about HIV or hold misconceptions about the virus, including how it is prevented and transmitted. The resulting misperception of self-risk and perpetuation of HIV-related stigma and discrimination can deter people from learning their status, accessing prevention services, seeking or remaining in care, or supporting people who need diagnostic, prevention, care, or treatment services.

More must be done to increase HIV awareness among everyone, but especially among people, communities, and the health workforce where HIV is most heavily concentrated. Messaging must be clear, specific, consistent, and [culturally and linguistically appropriate](#) and must reflect today's scientific knowledge of HIV disease progression, its impact on community and individual health, the importance of early and sustained HIV treatment, and the health and prevention benefits of viral suppression. Once developed, the messaging should be broadly and persistently disseminated as educational campaigns using both traditional and social media delivered by trusted community members and community influencers.

School-based health programs that include sexual health education and connect youth to services serve to create safer and more supportive school environments, particularly for LGBTQI+ youth.⁸² These environments help prevent HIV among adolescents by providing students with the knowledge and skills to help them be healthy and avoid HIV. Comprehensive school-based health programs ensure that students can access the services they need, and promote protective factors, such as school connectedness, that have long-term impact on risk for HIV. HIV prevention implemented in schools includes curricula that are medically accurate, developmentally appropriate, affirming, culturally relevant, accessible, and universally designed with content and skills that target key behavioral outcomes and promote healthy sexual development. Efforts to improve the safety and supportiveness of school environments include the provision of policies and practices that support LGBTQI+ students as well as activities that increase school connectedness and parent engagement.

Suitable primary prevention approaches focused on youth should be age-appropriate, linguistically and culturally informed, community-centered, accessible and universally designed, inclusive, stigma-reducing, and grounded in science and medicine. According to the American Academy of Pediatrics, developmentally appropriate and evidence-based education about human sexuality and sexual reproduction provided over time by pediatricians, schools, other professionals, and parents is important to help children and adolescents make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health.⁸³ Similar recommendations were presented in a 2021 report issued by the National Academies of Sciences, Engineering, and Medicine, which called for the adoption of a holistic sexual health paradigm, among other actions, to reduce STIs.⁸⁴ School-based programs that use strategies to increase sexual health education, connect youth to needed services, and increase the safety and supportiveness of school environments have been demonstrated to reduce sexual risk behavior, experience of sexual violence, and substance use.⁸³ Primary prevention should be a part of comprehensive sexual education, particularly for youth, including delayed initiation of sexual activity for those who are not yet sexually active, and non-judgmental and affirming information about safer sexual activity for those who are sexually active.

These efforts must engage organizations and people who shape and influence knowledge, attitudes, beliefs, and behaviors, particularly among populations that experience risk of HIV, as well as leverage digital strategies and new technologies to reach the highest number of people at relevant access points.

Strategies

- 1.1.1 Develop and implement campaigns, interventions, and resources to provide education about comprehensive sexual health; HIV risks; options for prevention, testing, care, and treatment; and HIV-related stigma reduction.
- 1.1.2 Increase knowledge of HIV among people, communities, and the health workforce in geographic areas disproportionately affected.
- 1.1.3 Integrate HIV messaging into existing campaigns and other activities pertaining to other parts of the syndemic, such as STIs, viral hepatitis, and substance use and mental health disorders, as well as in primary care and general wellness, and as part of annual reproductive health visits and wellness visits.

Objective 1.2 Increase knowledge of HIV status

In addition to general knowledge about HIV, it is important for people with HIV to receive a diagnosis (also known as knowledge of HIV status), which would allow them to take control of their health. Full implementation of CDC and USPSTF screening and testing guidelines is critical to increasing knowledge of status (see Box 4). Innovative models and approaches that expand access to and availability of testing in various settings such as routine opt-out testing in clinical settings, testing in retail pharmacies, self-testing, testing in correctional facilities, mobile testing, and self-testing offered via social networks are required. Early detection coupled with prompt linkage to care and immediate initiation of treatment is also critical and can lead to improved individual and community

health outcomes. The U.S. Department of Veteran Affairs (VA) provides an innovative solution in which pharmacists developed a clinical dashboard that lists patients needing action, including a shared electronic medical record to span HIV, STI, viral hepatitis, and PrEP needs of VA patients. The dashboard enables staff to access quality improvement data, benchmarks against other comorbidities, and comparative analysis by year for improvement purposes.



BOX 4 HIV TESTING RECOMMENDATIONS

U.S. Preventive Services Task Force (USPSTF) Recommendation (2019)—USPSTF recommends that clinicians screen for HIV in adolescents and adults aged 15–65 years. Younger adolescents and older adults who experience increased risk of infection should also be screened. USPSTF also recommends that clinicians screen for HIV infection in all pregnant women, including those who present in labor or at delivery with unknown HIV status. [Read the recommendation.](#)

Centers for Disease Control and Prevention (CDC) Recommendations (2006)—CDC recommends that everyone aged 13–64 years get tested for HIV at least once as part of routine health care. For those with specific risk factors, CDC recommends testing at least annually. [Read the recommendations.](#)

Expansion of the status-neutral approach to HIV care allows for ongoing engagement in HIV prevention, care, and treatment regardless of a person’s HIV status (see Box 5). Embracing a status-neutral approach helps improve care and service provision and eliminates structural HIV and other intersecting stigma by meeting people where they are, offering a “whole person” approach to care, and putting the needs of the person ahead of their HIV status. By embedding HIV prevention and care into routine care, this approach advances health equity by integrating HIV prevention and care with strategies that address social determinants of health and barriers to accessing and remaining engaged in care. HIV testing serves as the entry point to services—the pathway to prevention and treatment. In addition, people are assessed for and engaged in continuous care and supportive services if needed to improve health and prevent new infections (see Figure 7). Health care providers and public health partners play critical roles in a status-neutral approach.

Strategies

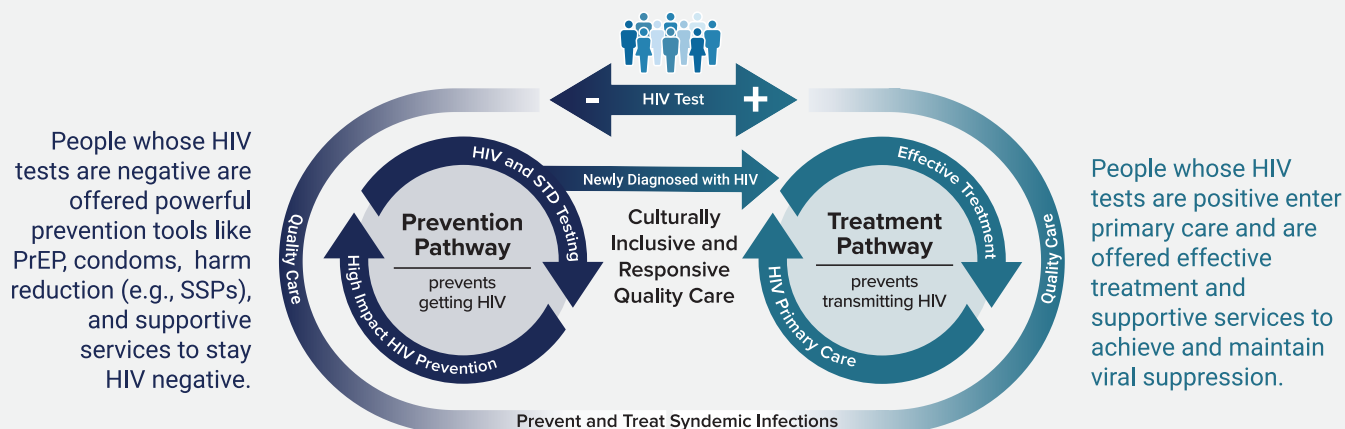
- 1.2.1 Test all people for HIV according to the most current USPSTF recommendations and CDC guidelines.
- 1.2.2 Develop new and expand implementation of effective, evidence-based or evidence-informed models for HIV testing that improve convenience and access.
- 1.2.3 Incorporate a status-neutral approach to HIV testing, offering linkage to prevention services for people who test negative and immediate linkage to HIV care and treatment for those who test positive.
- 1.2.4 Provide partner services to people diagnosed with HIV or other STIs and their sexual and/or syringe-sharing partners.



BOX 5 STATUS-NEUTRAL APPROACH TO HIV SERVICES

Adoption of a status-neutral approach to HIV services—in which HIV testing serves as an entry point to services regardless of positive or negative result—can improve testing as well as prevention and care outcomes.

Status-Neutral HIV Prevention and Care



Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.

Figure 7. CDC's HIV status-neutral approach to HIV services

People who receive a negative HIV test result are offered powerful tools that prevent HIV, which may include pre-exposure prophylaxis (PrEP) and information about access to condoms and sexual health and harm reduction services. The prevention pathway emphasizes a consistent return to HIV testing and facilitates seamless entry to treatment for people who later receive a positive test result.

People who receive a positive HIV test result should be quickly engaged in HIV primary care and prescribed effective treatment to help them achieve and maintain an undetectable viral load and to tend to their other non-HIV-related health care. An undetectable viral load essentially eliminates the risk of sexual HIV transmission and enables people with HIV to live long, healthy lives.

Objective 1.3 Expand and improve implementation of safe, effective prevention interventions, including treatment as prevention, PrEP, PEP, and SSPs, and develop new options

Today, a range of highly effective prevention methods are available for use in combination or on their own. However, they do not yet reach everyone who needs them. Scaling up combinations of scientifically proven, cost-effective interventions targeted to the right populations in the right geographic areas is key to preventing new HIV infections. Especially important is scaling up highly effective, biomedical interventions: treatment as prevention (U=U), PrEP, and PEP, along with other highly effective prevention interventions including delayed initiation of sexual

activity, correct and consistent condom usage, HIV and viral hepatitis testing, STI testing and treatment, SSPs and harm reduction services, universal HIV testing and linkage to care in primary care settings, and behavioral health services.⁸⁵⁻⁸⁹

These interventions must be available to people who need them in a variety of traditional health care and public health settings as well as nontraditional settings. Public health and health care systems can better meet the HIV prevention needs of the people they serve by developing or adopting culturally competent, linguistically appropriate, and accessible approaches and policies for service design and delivery. Examples of interventions include models that allow for low-barrier access to prevention and supportive services such as expanded service hours, drop-in appointments, telehealth, peer navigators, community health workers, and co-located service delivery.⁹⁰

Schools can offer on-site sexual health services through their own health care infrastructure, such as school-based health centers and school nurses, or can establish referral systems to community partners to provide services, such as periodic, school-wide HIV and STI screening events or mobile clinics. In addition, treatment for alcohol use disorder, other substance use disorders, and mental health conditions can also reduce HIV.⁹¹

Policy and other systemic changes can support the expansion or improvement of these prevention interventions and can often be cost-neutral or cost-saving, as resources are realigned and services are provided at focused hours and delivery is tailored to people seeking assistance.⁹² For example, structural barriers such as state or local laws or policies may require review and revision to facilitate expanded access to HIV prevention services, such as permitting SSPs, working with law enforcement to strengthen training on harm reduction as an effective public health intervention, or expanding prescribing authority and reimbursement of services for PrEP and PEP to pharmacists and other providers.

Ongoing implementation research on how best to use new and existing HIV prevention tools is needed, as is continued research into new tools that make HIV prevention more convenient and accessible. Research must pursue biomedical interventions that simplify implementation, such as long-acting, extended-release tools that can protect against HIV infection without daily pills, as well as non-systemic tools that expand user options such as lubricant- or douche-based microbicides or multi-purpose tools that might protect women from both HIV and pregnancy. Research is needed to identify strategies to most effectively integrate such tools into HIV prevention services when they become available. Other prevention tools also warrant further investigation, including antibody-mediated protection strategies, effective vaccines, and behavioral and social-structural interventions.

Strategies

- 1.3.1 Engage people who experience risk for HIV in traditional public health and health care delivery systems, as well as in nontraditional community settings.
- 1.3.2 Scale up treatment as prevention (i.e. U=U) by diagnosing all people with HIV, as early as possible, and engaging them in care and treatment to achieve and maintain viral suppression.
- 1.3.3 Make HIV prevention services, including condoms, PrEP, PEP, and SSPs, easier to access and support continued use.
- 1.3.4 Implement culturally competent and linguistically appropriate models and other innovative approaches for delivering HIV prevention services.
- 1.3.5 Support research into the development and evaluation of new HIV prevention modalities and interventions for preventing HIV transmissions in priority populations.
- 1.3.6 Expand implementation research to successfully adapt evidence-based interventions to local environments to maximize potential for uptake and sustainability.

Objective 1.4 Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV

Expanding awareness, access, uptake, and adherence to effective HIV prevention interventions and improving availability of HIV testing for people with undiagnosed infection or ongoing risk of acquisition are actions that fall largely under the purview of the health care and public health systems. Therefore, steps must be taken to strengthen and expand capacity to ensure that these services are more commonly available in clinical and nonclinical settings including primary care, health centers, community-based organizations, emergency departments, pharmacies (see Box 6), Title X family planning sites, STI specialty clinics (see Box 3), substance use disorder treatment facilities, correctional settings, home- and community-based services, and other settings.

One step involves training all staff, ranging from those performing administrative duties to those delivering direct care, on trauma-informed care, cultural competency, stigma and discrimination, and unrecognized bias. Health care services that are respectful of and responsive to the health beliefs, practices, and cultural, developmental, and linguistic needs of diverse patients can also help bring about positive health outcomes.⁹³ Another step involves providing resources, incentives, training, and technical assistance to organizations to expand workforce and systems capacity especially in areas with limited availability of prevention and other health care and supportive services.⁹⁴ Available mechanisms to increase the number of HIV providers include health professions training grants, the National Health Service Corps Scholarship and Loan Repayment Programs, financial incentives to compensate providers for HIV care management, and program coordination so that providers who are not HIV specialists are adequately equipped to provide prevention services to high-risk populations and link patients who test positive to HIV clinical care providers.

These efforts must seek to expand the number, variety, diversity, and distribution of health care providers who routinely provide HIV testing, prevention counseling, and linkage to specialty care. A recent study showed that a low proportion of primary care providers were familiar with PEP and PrEP.⁹⁵ In some settings, these efforts require addressing the “purview paradox,” a contradiction in which primary care physicians and HIV specialists sometimes consider PrEP to be beyond their purview.⁹⁶ Thus, HIV prevention and testing must become the purview of providers of all types who care for patients who may experience risk. Further, health care providers in high HIV prevalence jurisdictions must understand the relationship of epidemiological context and HIV acquisition. In these jurisdictions, providers may be encouraged to offer universal opt-out HIV testing and integrate PrEP screening as a part of routine care for all clients.

The nation’s more than 13,500 health center service delivery sites span every U.S. state, U.S. territory, and the District of Columbia, and serve 1 in 11 people across the country. In 2020, health centers logged nearly 2.5 million visits for HIV tests and provided more than 389,000 people with access to PrEP.⁹⁷ Further strengthening and supporting the capacity of health centers to respond to the needs of individuals experiencing risk for HIV or living with HIV, including creating affirming and welcoming environments and providing HIV services with integrated behavioral health and family support models, is a promising approach to increasing availability of high-quality HIV prevention and care services for those who need them.



BOX 6 PHARMACISTS' ROLES IN HIV PREVENTION AND CARE

Pharmacists' knowledge and accessibility in nearly every urban and rural community can be leveraged as part of a comprehensive HIV prevention and care strategy to expand access to care and improve population health. As trusted health care professionals, pharmacists develop a strong rapport with patients and may be the key to addressing current disparities in PrEP-prescribing patterns as well as serving as an essential liaison between patients and other members of the multidisciplinary care team.⁹⁸ Pharmacists and community pharmacies can also be utilized to expand rapid, point-of-care HIV testing in communities.⁷² In addition, studies have shown that engaging pharmacists as key players in a care team can increase retention in care and adherence to ART and maintain viral suppression.⁹⁹⁻¹⁰¹

Strategies

- 1.4.1 Provide resources, incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent, linguistically appropriate, and accessible HIV testing, prevention, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 1.4.2 Increase the diversity of the workforce of providers who deliver HIV prevention, testing, and supportive services.
- 1.4.3 Increase the inclusion of paraprofessionals on prevention teams by advancing training, certification, supervision, financing, and team-based care service delivery.
- 1.4.4 Include comprehensive sexual health and substance use prevention and treatment information in curricula of medical and other health workforce education and training programs.

Indicators of Progress

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

- Indicator 1** Increase knowledge of status to 95% from a 2017 baseline of 85.8%.
- Indicator 2** Reduce new HIV infections by 75% from a 2017 baseline of 37,000.
- Indicator 3** Reduce new HIV diagnoses by 75% from a 2017 baseline of 38,351.
- Indicator 4** Increase PrEP coverage to 50% from a 2017 baseline of 13.2%.



GOAL 2: IMPROVE HIV-RELATED HEALTH OUTCOMES OF PEOPLE WITH HIV

THE OPPORTUNITY

Starting and staying on HIV treatment as soon as possible following HIV diagnosis is necessary for all people with HIV to improve health outcomes and to prevent HIV transmissions.¹⁰²⁻¹⁰⁴ People who start HIV treatment early and remain adherent to antiretroviral medications can live a normal lifespan. Improving the health of people with HIV requires continued focus on the HIV continuum of care to identify gaps and disparities at each step of the continuum to target resources and interventions (see Figure 8). Increasing access to comprehensive health care through expansion of Medicaid programs, counseling about private insurance through the Affordable Care Act and the American Rescue Plan, and implementing programs to support maintaining insurance such as co-pay and premium assistance through the RWHAP will increase access.

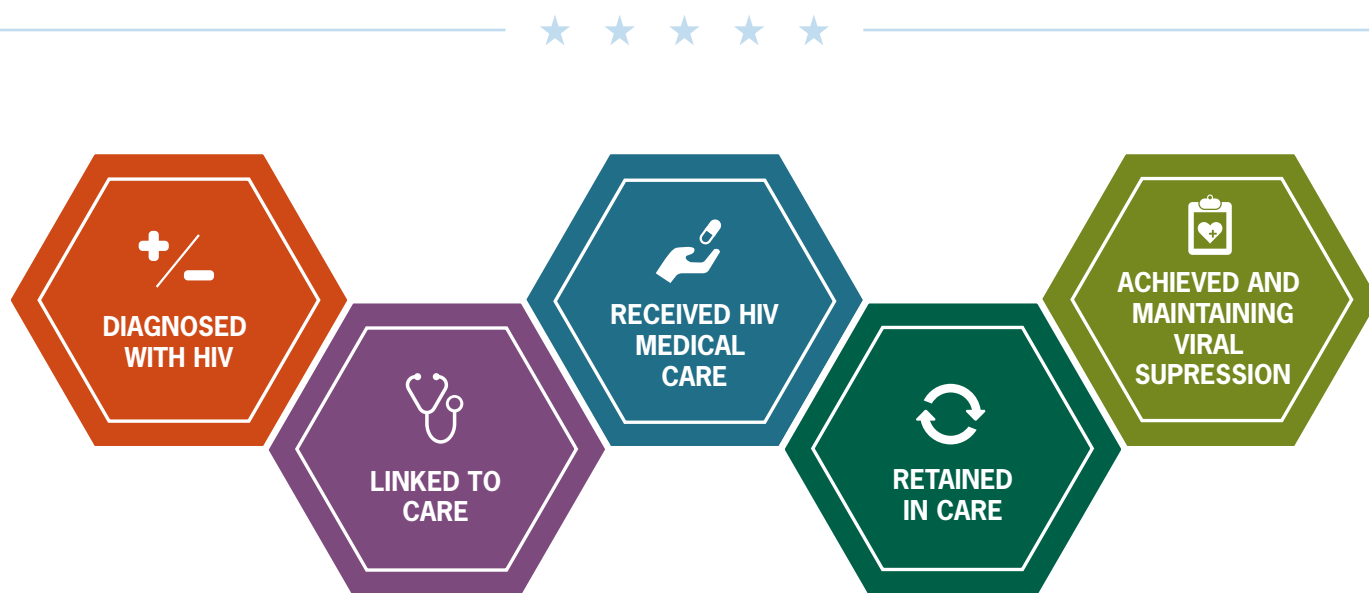


Figure 8. The HIV care continuum outlines the steps that people with HIV take from diagnosis to achieving and maintaining viral suppression. Source: HIV.gov.¹⁰⁵

One common gap is the lack of understanding about the personal and public health benefits of entering treatment immediately and achieving and maintaining viral suppression. Increasing HIV education and available treatment along with strengthening relationships between patients and providers can play an even larger part in supporting people with HIV to begin, or reengage in, care and treatment and improve long-term health outcomes. Developing and expanding partnerships between providers of HIV specialty care and other providers (such as primary care and other health care providers as well as community organizations, health departments, community-based substance use and harm reduction programs, jails and prisons, and others) can leverage existing resources, allowing for seamless transitions between each step of the continuum from diagnosis to achieving and maintaining viral suppression. In addition, government, academic, and pharmaceutical industry research has provided simpler, more easily tolerated therapies than the initial generation of effective antiretroviral therapies. Continued advances such as long-acting injectables could result in the introduction of new HIV treatments during the course of this 5-year plan. These new options could help address challenges with adherence to a daily pill regimen.

Several approaches exist to support treatment initiation and adherence as well as retention in care across the continuum, including:

- **Rapid start programs.** Programs focusing on the immediate (ideally same day or within 7 days after diagnosis) initiation of ART have demonstrated success and are expanding in communities across the nation. Such “rapid start” or “red carpet” programs require structural or other changes to improve linkage to care, care coordination, patient navigation, adequate staffing, specialized services, and clinical provider evaluation.
- **Evidence-based strategies.** Every year evidence-informed best practices are added to the compendia of recommended interventions designed to improve treatment adherence and retention in care. Although interventions are often not a one-size-fits-all approach, health departments, clinics, and community organizations have additional tools to implement and receive a wide range of adaptations that have worked in different settings, in different population sizes, and for specific populations. Increasing the use of evidence-based strategies and best practices, coupled with community input, to reengage people who have fallen out of care, and people never in care, is necessary.
- **Health literacy.** Limited health literacy is associated with poorer health outcomes.¹⁰⁶ At all levels, further effort is needed to construct organizations, institutions, systems, and a workforce that embrace and implement the concepts and principles of health literacy. Efforts to create more health-literate public and private health systems at the federal, state, tribal, territorial, and local levels will help patients understand the health care system and the importance of HIV prevention, care, and treatment, and the benefits of viral suppression. Patient education is a necessary aspect of people-centered care, but it requires systems and providers to end the use of jargon, take the time to educate and explain in plain language, alter websites and brochures, proactively counter medical misinformation, use social media differently, and consider other culturally appropriate and accessible ways to deliver key information. Understanding HIV, the importance of treatment, and the risks of transmission to others can also lead to less stigma and shame, which in turn can lead to increased interactions with the health system and positive health outcomes.¹⁰⁷ Efforts to increase health literacy can also aid in addressing the mistrust of the medical system prevalent among many minority groups because of the historical systemic racism in many health care settings.
- **Comprehensive array of clinical and support services.** Current systems of HIV care and treatment have produced tremendous results, and the nation has more providers treating people with HIV than ever before. Today, people with HIV who are on treatment are living longer and healthier lives, and more than one-half of the people with HIV in the United States are over age 50. Researchers and clinicians are identifying and providing services to address the comorbidities experienced by people aging with HIV as well as people with HIV across the entire lifespan whose health can be impacted by noncommunicable comorbidities or coinfections. Other key



GOAL 2: IMPROVE HIV-RELATED HEALTH OUTCOMES OF PEOPLE WITH HIV

Objectives

- 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment
- 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed
- 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs
- 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV
- 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors
- 2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure

population groups, such as youth, transgender people, people with substance use disorders, justice-involved people, people with disabilities, or people experiencing homelessness, require different combinations of tailored services to help improve their health outcomes.¹⁰⁸ Work continues to scale up evidence-based and evidence-informed programs that provide enhanced case and care management for people with HIV specific to their comorbidities or co-occurring conditions such as homelessness, food insecurity, and lack of employment.

- **Capacity of the health care delivery system.** As providers engage and reengage people in care and implement rapid start models, the number of people in care will increase. However, workforce needs may not be able to keep pace. The existing highly skilled and dedicated workforce, combined with a growing number of federally funded health centers of all types treating people with HIV, are key to ensuring positive health outcomes. There is an opportunity to examine ways to restructure staff and clinic workflows, implement technological solutions, enhance quality improvement programs, consolidate paperwork requirements, and examine task sharing to create new efficiencies and revamp the ability to use peers in key places along the HIV care continuum. Continuing to find innovative ways to encourage clinical and nonclinical providers to specialize in HIV care and treatment and engaging primary care providers in care and treatment of HIV, viral hepatitis, and STIs will remain important.
- **Meaningful involvement of people with HIV in program design and implementation.** People with HIV are central to the response to the epidemic and must be included in all elements of programming and service delivery to achieve the Strategy's goals. People with HIV must be included in program design and implementation, quality improvement initiatives, and campaigns; engaged as peers in prevention and care services; employed in HIV service delivery organizations; and involved in large-scale structural and policy initiatives. COVID-19 has presented opportunities for engaging people with HIV and communities in new and different ways, and program implementers must continue to create mechanisms for the meaningful engagement of interested individuals.

CHALLENGES

The following challenges hinder efforts to improve HIV-related health outcomes:

- Health care capacity and workforce shortages exist in critical geographic areas, particularly in the Southern United States.
- Services to address intersecting conditions of mental health, substance use disorders, homelessness or housing instability, and incarceration are limited and/or fragmented.
- HIV-related stigma, other forms of stigma associated with people with HIV, and discrimination continue to impede optimal health outcomes for people with HIV.
- There is a need for new and innovative health care delivery strategies and therapeutics to better support and retain people most vulnerable to not adhering to or dropping out of care.
- There is a lack of ongoing, diverse, meaningful, and engaged community input in some HIV programs and services.
- Medical mistrust and medical misinformation must be addressed.
- Lack of Medicaid expansion, particularly in Southern states disproportionately affected by HIV, limits access to HIV prevention and care services for many who need them.

SUMMARY OF OBJECTIVES

A concerted national effort to engage people with HIV in care is essential to achieving the Strategy's vision. The following steps are critical to achieving success:

- 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment.
- 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed.

- 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs.
- 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV.
- 2.5 Expand capacity to provide whole-person care to older adults with HIV and long-term survivors.
- 2.6 Advance the development of next-generation HIV therapies and accelerate research for HIV cure.

OBJECTIVES AND STRATEGIES

Objective 2.1 Link people to care immediately after diagnosis and provide low-barrier access to HIV treatment

Achieving improved health outcomes for people with HIV begins with ensuring that they are promptly linked to effective HIV care and treatment upon diagnosis. Linkage to HIV care and treatment immediately or as early as possible following HIV diagnosis leads to faster time to viral suppression, increased rates of retention in care and ongoing viral suppression, and reduction in transmission risk.¹⁰⁹⁻¹¹¹ Programs must continue to build capacity and shrink the amount of time between diagnosis and linkage to care so that immediate linkage to care becomes the standard across the United States, allowing people to begin receiving care and treatment within hours or days of their diagnosis no matter where they live. This effort may require that some clinics and health departments work to reduce facility-based, government-based, workforce, or administrative barriers to initiating care and treatment. Red carpet and warm-handoff programs provide low-barrier access by linking newly diagnosed people to care and treatment services, often within the same day.^{112, 113} For example, these programs, which often integrate robust navigation services, may schedule medical appointments on behalf of the patient, drive newly diagnosed people who lack transportation from an HIV testing site to a trusted clinic, or help people who need assistance complete required forms and paperwork.

Strategies

- 2.1.1 Provide same-day or rapid (within 7 days) start of antiretroviral therapy for persons who are able to take it; increase linkage to HIV health care within 30 days for all persons who test positive for HIV.
- 2.1.2 Increase the number of schools providing on-site sexual health services through school-based health centers and school nurses, and linkages to HIV testing and medical care through youth-friendly providers in the community.

Objective 2.2 Identify, engage, or reengage people with HIV who are not in care or not virally suppressed

Although improvements have been made over time, only 58% of people with diagnosed HIV were retained in care in 2019² and 81% of people with diagnosed HIV were rapidly linked to care within 1 month of diagnosis. In addition, 23% of people with HIV who are not receiving care account for 43% of new infections.²⁸ This population often needs highly tailored approaches to identify, conduct outreach, ascertain barriers to care, and create individualized care plans to facilitate entry into care, followed by navigation and other services to support retention in care, such as short- or long-term housing assistance, benefits counseling across the social services spectrum, and employment counseling. New solutions must be identified to engage and reengage populations that, to date, systems have been unsuccessful in reaching and retaining in care. Feedback and evaluations of services from people with HIV are critical to understanding and improving how services are received by those who need them the most. Attention should also be paid to eligibility and other requirements placed on people seeking care such as eligibility processes and duplicative paperwork requests.

Data-to-care models based on solid, interwoven data points, and other evidence-based interventions focused on finding people not in care and people who are not yet virally suppressed, are proven strategies to reengage people over the long term.¹¹⁴ Disparate data systems must first be linked to identify people who have tested HIV positive but do not have recent indicators of quality care, people who have fallen out of care, people in care who lack timely prescription refills, and people in care who have not achieved or maintained viral suppression. Entering into formal data sharing agreements ensures that the uses of the data, responsibilities, and protections are clearly delineated for all parties. Such agreements are needed among state public health surveillance systems, state and local health departments, tribes, tribal organizations, urban Indian organizations, the RWHAP, federally funded health centers of all types, community-based organizations, STI specialty clinics, HOPWA programs, Medicaid, Departments of Corrections, pharmacies and pharmacy benefits managers, and other components of the health system serving people with HIV in a geographic area. A goal of data sharing agreements is to reduce administrative burden on providers as well as individuals, thereby avoiding redundant intakes, increasing efficiency, and preparing providers to work alongside clients to develop comprehensive treatment plans without delay.

Strategies

- 2.2.1 Expand uptake of data-to-care models using data sharing agreements, integration and use of surveillance, clinical services, pharmacy, and social/support services data to identify and engage people not in care or not virally suppressed.
- 2.2.2 Identify and address barriers for people who have never engaged in care or who have fallen out of care.

Objective 2.3 Increase retention in care and adherence to HIV treatment to achieve and maintain long-term viral suppression and provide integrative HIV services for HIV-associated comorbidities, coinfections, and complications, including STIs

People with HIV need ongoing support to stay in care and adhere to ART to achieve and maintain viral suppression.¹¹⁵ Approaches to increase retention in care include higher levels of personal contact with a patient navigator or community health worker to ensure care receipt; reminders about appointments and calls to discuss why appointments were missed; patient navigation services designed to help patients identify, apply for, and receive necessary services to bolster medical care; medical case management; financial incentives; and low-threshold care including walk-in appointments and on-site pharmacies.^{116, 117} Among adherence interventions are those designed to ensure the efficiency of receiving and taking medications such as 90-day prescriptions, options for medication pick-up or receipt by mail, use of technology such as medication reminder apps, and adherence counseling. Other interventions must address common barriers to adherence and retention, such as providing co-located treatment for HIV and mental health and substance use disorders.

Ongoing research in a variety of disciplines is also needed to improve care retention, medication adherence, and sustained viral suppression. Research topics include next-generation therapeutics that are longer-acting, less toxic, and have fewer side effects and complications, as well as behavioral and social sciences to better understand and address barriers to treatment uptake and adherence, as well as disparities. Biomedical, behavioral, and implementation research approaches can be combined to increase viral suppression, reduce HIV transmission, and improve health for all affected populations. Basic, translational, and clinical research can increase understanding of HIV-related comorbidities, coinfections, and complications, which can interfere with retention, adherence, or viral suppression.

New and differentiated models of care, especially those that integrate HIV prevention, care, and supportive services, alongside broader structural interventions, must be tailored and implemented for priority populations. Many populations such as youth transitioning from pediatric to adult care, people without consistent and stable housing, and people released from correctional facilities need well-coordinated interventions that span systems, providers, and payers and address structural, medical, behavioral, and support service concerns.

Strategies

- 2.3.1 Support the transition of health care systems, organizations, and patients/clients to become more health literate in the provision of HIV prevention, care, and treatment services.
- 2.3.2 Develop and implement effective, evidence-based or evidence-informed interventions and supportive services that improve retention in care.
- 2.3.3 Expand implementation research to successfully adapt effective evidence-based interventions, such as HIV telehealth, patient and peer navigators, accessible pharmacy services, community health workers, and others, to local environments to facilitate uptake and retention to priority populations.
- 2.3.4 Support ongoing clinical, behavioral, and other research to support retention in care, medication adherence, and durable viral suppression.

Objective 2.4 Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

Increasing viral suppression requires expanded capacity of public health, health care and support service delivery systems, and the health workforce to be flexible and responsive to the needs of people with HIV. COVID-19 has strained HIV care and prevention systems and has highlighted gaps within our nation's response. Federal and state programs focused on HIV should work to identify opportunities to expand the HIV workforce, including partnerships with medical colleges, particularly Historically Black Colleges and Universities, and incentives for clinicians to provide HIV and related services. Increasing the diversity of providers offering HIV prevention and care services is one important capacity-building approach. In addition, publicly funded organizations can increase the diversity of their workforce and provide training to ensure culturally competent care and knowledge of best practices for caring for people from diverse backgrounds.¹¹⁸ Health care and support systems can also take advantage of different types of health professionals such as nurses, advanced practice providers, pharmacists, and behavioral health specialists to ensure that any workforce shortages can be addressed. Innovative staffing models can also build capacity to better meet the needs of people with HIV including the use of community health workers, linkage to care and reengagement specialist teams, task sharing, integrated care teams, and use of peer mentors.¹¹⁹ Organizations should also work to ensure that their staff represents the populations served, including hiring pathways for people with HIV and providing opportunities for leadership and leadership development. In addition, sustained continuous quality improvement programs must be utilized to ensure that up-to-date and high-quality care is being provided by integrated and diverse care teams.

In addition to the RWHAP, patient-centered medical homes and health homes create opportunities to address medical and support service needs of people with HIV through coordinated, team-based, and accessible programs including co-location of mental health, substance use, geriatric, reproductive, and other related health care services. Similar to HIV prevention, expanding care and treatment capacity must also include delivery of additional resources, incentives, training, and technical assistance to existing systems as well as development of new systems in areas with limited availability. For example, establishing new partnerships and advancing telehealth arrangements to expand access to professionals with specialized backgrounds should be explored to increase access to services in geographically underserved areas, as well as expanding broadband access, so that those in underserved and rural areas may have equitable access to telehealth arrangements. The design of programs to reach and engage people out of care, people never in care, and people who are challenged to stay in care may require novel approaches, services, and partnerships to address issues of trauma, poverty, and associated conditions that are obstacles to care. The creation and implementation of new programs should involve input and feedback from people with HIV because they have unique knowledge to share. Systems should also offer low-threshold capacity-building resources to organizations and retail health clinics led and staffed by local members of the priority populations to enhance their

ability to apply for and receive grants and foundation funds to increase the number of services being provided in and by affected communities.

In addition, to address the unique needs of people aging with HIV and long-term survivors, federal and state programs and community-based organizations must conduct analyses to identify gaps in service delivery for this population so that programs can be implemented to address shortfalls. This analysis should include federal programs such as Medicare and the RWHAP to ensure adequacy of care and support services, benefits, and policies.

Strategies

- 2.4.1 Provide resources, value-based and other incentives, training, and technical assistance to expand workforce and systems capacity to provide or link clients to culturally competent and linguistically appropriate care, treatment, and supportive services especially in areas with shortages that are geographic, population, or facility based.
- 2.4.2 Increase the diversity of the workforce of providers who deliver HIV care and supportive services.
- 2.4.3 Increase inclusion of paraprofessionals on teams by advancing training, certification, supervision, reimbursement, and team functioning to assist with screening/management of HIV, STIs, viral hepatitis, and mental and substance use disorders and other behavioral health conditions.

Objective 2.5: Expand capacity to provide whole-person care to older adults with HIV and long-term survivors

More than one-half (52%) of people in the United States with diagnosed HIV were aged 50 and older in 2019.³ Of the more than 500,000 clients served by the RWHAP in 2019, 46.8% were aged 50 years and older—an increase from 31.6% in 2010. Of clients aged 50 years and older receiving RWHAP HIV medical care, 90.9% were virally suppressed, which was slightly higher than the national RWHAP average (88.1%).¹²⁰ The proportion of older adults with HIV is expected to continue to rise because of the effectiveness of ART, as well as new diagnoses within this age group, which accounts for approximately 17% of all diagnosed HIV in the United States.

People aging with HIV, many of whom are long-term survivors, have unique mental health and physical health needs.¹²¹ Although people with HIV over age 50 have the highest viral suppression rates and the lowest incidence rates of any age group, the effects of aging, chronic inflammation, frailty, and distinctive behavioral health issues can compound the care and support service needs for this population.

Although modern antiretroviral therapies increase the life expectancy of people living with HIV, many challenges and opportunities for the treatment of HIV and HIV-associated comorbidities, coinfections, and complications across the lifespan persist. Even when long-term viral suppression is achieved, people living with HIV over age 50 are more likely than their peers without HIV to experience age-related complications such as cardiovascular disease, lung disease, infection-related and non-infection-related cancers, neurocognitive and neuropsychiatric disorders, osteopenia/osteoporosis, liver cirrhosis, and renal disease. In addition, people living with HIV infection may suffer from multiple morbidities, polypharmacy, declining physical and cognitive function, alterations in body composition, social isolation, and increased caregiver burden.

Older adults with HIV and long-term survivors of HIV often experience social isolation, loneliness, and a lack of social support, as well as HIV- and age-related stigma. These issues may prevent them from seeking or staying in care and can contribute to poor mental and physical health. The U.S. HIV care and treatment system must adapt to ensure that people aging with HIV can receive whole-person care that addresses their HIV- and aging-related health needs, along with support services such as mental health, transportation, housing, food and nutrition, and benefits counseling, among many others. Relatedly, our nation's programs designed to serve older adults—including Medicare, Medicaid, and programs supported through the HHS Administration for Community Living including

State Units on Aging, Area Agencies on Aging, and other community-based organizations and social service providers—must be prepared to meet the needs of people with HIV. Partnerships between HIV care providers and community-based organizations can greatly enhance the ability of people aging with HIV to maintain independence and experience improved quality of life (see Box 8 for a discussion of HIV Prevention and Care Across the Lifespan).

Strategies

- 2.5.1 Identify, implement, and evaluate models of care that meet the needs of people with HIV who are aging and ensure quality of care across services.
- 2.5.2 Identify and implement best practices related to addressing psychosocial and behavioral health needs of older people with HIV and long-term survivors including substance use treatment, mental health treatment, and programs designed to decrease social isolation.
- 2.5.3 Increase HIV awareness, capability, and collaboration of service providers to support older people with HIV, including in settings such as aging services, housing for older adults, substance use treatment, and disability and other medical services.
- 2.5.4 Promote research, cross-agency collaborations and sharing of research discoveries that address specific aging-related conditions in people with HIV, and other comorbidities and coinfections that can impact people with HIV of all ages.
- 2.5.5 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people living with HIV at various life stages to support healthy aging with HIV.

Objective 2.6: Advance the development of next-generation HIV therapies and accelerate research for HIV cure

Research and programmatic implementation of varied HIV therapeutic modalities that meet the needs of diverse communities of people with HIV is critical to reduce onward transmission and to achieve complete virus remission, eradication, and HIV cure. Collaboration must exist on a global scale, as much of the research on these new therapies is being done in highest incidence settings.

Novel ART classes and drugs that target the HIV lifecycle are in various stages of preclinical and clinical development and are under investigation in clinical trials. Next-generation therapeutics research includes basic and clinical studies to optimize efficient delivery of therapies and interventions that address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.

Numerous novel diagnostic and delivery systems are similarly being developed and tested, including subcutaneous, intravenous, topical, implantable, and long-acting oral formulations. New delivery systems and technologies will improve adherence to drug regimens and reduce the burden on health systems.

Research toward safer, effective, and long-lasting therapeutics that successfully achieve viremic control in the absence of ART or completely eradicate the HIV infection (cure) must continue, and must seek a better understanding of the viral reservoir dynamics, persistent viral replication consequences, and the host immune system clearance capacity to remove residual infection.

In parallel to research efforts, safe, long-acting, more efficacious regimes must be rapidly approved and implemented to meet the needs of communities of people with HIV. Achieving these goals will benefit from robust public-private partnerships both in basic and clinical research as well as in implementation planning and delivery to ensure community involvement and advocacy.

Strategies

- 2.6.1 Promote research and encourage public-private partnerships to accelerate new therapies to achieve sustained viral suppression and to address drug toxicity, viral resistance, adherence, and retention in care and stigma associated with ART use.
- 2.6.2 Increase investment in innovative basic and clinical research to inform and accelerate a research agenda to discover how to sustain viral suppression, achieve ART-free remission, reduce and eliminate viral reservoirs, and achieve HIV cure.

INDICATORS OF PROGRESS

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

- Indicator 5** Increase linkage to care within 1 month of diagnosis to 95% from a 2017 baseline of 77.8%.
- Indicator 6** Increase viral suppression among people with diagnosed HIV to 95% from a 2017 baseline of 63.1%.



GOAL 3: REDUCE HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

THE OPPORTUNITY

Advances in HIV prevention, testing, care, treatment, and supportive services have led to significant declines in new HIV transmissions and deaths. They also make it possible for the nation to envision ending the HIV epidemic. However, realizing this vision requires that every person across the United States with or who experiences risk for HIV has access to high-quality and culturally competent prevention, diagnostic, care, treatment, and supportive services that are non-stigmatizing, non-discriminatory, inclusive, and responsive to their needs. Further, issues such as discrimination and systemic racism that contribute to differences in the quality of and access to health care and other necessities such as housing and behavioral and substance use services, and lead to ongoing disparities among racial, ethnic, and sexual and gender minority populations, must be addressed.

The Strategy recognizes racism as a serious public health threat that directly affects the well-being of millions of Americans. Racism is not only the discrimination against one group based on the color of their skin or their race or ethnicity, but also the structural barriers that impact racial and ethnic groups differently to influence where a person lives, where they work, where they play, and where they gather as a community. Over generations, these structural inequities have resulted in racial and ethnic health disparities that are severe, far-reaching, and unacceptable.¹²² Across the country, federal, state, and local leaders are declaring racism to be a public health crisis, an important step in the movement toward equity.¹²⁰ This recognition comes with the need for a more equitable HIV response that focuses on populations with the greatest need.

Reducing these disparities entails focusing on the needs of disproportionately affected populations, supporting racial justice, combating HIV-related stigma and discrimination, providing leadership and employment opportunities for people with or who experience risk for HIV, and addressing social determinants of health and co-occurring conditions to reduce health inequities and disparities. Therefore, the Strategy fully recognizes that the national HIV goals can only be achieved through collaborative efforts at the federal, state, tribal, territorial, and local levels that focus on reducing HIV-related disparities and by ongoing commitment to understand and address the central factors that create HIV inequities.

In recent years, the nation and individual states have made progress in the area of HIV-related disparities. For example:

- **The RWHAP significantly reduced viral suppression disparities among client populations**, particularly women, transgender people, youth, Blacks, and people with unstable housing. Overall, 88% of clients receiving medical care in the RWHAP were virally suppressed in 2019.⁵ From 2010 to 2019, the gap between male and female clients decreased from nearly 5 percentage points to <1 percentage point. In addition, the gap between male and transgender clients decreased from 9 percentage points to 5 percentage points. Similarly, the disparity between viral suppression rates in Black clients and White clients was 13 percentage points in 2010 but 7 percentage points in 2019.^{5, 6} HRSA and its RWHAP recipients have continued to use these data to drive programs and decision-making.
- **Disparities in rates of new infections declined in some populations.** From 2015 to 2019 the United States saw reductions of disparities in the rates of new HIV infections among gay and bisexual men, Black gay and bisexual men, and Black women.¹¹
- **Since 2014, at least nine states (CA, CO, IA, IL, MI, MO, NV, NC, VA) have modernized or repealed their HIV criminal exposure laws.** Changes have included removing HIV prevention issues from the criminal code and including them instead under disease control regulations, requiring intent to transmit or actual HIV transmission, or providing for defenses for taking measures to prevent transmission.

CHALLENGES

The following challenges hinder efforts to reduce HIV-related disparities and health inequities:

- Disparities in HIV prevalence persist.¹²⁴
- The South bears a disproportionate HIV burden.
- Disparities are also evident in the proportion of people with HIV with viral suppression.²
- Significant disparities exist in PrEP uptake by age, race, sex at birth, and geographic location.^{11, 63, 64}

Research to better understand and address such disparities and inequalities—including through community-based participatory research methods—can help improve HIV testing and engagement and retention in prevention and care services and can enhance the health and well-being of people with or who experience risk for HIV in underserved and marginalized communities.

Also important is consideration of and appropriate and proportional response to HIV among groups that represent a small share of both the population and of HIV infections. Although it is vital to focus national efforts in communities with the highest burden, HIV prevention, care, and treatment must continue to be supported in localities with concentrations of groups such as Asian Americans and Pacific Islanders and American Indians/Alaska Natives, and informed by the best available data.

A Focus on Health Inequities

Certain racial and ethnic minority groups have higher rates of HIV incidence, prevalence, poor health outcomes (lower viral suppression), and mortality, compared to non-Hispanic Whites.¹²⁵ Health disparities can stem from inequities in the social determinants of health and highlight the need to focus on not only HIV prevention and care efforts, but also how programs, practices, and policies affect racial and ethnic minority communities. Persons from racial and ethnic minority groups are more likely to be uninsured compared to non-Hispanic Whites,¹²⁶ limiting their access to health care. Sexual and gender minorities also face health inequities. Sexual and gender minorities have lower levels of health insurance and access to regular health care compared to their heterosexual counterparts.^{37, 38} Barriers to health care access include lack of transportation and childcare, inability to take time off from work, communication and language barriers, racism, discrimination, and lack of trust in health care providers.¹²⁷ Further, CDC's 2019 Youth Risk Behavior Survey data show that substantial health disparities exist among an estimated 2.6 million sexual minority students, placing them at risk for negative health outcomes, including HIV infection.

The Strategy recognizes the importance of addressing social determinants of health to improve health outcomes for racial, ethnic, and sexual and gender minority groups. By working to establish policies and programs that positively



GOAL 3: REDUCE HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

Objectives

- 3.1 Reduce HIV-related stigma and discrimination
- 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum
- 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV
- 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities
- 3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including health care workers, researchers, and community partners, particularly from underrepresented populations
- 3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust

influence social and economic conditions and by supporting changes in individual behavior, health can be improved and sustained, and disparities reduced. Improving the conditions in which we live, learn, work, play, age, and worship and the quality of our relationships will create a healthier population, society, and workforce.¹²⁸ Application of a “health in all policies” strategy, a cross-sector collaborative approach to integrating health into policies and programs to close the health gaps,¹²⁹⁻¹³⁰ can be implemented across all areas and levels of government and in the community to foster achievement of these aims.

SUMMARY OF OBJECTIVES

The following objectives are critical to reducing HIV-related disparities and health inequities:

- 3.1 Reduce HIV-related stigma and discrimination
- 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum
- 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV
- 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities
- 3.5 Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including healthcare workers, researchers, and community partners, particularly from underrepresented populations
- 3.6 Advance HIV-related communications to achieve improved messaging and uptake, as well as to address misinformation and health care mistrust

OBJECTIVES AND STRATEGIES

Objective 3.1 Reduce HIV-related stigma and discrimination

Many people with HIV experience stigma and discrimination because of their HIV status. Stigma is an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable. Discrimination is often a consequence of stigma, occurring when unfair and often unlawful actions are taken against people based on their belonging to a particular stigmatized group. HIV stigma and discrimination can pose complex barriers for people with or who experience risk for HIV, preventing them from seeking prevention tools, learning their HIV status, and accessing medical care, treatment, and supportive services. Interested parties and organizations from all sectors of society, including government, faith communities, businesses, schools, and others, must work to combat stigma and discrimination in order to reduce new transmissions and improve health outcomes for people with HIV.

Ending the HIV epidemic requires addressing structural barriers to HIV prevention and care. HIV-specific criminal laws perpetuate HIV-related stigma, and discrimination can also deter individuals from getting tested. Some of these laws criminalize behavior that pose low or no risk for transmitting HIV and apply regardless of actual HIV transmission. These outdated laws do not reflect our current understanding of HIV and should be repealed or updated. At least nine states have done so since 2014. Such efforts must ensure that criminal laws and policies regarding HIV transmission are based on the latest scientific evidence and reflect effective public health strategies, and that legislators, prosecutors, and law enforcement officials have an accurate understanding of HIV transmission risks (see Box 7).

Discriminatory practices cause stress and play a role in the health outcomes of minorities.¹³¹ Public health and health care systems should be respectful of and responsive to the health beliefs, practices, accessibility needs, and cultural and language needs of diverse patients.¹³² At the community level, interested parties and advocates should

be equipped with knowledge and tools to address misconceptions and change norms that are associated with HIV-related stigma and discrimination. At the individual level, multiple approaches to address interpersonal and internalized stigma should be available to people with or who experience risk for HIV as well as their family, friends, health care providers, and others.

HIV-related stigma and discrimination and their effects on people with or who experience risk for HIV should not be viewed in a silo. Stigma and discrimination come in different forms and are often complicated when people also experience stigma and discrimination related to—among other identities or experiences—race and ethnicity, sexual orientation or sexual behavior, other STIs, gender identity, substance use, mental health, homelessness, socioeconomic circumstance, justice involvement, immigration status, age, disability, or sex work.^{108, 133} Additional research, innovative solutions, and replication of global efforts, such as those from the President’s Emergency Program for Emergency AIDS Relief (PEPFAR), to address the drivers, facilitators, and manifestations of stigma are needed.¹³⁴ These solutions should be integrated into the delivery of services that are responsive and sensitive to the unique needs of populations that face intersectional stigmas and intersectional discrimination.

Strategies

- 3.1.1 Strengthen enforcement of civil rights laws (including language access services and disability rights), promote reform of state HIV criminalization laws, and assist states in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status, homophobia, transphobia, xenophobia, racism, substance use, and sexism.
- 3.1.2 Ensure that health care professionals and front-line staff complete education and training on stigma, discrimination, and unrecognized bias toward populations with or who experience risk for HIV, including LGBTQI+ people, immigrants, people who use drugs, and people involved in sex work.
- 3.1.3 Support communities in efforts to address misconceptions and reduce HIV-related stigma and other stigmas that negatively affect HIV outcomes.
- 3.1.4 Ensure resources are focused on the communities and populations where the need is greatest, especially Black, Latino, and American Indian/Alaska Native and other people of color, particularly those who are also gay and bisexual men, transgender people, people who use substances, sex workers, and immigrants.
- 3.1.5 Create funding opportunities that specifically address social and structural drivers of health as they relate to Black, Latino, and American Indian/Alaska Native and other people of color.



BOX 7 STATE HIV CRIMINALIZATION LAWS

During the early years of the HIV epidemic, many states implemented HIV-specific criminal exposure laws to discourage behavior that they believed might lead to transmission, promote safer sex practices, and, in some cases, receive funds to support HIV prevention activities. These laws were passed at a time when very little was known about HIV, including how it was transmitted and how best to prevent or treat it. For example, many were enacted before the advent of pre-exposure prophylaxis (PrEP), which reduces the risk of acquiring HIV sexually by 99% when taken daily, or the availability of antiretroviral therapy (ART), which—when taken as prescribed—helps an individual with HIV achieve and maintain a suppressed viral load so that they have effectively no risk of transmitting HIV to sexual partners. As such, many of these state laws criminalize [behavior that cannot transmit HIV](#) and apply regardless of actual transmission.



BOX 7 STATE HIV CRIMINALIZATION LAWS (CONTINUED)

Criminalization of potential HIV exposure is largely a matter of state law, with some federal legislation addressing criminalization in discrete areas, such as blood donation and sex work. In 2021, CDC assessed state laws and grouped them into four categories:

1. HIV-specific laws that criminalize or control behaviors that can potentially expose another person to HIV.
2. STI, communicable, contagious, infectious disease laws that criminalize or control behaviors that can potentially expose another person to STIs/communicable/infectious disease, perhaps including HIV.
3. Sentence enhancement laws specific to HIV or STI that do not criminalize a behavior but increase the sentence length when a person with HIV commits certain crimes.
4. No specific criminalization laws.

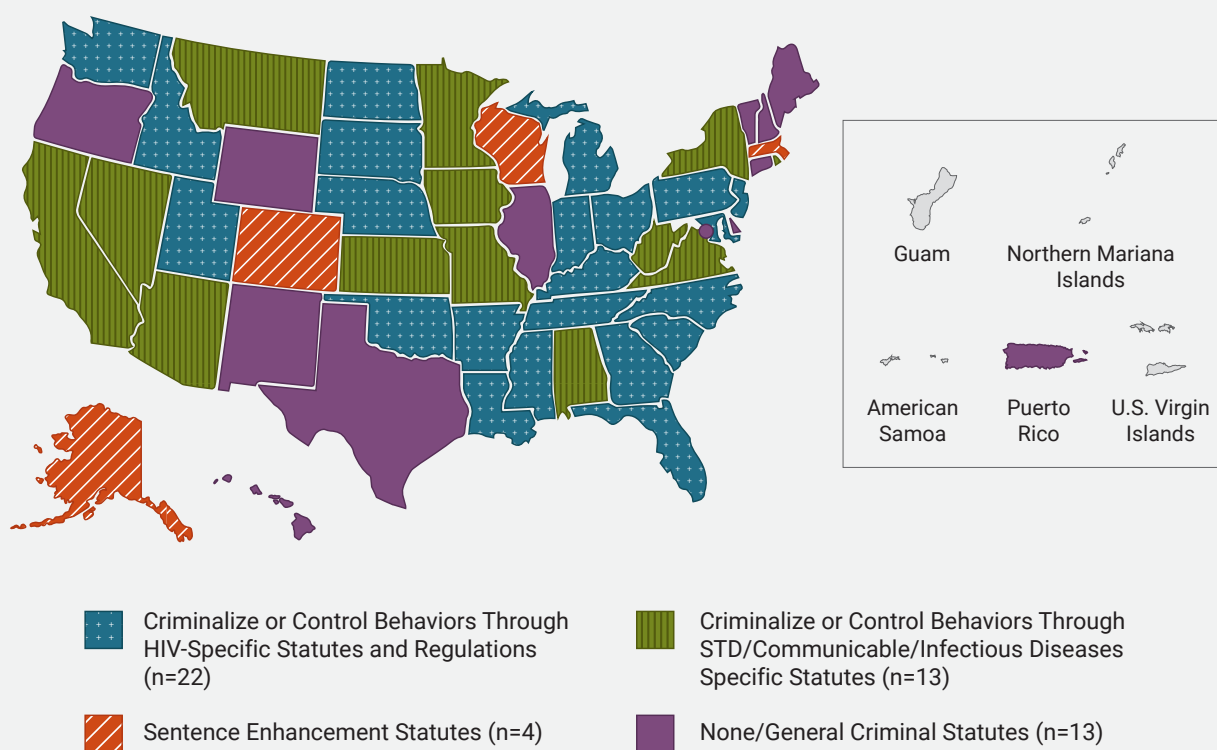


Figure 9. State criminal HIV exposure laws, as of 2021

As shown in Figure 9, these laws vary as to what behaviors are criminalized or what behaviors result in additional penalties. Several states criminalize one or more behaviors that pose a low or negligible risk for HIV transmission. Only 9 of the 35 states with HIV criminalization laws account for HIV prevention measures that reduce transmission risk, such as condom use and ART.



BOX 7 STATE HIV CRIMINALIZATION LAWS (CONTINUED)

Since 2014, at least nine states have modernized or repealed their HIV criminal laws: California, Colorado, Illinois, Iowa, Michigan, Missouri, Nevada, North Carolina, and Virginia. Changes have included removing HIV prevention issues from the criminal code and including them under disease control regulations, requiring intent to transmit or actual HIV transmission, or providing defenses for taking measures to prevent transmission such as viral suppression or being noninfectious, condom use, and partner PrEP use.

After more than 30 years of HIV research and significant biomedical advancements to treat and prevent HIV transmission, many state laws are still outdated and do not reflect our current understanding of HIV. In many cases, this same standard is not applied to other treatable diseases. Further, these laws have not increased disclosure and may discourage HIV testing, increase stigma against people with HIV, and exacerbate disparities. To end the HIV epidemic, public health, criminal justice, and legislative systems must work together to ensure that laws protect the community, are evidence-based and just, and support public health efforts. When a law meant to protect the public is not working as intended, is unjust, and may be hurting efforts to keep communities healthy, common solutions must be found to better meet public health and public safety goals. States should repeal or update these outdated laws and practices.

Source: CDC^{135, 136}

Objective 3.2 Reduce disparities in new HIV infections, in knowledge of status, and along the HIV care continuum

Monitoring of progress toward HIV targets should identify, raise awareness of, and inform appropriately tailored interventions to respond to ongoing and emerging disparities among various populations and in geographic areas. With improved mechanisms to measure, monitor, and report data in a timely manner and enhanced quality, accessibility, sharing, and use of data (see Goal 4), governments and organizations can more quickly identify disparities and direct resources appropriately.

When disparities are identified, tailored interventions must be developed in partnership with the affected populations. Specific populations may have unique or specialized needs and face challenges that require more tailored approaches based on sociodemographic, geographic, cultural, and other characteristics that may be associated with HIV risk or health-promoting behaviors.

Strategies

- 3.2.1 Increase awareness of HIV-related disparities through data collection, analysis, and dissemination of findings.
- 3.2.2 Develop new and scale up effective, evidence-based or evidence-informed interventions to improve health outcomes among priority populations and other populations or geographic areas experiencing disparities.

Objective 3.3 Engage, employ, and provide public leadership opportunities at all levels for people with or who experience risk for HIV

Achieving the goals of this Strategy and ending the HIV epidemic demand a whole-of-society effort that must include and elevate the diverse voices and experiences of people with or who experience risk for HIV, as well as

their partners, families, and communities. Jurisdictions and organizations must meaningfully engage and employ people with or who experience risk for HIV in the development, implementation, monitoring, and assessment of policies, programs, and services. This includes creating opportunities for employment and advancement, as well as fair compensation, wherever possible, particularly for individuals from the priority populations identified in this Strategy. Their experiences and expertise can inform efforts to remove barriers that hinder access to needed information or services and to design services that meet unique needs as well as enhance cultural competency. Governments and other institutions working to meaningfully engage people with or who experience risk for HIV must develop partnerships with networks of people with or who experience risk for HIV and other organizations that engage and serve populations most affected by HIV in each community, thereby identifying ways to optimize messages and services and to combat stigma and discrimination. This includes meaningful engagement of Black, Latinx, American Indian/Alaska Native, and other people of color communities—especially people with or experiencing risk for HIV, people who inject drugs, people with a history of justice involvement, immigrants, sex workers, transgender people, and gay and bisexual men—in HIV planning, service delivery, program monitoring/assessment, research, and policymaking.

Strategies

- 3.3.1 Create and promote public leadership opportunities for people with or who experience risk for HIV.
- 3.3.2 Work with communities to reframe HIV services and HIV-related messaging so that they do not stigmatize people or behaviors.

Objective 3.4 Address social and structural determinants of health and co-occurring conditions that impede access to HIV services and exacerbate HIV-related disparities

Addressing social determinants of health and co-occurring conditions, such as noncommunicable comorbidities and coinfections, is essential to reducing HIV-related health disparities and inequities. For many people with or who experience risk for HIV, addressing basic and immediate needs, such as safety and/or shelter, takes precedence over HIV testing, prevention, care, or treatment. Lack of continuous health insurance coverage, inability to pay for care and treatment, inadequate housing, food insecurity, under- and unemployment, medical mistrust, provider misconceptions and bias, low health literacy, language barriers, and involvement in the justice system all act as barriers to improved HIV outcomes.

In other cases, people may be interested in HIV services, but shortages of a skilled and competent workforce or lack of nearby HIV services hinder their ability to access them. These limitations are made worse by inadequate infrastructure, including limited or no broadband internet services and lack of public transportation.⁹⁴ Structural barriers such as laws or policies can also impede the availability of or access to HIV services. For example, support for the legalization or expansion of SSPs is needed in many jurisdictions, particularly in areas with a significant population of people who inject drugs.

Ending the HIV epidemic requires recognition of the need for interventions and pooled resources to address upstream factors often rooted in racism and other social and structural barriers.¹³⁷ Programs could destigmatize HIV services, increase service utilization, address social determinants of health, and improve health outcomes by integrating them in multi-disease, community-based testing, care, and treatment models.¹³⁸ Ultimately, the success of biomedical and behavioral interventions may be directly impacted by whether structural interventions are effectively integrated to support them. Such integration supports person-centered care that considers all of the patient's needs and lived experiences, including those separate from HIV that vary across the lifespan (see Box 8). Integration also includes establishing additional opportunities to engage in partnerships that make it possible to address clients' unmet needs, maximize reach, and promote efficiency and sustainability.



BOX 8

ADDRESSING HIV PREVENTION AND CARE ACROSS THE LIFESPAN

Responsive services that recognize and support variable and episodic needs across the lifespan are necessary to best support people with or who experience risk for HIV.

Much progress has been achieved in preventing perinatal transmission of HIV in the United States; only 65 HIV infections were attributed to perinatal transmission in 2018.¹³⁹ Although rare, perinatal transmission of HIV still occurs in the United States but disproportionately impacts Black children.¹³⁹ Limited antiretroviral therapy (ART) formulations for infants and children make HIV management in these age groups challenging. Questions remain about the impact of HIV and ART exposure in utero, as well as HIV infection and long-term ART on the growing and developing child. While early treatment reduces morbidity and mortality from HIV, whether very early ART can ameliorate complications of HIV and preserve neurodevelopment, optimal cognitive functioning, and mental health in children with HIV is unclear. Preventing mother-to-child transmission requires intensive case management and coordination across many systems and payors.

Youth experience worse HIV outcomes on status awareness, pre-exposure prophylaxis uptake, and health outcomes. Children and young adults with HIV need tailored and often more intensive medical and support services to support them as they grow and become young adults. Schools play an important role in the primary prevention of HIV in youth by offering comprehensive sexual health education and on-site sexual health services through school-based health centers and school nurses, or in collaboration with community partners that provide services, such as periodic, school-wide HIV and STI screening events or mobile clinics. Schools that cannot provide direct sexual health services can establish integrated referral systems that link students to youth-friendly providers in the community. There is a need for both primary prevention approaches and HIV care models that are tailored to groups of youth at disproportionate risk of HIV, including young gay, bisexual, and other men who have sex with men and people who inject drugs.

Across the lifespan, individuals with HIV will also experience a spectrum of non-HIV-specific needs, which may require coordination across various health and social services systems, such as sexual and reproductive health or transition-related care for transgender individuals, in order to ensure affirming whole-person care.

Similarly, tailored approaches are required to meet the HIV prevention, testing, and care needs of older adults. Older Americans are more likely than younger Americans to be diagnosed with HIV infection late in the course of their disease, meaning they get a late start to treatment and possibly experience more damage to their immune system. Thanks to effective HIV care and treatment, people with HIV who are diagnosed early in their infection, and who get and stay on ART, can keep the virus suppressed and live long and healthy lives. Therefore, the number of older adults with HIV is growing; more than one-half of people with diagnosed HIV in the United States were aged 50 and older in 2018.¹²⁵

Older people with HIV, especially long-term survivors, face different health and psychosocial issues than their younger counterparts and thus require appropriately tailored HIV care and treatment services. These unique needs include screening for, assessment of, and treatment of HIV-associated, non-AIDS conditions as well as age-associated diseases for which people with HIV experience increased risk, and addressing social challenges such as social isolation or depression faced by many people aging with HIV and especially those who are long-term survivors of the disease. As this population continues to age, it will be necessary to research, develop, and implement effective interventions, and adapt and appropriately fund systems of care, with attention to comorbidities related to aging.

**BOX 8****ADDRESSING HIV PREVENTION AND CARE ACROSS THE LIFESPAN
(CONTINUED)**

HIV systems of care must incorporate and form partnerships with service providers for older adults, including local Area Agencies on Aging and housing for older adults, to ensure that older people with HIV can also access social services as well as qualified mental health and substance use services that are provided by people experienced in elder care and HIV. Ensuring that agencies focused on elder services can provide age-friendly, affirming care to LGBTQI+ individuals and those with HIV is imperative as the population in need of those services continues to grow.

There is a clear need for both primary prevention approaches and HIV care models tailored to different life stages. Cross-agency efforts are needed to develop, adapt, and implement treatments and interventions specific for the different life stages in order to improve and sustain HIV health outcomes.

Sources: Mandsager et al.⁶, McNeil and Rowe¹⁴⁰

Strategies

- 3.4.1 Develop whole-person systems of care and wellness that address co-occurring conditions for people with or who experience risk for HIV.
- 3.4.2 Adopt policies and laws that reduce cost, payment, coverage, and/or access barriers to improve the delivery and receipt of services for people with or who experience risk for HIV.
- 3.4.3 Improve screening and linkage to services for people with or who experience risk for HIV who are diagnosed with and/or are receiving services for co-occurring conditions.
- 3.4.4 Develop and implement effective, evidence-based and evidence-informed interventions that address social and structural determinants of health among people with or who experience risk for HIV including lack of continuous health care coverage, HIV-related stigma and discrimination in public health and health care systems, medical mistrust, inadequate housing and transportation, food insecurity, unemployment, low health literacy, and involvement with the justice system.
- 3.4.5 Increase the number of schools that have implemented LGBTQ-supportive policies and practices, including (1) having a Gay/Straight Alliance (GSA), Gender Sexuality Alliance, or similar clubs, (2) identifying safe spaces, (3) adopting policies expressly prohibiting discrimination and harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development, (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- 3.4.6 Develop new and scale up effective, evidence-based or evidence-informed interventions that address intersecting factors of HIV, homelessness or housing instability, mental health and violence, substance use, and gender especially among cis- and transgender women and gay and bisexual men.

Objective 3.5: Train and expand a diverse HIV workforce by further developing and promoting opportunities to support the next generation of HIV providers including healthcare workers, researchers, and community partners, particularly from underrepresented populations

Continuous building of a diverse HIV workforce is critical to achieve HIV epidemic control. Supporting and promoting equity and diversity is fundamentally important to adequately and effectively advance research and

enhance innovation. Diversity, inclusion, and community representation are key to achieving creative problem-solving perspectives, and to ensuring the comprehensive cultural spectrum necessary to understand epidemic dynamics.

Multiple obstacles, including the lack of opportunity for minority institutions and communities, paucity of adequate mentorship, and resource limitations, impede achieving equity and diversity in the health workforce. Such structural barriers create challenges at all levels of the workforce development ladder, from recruitment to education, promotion, and retention of HIV providers including researchers, community health workers, and other health care providers.

Together with the development of a diverse health workforce, research that effectively reduces and eliminates health disparities in HIV will require the participation of all sectors of the community. Inclusion of all sectors is fundamental to better understand current needs and develop effective actions to mitigate existing gaps in HIV research and service delivery.

A multipronged approach will be necessary to achieve the interrelated goals of a more diverse and appropriately trained research and health workforce and improved community engagement. Successful approaches should address both individual factors and social factors and involve funding agencies, academic institutions, professional societies, and peer collaboration.

Strategies

- 3.5.1 Promote the expansion of existing programs and initiatives designed to increase the numbers of non-White research and health professionals.
- 3.5.2 Increase support for the implementation of mentoring programs for individuals from diverse cultural backgrounds to expand the pool of HIV research and health professionals.
- 3.5.3 Encourage the implementation of effective recruitment of community partners through community-based participatory research and social networking approaches.

Objective 3.6: Advance HIV-related communications to achieve improved messaging and uptake, as well as address misinformation and health care mistrust

Accurate and accessible health communication is essential to ending the HIV epidemic. Communication science provides the tools and strategies for developing communications tailored to the needs of people with HIV and experiencing risk for HIV. Effective HIV communication science involves best practice principles applied to communicator choice and the design, content, tone, and timing of messages. Communications must be responsive to life contexts, community circumstances and feedback, and changes over time.

The U.S. Surgeon General’s “Advisory on Building a Healthy Information Environment” states that the nation has the power to build a healthier information reality.¹⁴¹ Such an environment improves health by enabling informed decision-making and bolsters trust. Dissemination of accurate and accessible health information has been pivotal in the success of HIV prevention and treatment strategies. HIV health communication plays a significant role in decreasing transmission, increasing treatment, and reducing stigma.

Health communication science is a key to understanding and addressing inaccurate health information, whether unintentional misinformation or deliberate and strategic disinformation. Increased investment in new communication implementation research will improve HIV-related health communication strategies and decrease vulnerability to misinformation and disinformation. Addressing communication challenges requires a sustained whole-of-government approach and engagement with multi-sector partnerships and communities.

Strategies

- 3.6.1 Develop and test strategies to promote accurate creation, dissemination, and uptake of information and to counter associated misinformation and disinformation.
- 3.6.2 Increase diversity and cultural competence in health communication research, training, and policy.
- 3.6.3 Expand community engagement in health communication initiatives and research.
- 3.6.4 Include critical analysis and health communication skills in HIV programs to provide participants with the tools to seek and identify accurate health information and to advocate for themselves and their communities.
- 3.6.5 Expand effective communication strategies between providers and consumers to build trust, optimize collaborative decision-making, and promote success of evidence-based prevention and treatment strategies.

INDICATORS OF PROGRESS

Working together to pursue these objectives, the nation can achieve the following targets by 2025:

Indicator 7 Decrease stigma among people with diagnosed HIV by 50% from a 2018 baseline median score of 31.2 on a 10-item questionnaire.

Indicator 8 Reduce homelessness among people with diagnosed HIV by 50% from a 2017 baseline of 9.1%.

Indicator 9 Increase the median percentage of secondary schools that implement at least 4 out of 7 LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%

In addition to these indicators, the Strategy identifies a disparities indicator to measure progress toward reducing significant HIV-related disparities. Core indicator 6 on viral suppression serves as this disparities indicator and is stratified by each of the priority populations identified in the Strategy:

Indicator 6a Increase viral suppression among MSM diagnosed with HIV to 95% from a 2017 baseline of 66.1%.

Indicator 6b Increase viral suppression among Black MSM diagnosed with HIV to 95% from a 2017 baseline of 58.4%.

Indicator 6c Increase viral suppression among Latino MSM diagnosed with HIV to 95% from a 2017 baseline of 64.9%.

Indicator 6d Increase viral suppression among American Indian/Alaska Native MSM diagnosed with HIV to 95% from a 2017 baseline of 67.3%.

Indicator 6e Increase viral suppression among Black women diagnosed with HIV to 95% from a 2017 baseline of 59.3%.

Indicator 6f Increase viral suppression among transgender women in HIV medical care to 95% from a 2017 baseline of 80.5%.

Indicator 6g Increase viral suppression among people who inject drugs diagnosed with HIV to 95% from a 2017 baseline of 54.9%.

Indicator 6h Increase viral suppression among youth aged 13–24 diagnosed with HIV to 95% from a 2017 baseline of 57.1%.



GOAL 4: ACHIEVE INTEGRATED, COORDINATED EFFORTS THAT ADDRESS THE HIV EPIDEMIC AMONG ALL PARTNERS AND INTERESTED PARTIES

THE OPPORTUNITY

Since the NHAS was first published in 2010, it has inspired all sectors of society—including government agencies, nongovernmental organizations, and the private sector—to better coordinate the nation’s response to the HIV epidemic. This iteration of the Strategy continues to recognize the importance of more integrated, coordinated efforts.

Even greater coordination is possible and essential to ending the HIV epidemic in America. Opportunities include partnerships to meet unmet needs, maximize reach, share best practices to overcoming common challenges, leverage available data, use new and evolving technologies, and promote efficiency and sustainability. Greater integration of services is crucial to meeting the nation’s HIV testing, prevention, care, treatment, and supportive service needs, especially for people living in under-resourced areas and/or who are not effectively reached and engaged by existing programs and services.

It is also essential to address the syndemic of HIV, STIs, viral hepatitis, and alcohol and substance use and mental health disorders. Collaborative efforts cannot be a one-way street, only benefiting the goals of HIV programs; rather, they should address how HIV programs can facilitate the attainment of other programs’ goals that contribute to the overall health and well-being of the populations served.

Activities that exemplify improved integration and coordination of efforts include the following:

- **CDC and HRSA’s joint guidance to health departments and planning groups about single, multi-year Integrated HIV Prevention and Care Plans.** In June 2021, CDC and HRSA issued Integrated Plan Guidance for CY 2022–2026, which intends to accelerate progress toward meeting national goals while allowing each jurisdiction to design an HIV services delivery system that reflects local vision, values, and needs. This guidance built on the first such guidance issued in 2015;¹⁴² reduced duplicative planning and reporting for grantees; streamlined the work of health department staff and HIV planning groups; and promoted improved collaboration and coordination in the use of data to inform HIV prevention and care program planning, resource allocation, evaluation, and continuous quality improvement.
- **Integration of CDC funding for health department HIV surveillance and prevention.** In 2018, CDC renewed and strengthened its flagship funding program to support HIV surveillance and prevention efforts led by state, territorial, and local health departments with 5-year funding awards that integrated HIV surveillance and prevention programs for the first time. Integration helps health departments plan and execute more efficient, coordinated, and data-driven prevention efforts.
- **Pilot programs that have demonstrated the effectiveness of collaborative data-to-care (D2C) approaches.** Using HIV surveillance and other data to improve continuity of HIV care, these CDC-supported pilot programs integrated data from public health and health care delivery to identify people with an HIV diagnosis who were not engaged in medical care and facilitated linkage to care. The pilots demonstrated effectiveness in achieving their goal of increasing the number of people with HIV who are reengaged in care and virally suppressed.¹⁴³
- **Integration of data across programs to improve design and delivery of services.** HRSA and the Department of Housing and Urban Development collaborated to better coordinate HIV care and housing services for people with HIV through data integration and to ultimately improve health outcomes along the HIV care continuum.¹⁴⁴

- **HRSA, NIH, and CDC Implementation Science**

Workgroup. In 2018 the HRSA HIV/AIDS Bureau began a close collaboration with the CDC Division of HIV/AIDS Prevention and the National Institutes of Health's National Institute of Mental Health to create a platform for dialogue across federal agencies working to apply implementation science in HIV, establishing the Federal Implementation Science Workgroup. The resulting funding opportunity announcements seek to strengthen research/service delivery collaborations between NIH investigators and implementers such as sites funded by CDC, HRSA, the Indian Health Service (IHS), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other providers of HIV prevention and care services. Applicants develop creative, locally defined, and culturally sensitive concepts that align with the EHE jurisdictional plans.¹⁴⁵

- **A growing awareness of the need to better integrate services for populations vulnerable to multiple health concerns.**

For example, a 2019 National Academies of Sciences, Engineering, and Medicine workshop highlighted the importance of addressing infectious diseases as part of an improved, comprehensive opioid response and noted that separately administered substance use disorder treatment and infectious disease services often inhibit comprehensive care.¹⁴⁶ In addition, in 2020 SAMHSA published [Prevention and Treatment of HIV Among People Living with Substance Use and/or Mental Disorders](#), a guide that addresses the co-occurrence of HIV and mental illness and/or substance use disorders and reviews effective programs and practices to prevent HIV and, for people with HIV, to increase linkage and retention in care in order to improve health outcomes.

- **Use of new HIV surveillance techniques.** CDC has supported several jurisdictions to detect possible HIV infection clusters more quickly and then coordinate swift responses across programs to deliver needed prevention and treatment services to people who need them. As work continues to expand the ability to identify and quickly respond to new HIV infections, health departments and communities must work together to collectively address the consent, privacy, and data use concerns.

- **Provisions in the 21st Century Cures Act on the interoperability of health information.** These provisions, including those related to social determinants of health, put the patient at the center of care and promote secure health information exchange to enable improved coordination, targeting of resources, and research that can support achieving the Strategy's goals. In March 2020, the Office of the National Coordinator for Health IT (ONC) issued a final rule to implement key interoperability provisions of the 21st Century Cures Act, including promoting patient access to their electronic health information, supporting provider needs, advancing innovation, and addressing industry-wide information blocking practices.¹⁴⁷



GOAL 4: ACHIEVE INTEGRATED, COORDINATED EFFORTS THAT ADDRESS THE HIV EPIDEMIC AMONG ALL PARTNERS AND INTERESTED PARTIES

Objectives

- 4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence
- 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community
- 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data
- 4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances
- 4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals

- **Partnerships with Medicaid programs.** Through these partnerships, several state HIV programs have been able to implement performance measures that reward providers who have increased the numbers of patients who have achieved and maintained viral suppression.
- **Enhanced efforts to integrate services and disciplines in health care delivery.** In recent years, greater emphasis has been placed on integrating behavioral health (mental health and substance use disorder) services and primary care and vice versa. Expanding availability of medications for treatment for substance use disorders in primary care settings is one example. Similarly, to serve the growing population of people with HIV over age 50, more clinics are adopting a geriatric multidisciplinary approach to health care, addressing the domains of medical problems, cognitive and functional abilities, psychiatric disorders, and social circumstances.¹⁴⁸
- **Updating the United States Core Data for Interoperability (USCDI) as a Foundation for Interoperability.** In July 2021, ONC released version 2 of the USCDI. The update expands the standardized set of health data classes and elements for nationwide, interoperable health information exchange. The new data elements support efforts to advance health equity by addressing sexual orientation, gender identity, and social determinants of health.¹⁴⁹

THE CHALLENGES

The following challenges hinder efforts to achieve more integrated and coordinated efforts that address the HIV epidemic among all partners and interested parties:

- Rising rates of substance use have resulted in concurrent infectious diseases epidemics.
- Coordination at the federal, state, and local levels has not expanded to include other necessary government, community-based, and civic partners.
- Data sharing and integration is not timely across programs.
- Local HIV plans are not adequately supported.
- The COVID-19 pandemic continues to divert resources.
- Legislation, budget allocations, and payment systems are not aligned with models of integrated care.

SUMMARY OF OBJECTIVES

The following objectives are critical to achieving integrated, coordinated efforts that address the HIV epidemic among all partners and interested parties:

- 4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence.
- 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community.
- 4.3 Enhance the quality, accessibility, sharing, and use of data, including HIV prevention and care continuum data and social determinants of health data.
- 4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances.
- 4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals.

OBJECTIVES AND STRATEGIES

Objective 4.1 Integrate programs to address the syndemic of HIV, STIs, viral hepatitis, and substance use and mental health disorders in the context of social and structural/institutional factors including stigma, discrimination, and violence

The syndemic of HIV, STIs, viral hepatitis, substance use and mental health disorders in the United States highlights overlapping risk factors as well as associations with social determinants of health such as poverty, lack of health insurance, housing instability, and other related inequities. An effective response to the syndemic requires integration of programs to enable increased flexibility in utilization of allocated resources; better coordinated policy and program planning, development, and delivery; and rapid adjustment to new data or scientific advances. For such integration to occur, major shifts in policy, systems, and societal norms and attitudes must occur, and the willingness to explore new and nontraditional approaches and strategies must increase.

A National Academies report recommends that the syndemic be addressed via integrated medical services in place of often siloed services.¹⁴⁶ Opportunities are missed every day to test people for multiple infections and to scale up HIV services in settings where people who experience risk receive other services. For example, in 2019 among health care settings and non-health-care settings, only 34% of CDC-funded HIV tests had at least one STI or hepatitis C test conducted concurrently.¹⁵⁰ These missed opportunities translate directly into lost time and resources and may result in harm to people who remain undiagnosed, untreated, and at risk of severe outcomes or of transmitting the infection to others. A reciprocal, integrated approach in responses to infectious diseases, the opioid crisis, and substance use and mental health disorders that puts patients first through a status-neutral and no-wrong-door approach will maximize their ability to access services that meet their health needs. In addition, creating a system that focuses on a whole-health approach and one that considers a myriad of needs can lead to enhanced life experiences for people living with HIV. For example, HIV testing programs can identify opportunities to screen for other STIs, viral hepatitis, substance use, and intimate partner violence. Similarly, STI, substance use disorder treatment, and viral hepatitis programs can integrate HIV testing and linkage to relevant HIV prevention or care services, as appropriate.

Strategies

- 4.1.1 Integrate HIV awareness and services into outreach and services for issues that intersect with HIV such as intimate partner violence, homelessness or housing instability, STIs, viral hepatitis, and substance use and mental health disorders.
- 4.1.2 Implement a no-wrong-door approach to screening and linkage to services for HIV, STIs, viral hepatitis, and substance use and mental health disorders across programs.
- 4.1.3 Identify and address funding, policy, data, workforce capacity, and programmatic barriers to effectively address the syndemic.
- 4.1.4 Coordinate and align strategic planning efforts on HIV, STIs, viral hepatitis, substance use disorders, and mental health care across national, state, tribal, territorial, and local partners.
- 4.1.5 Enhance the ability of the HIV workforce to provide naloxone and educate people on the existence of fentanyl in the drug supply to prevent overdose and deaths and facilitate linkage to substance use disorder treatment and harm reduction programs.

Objective 4.2 Increase coordination among and sharing of best practices from HIV programs across all levels of government (federal, state, tribal, local, and territorial) and with public and private health care payers, faith-based and community-based organizations, the private sector, academic partners, and the community

Ending the HIV epidemic requires a whole-of-society approach. Increasing coordination across all sectors of society enables better delivery of services and resources to people with or who experience risk for HIV. Likewise,

establishing trusted partnerships enables coalitions to develop, implement, and regularly evaluate and update policies and programs that address the social, economic, and political environments that shape and constrain individual, community, and societal outcomes.

Increased coordination at the federal level includes expanding the partners engaged in the nation's HIV response. This effort includes leveraging existing programs whose primary purpose may not be HIV services, but that could provide supportive services such as employment training or nutrition assistance to people with or who experience risk for HIV. Such coordination helps to ensure that resources are allocated according to current burden of disease and that the most effective prevention and care strategies are tailored to local community needs to achieve maximal results.

Better coordination involves fostering strong linkages among community-based organizations, health departments, other public programs and services, education agencies, pharmacies, health care providers and systems, and community leaders. Collaboration with community partners is particularly important to developing locally relevant plans for providing testing, prevention, care, treatment, and supportive services, including those that engage people not yet reached by existing programs and services. Collaboration also involves engaging and building capacity and competencies among partners and communities that are interested in providing HIV services but may not have had the opportunity or resources to do so. Expanded and strengthened partnerships can better equip communities to respond swiftly and effectively to identified outbreaks of HIV, STIs, and/or viral hepatitis. Greater involvement by our nation's technology and other business communities can boost efforts to provide accurate information, reach key populations, and develop innovative tools.

Attention must also be focused on service delivery and payment methods. Fee-for-service and other payment models do not adequately support integrated, comprehensive health care delivery models, such as behavioral health and medical care integration, patient-centered medical homes, services provided by pharmacists in nontraditional roles, integration with support services, oral health care, and care coordination. Grant funding to support pilots or demonstrations of such integrated models is limited and time-bound. Scaling up and sustaining these effective care delivery models require evolutions in public and private payer systems.

Strategies

- 4.2.1 Focus resources including evidence-based and evidence-informed interventions in the geographic areas and priority populations disproportionately affected by HIV.
- 4.2.2 Enhance collaboration among local, state, tribal, territorial, national, and federal partners and the community to address policy and structural barriers that contribute to persistent HIV-related disparities and implement policies that foster improved health outcomes.
- 4.2.3 Coordinate across partners to quickly detect and respond to HIV outbreaks.
- 4.2.4 Support collaborations between community-based organizations, public health organizations, education agencies and schools, housing providers, and health care delivery systems to provide linkage to and delivery of HIV testing, prevention, care, and treatment services as well as supportive services.

Objective 4.3 Enhance the quality, accessibility, sharing, and uses of data, including HIV prevention and care continua data and social determinants of health data

High-quality data are essential to increasing coordination, integration, and seamless delivery of services that are required to end the HIV epidemic. The appropriate collection and use of data can inform efforts to focus prevention and testing services on populations that need them most, can help ensure that people newly diagnosed with HIV are promptly linked to care, and can facilitate retention in effective HIV care. However, jurisdictions need resources, guidance, and support to strengthen HIV surveillance systems and activities, in accordance with applicable law, to

obtain the data needed to improve our response to the HIV epidemic, including viral load reporting and disparities data to ensure that populations or communities are not being left behind.

Appropriate use of secure electronic health information exchange can help to engage and retain or reengage people in care and to facilitate transitions across care and community settings. Further, sharing of treatment and outcome data can drive the science needed to develop new and better treatments, approaches to retention in care, and prevention interventions. Better use of data on social determinants of health can optimize prevention and testing efforts for groups experiencing greater risk of acquiring HIV, engage and retain people with HIV in care, support adherence to treatment, and inform ongoing research efforts to develop better treatment and prevention. Use of modeling and other analytical approaches may yield novel insights and inform planning.

Strategies

- 4.3.1 Promote the collection, electronic sharing, and use of HIV risk, prevention, and care and treatment data using interoperable data standards, including data from electronic health records, in accordance with applicable law.
- 4.3.2 Use interoperable health information technology, including application programming interfaces (APIs), clinical decision support tools, electronic health records and health IT products certified by the Office of the National Coordinator's Health IT Certification Program, and health information exchange networks to improve HIV prevention efforts and care outcomes.
- 4.3.3 Encourage and support patient access to and use of their individual health information, including use of their patient-generated health information and use of consumer health technologies in a secure and privacy-supportive manner.

Objective 4.4 Foster private-public-community partnerships to identify and scale up best practices and accelerate HIV advances

Effective private-public-community partnerships are necessary to enhance responses to critical implementation challenges. Partnerships should ensure local relevance and emphasize the leadership role of community members, academic investigators, public health departments and other collaborators through intentional involvement in all stages of research, from conceptualization of the research question to dissemination of results.

There is growing interest in developing closer partnerships among the private sector to increase the appropriate application of evidence in policy and practice. Private-sector resources and approaches that integrate multidisciplinary HIV prevention and treatment service delivery in different settings can reach communities in ways that government cannot. Emphasis on cross-disciplinary collaboration and input by allied health and community service providers as partners with the private sector in HIV research, prevention, and care will optimize program acceptability, uptake, and rollout; improve outcomes; and maximize the impact of translation of research results.

The response to the HIV epidemic has generated significant scientific advances and best practices. Implementation science provides a framework to identify factors that facilitate application of relevant and effective public health interventions and services. Community-centric implementation research is one important approach to rapidly and effectively translate new discoveries into practice at the local level, with fidelity. Effective partnerships can achieve an impact at the population level, to efficiently disseminate evidence-based interventions at scale through culturally appropriate public health initiatives and clinical practice (see Box 9).

There is a need to develop more opportunities and mechanisms for timely information sharing and peer technical assistance to support replication of best practices and use of lessons learned to address common barriers within and across jurisdictions. Activities supporting replication and scale-up of proven interventions should address infrastructure needs and include intentional sustainability planning to ensure continuity of care and services across all participating service settings.

Strategies

- 4.4.1 Adopt approaches that incentivize the scale up of effective interventions among academic centers, health departments, community-based organizations, allied health professionals, people with HIV and their advocates, the private sector, and other partners.
- 4.4.2 Expand opportunities and mechanisms for information sharing and peer technical assistance within and across jurisdictions to move effective interventions into practice more swiftly.
- 4.4.3 Develop and optimize collaborative multi-agency and multi-sectoral approaches and strategies to address emergent and evolving challenges facing people of all ages living with HIV.



BOX 9

LEVERAGING TECHNOLOGY INNOVATIONS TO IMPROVE HIV PREVENTION AND TREATMENT

Technological innovations have rapidly altered many aspects of life in the past decade. Many Americans have transformed their digital toolbox to include systems such as Zoom or FaceTime, email, and other applications to stay informed on their health and connected to health care systems. These innovations prove the potential to leverage technology in the HIV response.

Telehealth has proven to be a reliable resource for reaching populations experiencing risk or who are living with HIV and can address many of the factors identified as barriers to retention in HIV care. Telehealth can also broaden access to pre-exposure prophylaxis (PrEP), HIV care and treatment, and mental health and substance use treatment in rural areas, which often face workforce shortages and transportation challenges.¹⁵¹ Refining and sustaining telehealth services that were implemented in response to the COVID-19 pandemic will allow organizations to use these technological advances to improve the HIV response.

Expanded use of the internet and social media can help people involved in HIV prevention and treatment use mobile devices, websites, and applications as hubs for HIV information and collaboration to ensure that scientifically and medically accurate information is prioritized, and misinformation is combated. At the same time, these websites and applications can also make accessing information on HIV prevention, testing, and treatment more accessible and discrete. Wearable technology such as smartwatches can use health applications to provide real-time insights on an individual's health status and empower people to personalize and monitor their own health data. Electronic health records strengthen the HIV care continuum by providing accurate and timely information. Electronic health records can also use clinical decision support tools to help improve screening by identifying patients for whom an HIV test or PrEP might be recommended or facilitating reengagement in HIV care for those who may have left but present for other health care services elsewhere. Further advancements in the use of technology to improve HIV care could also be used to streamline patient pathways including enhanced remote patient monitoring techniques and other engagement opportunities made available through emerging fields such as digital therapeutics and at-home testing. Policymakers, clinicians, and private-sector partners must collaborate to uncover solutions and further innovation to leverage technology in the HIV response and improve patient engagement.

Objective 4.5 Improve mechanisms to measure, monitor, evaluate, and use the information to report progress and course correct as needed in order to achieve the Strategy's goals

There is a continued need to streamline and harmonize data reporting to reduce reporting burden and produce more regular, timely, and useful data. Support is also needed to adopt new analytic methods and approaches to

increase the timeliness of data, enhance the ability to characterize the burden of HIV across the nation, and use that information to allocate resources to achieve the greatest impact. In addition, complementary data sources such as health care payer databases, surveys, and linkages to electronic health records are necessary to ensure that robust information that can guide decision-making.

Timely data will improve accountability among federally funded organizations as they set and make progress toward measurable goals and targets aligned with this Strategy. Data for the indicators at the local, state, and national levels should be regularly and publicly reported and reviewed to identify successful efforts, indicate challenges, and facilitate ongoing dialogue about ways to continue moving forward. Such reporting and review require a monitoring plan that evaluates the implementation of the Strategy. A system of regular public reporting will help to sustain public attention and support at the national level. Organizations that struggle to engage new parties and organizations or fall short of expected outcomes should receive intensive capacity-building assistance and other supportive measures as a condition of continued funding. The nation can thus direct its funds to entities and initiatives that demonstrate the highest level of performance and accountability for high-impact HIV prevention.

Strategies

- 4.5.1 Streamline and harmonize reporting and data systems to reduce burden and improve the timeliness, availability, and usefulness of data.
- 4.5.2 Monitor, review, evaluate, and regularly communicate progress on the National HIV/AIDS Strategy.
- 4.5.3 Ensure that the National HIV/AIDS Strategy's goals and priorities are included in cross-sector federal funding requirements.
- 4.5.4 Strengthen monitoring and accountability for adherence to requirements, targets, and goals by funded partners.
- 4.5.5 Identify and address barriers and challenges that hinder achievement of goals by funded partners and other interested parties.

IMPLEMENTATION AND ACCOUNTABILITY

FEDERAL PARTNERS

The Strategy provides a framework for ending the HIV epidemic in the United States. Development of the Strategy was a collaborative process led by the White House that engaged federal partners across multiple departments and agencies with input from a diverse range of interested parties and organizations from across the nation.

Federal partners will collaborate to develop an implementation plan to pursue the Strategy goals, objectives, and strategies. The NHAS Federal Implementation Plan will set forth federal partners' commitments to policies, initiatives, and activities to meet the goals of the Strategy and will be published for transparency and accountability.

As part of their ongoing commitment to reduce HIV in this nation, federal partners have committed to serve on a Strategy implementation working group. This working group will collaborate to address HIV in an integrated fashion by including other infectious diseases as components of the syndemic. The working group will meet regularly to coordinate activities across agencies and departments, apply lessons learned from epidemiological data and research findings, monitor progress toward the indicator targets, course correct as needed, and report on national progress. As scientific, medical, and public health advances and challenges emerge, new and innovative policies will be developed to complement the existing Strategy.

NONFEDERAL PARTNERS

Addressing HIV is not solely a federal activity. Success depends on coordinated action by state, tribal, territorial, and local governments; community-based organizations and faith-based organizations; health plans and payers, health care providers, and other health-related organizations; private-sector partners; the criminal justice system; universities, schools, education agencies, and other venues for educational activities; researchers; families; and patients and their partners. Its success also depends on a holistic approach to the various parts of the syndemic, including STIs, viral hepatitis, substance use and mental health disorders, stigma and discrimination, and social and structural determinants of health.

Each community and stakeholder brings a unique perspective and plays a critical role in preventing and responding to HIV. Over the past several years many states and localities have engaged in community-wide efforts to develop their own plans to end the HIV epidemic. Interested parties and organizations are encouraged to use this Strategy to engage with others and build or update their own roadmap to reduce HIV and end the HIV epidemic among the populations and communities they serve. Interested parties and organizations should consider adopting the vision and goals of this Strategy; pursuing the objectives and implementing the strategies relevant to their role(s), populations served, and community circumstances; and identifying opportunities to adopt and use the Strategy's indicators and targets to measure their own progress. In doing so, communities and interested parties and organizations can also apply other evidence-based strategies that are appropriate for responding to HIV in their area and use all available data to identify where their resources and effort will have the most impact. A data-driven strategy will help interested parties and organizations focus efforts and efficiently and effectively use available resources. Integrating HIV testing, prevention, care, and treatment efforts with other components of the syndemic is also strongly encouraged.

APPENDIX A: PROCESS FOR DEVELOPING THE STRATEGY

On June 5, 2021, the Biden-Harris administration re-established the Office of National AIDS Policy (ONAP) within the White House. After discussions with staff of the White House Domestic Policy Council, it was agreed that the HIV National Strategic Plan (HIV Plan) released in January 2021 provided a strong foundation for ending the HIV epidemic but required updates to reflect Administration priorities, the latest data and research, and community feedback specific to the HIV Plan.

ONAP consulted with the federal department and agency representatives who served on the interagency Steering Committee that developed the HIV Plan (see Table A.1) to obtain recommendations to fulfill this mandate. In addition, ONAP received feedback from a variety of parties from the HIV community that could strengthen the Strategy to end the HIV epidemic by 2030. ONAP reviewed, considered, and integrated much from these various inputs into this Strategy, with support from the White House Office of National Drug Control Policy and the Office of Infectious Disease and HIV/AIDS Policy (OIDP), within the Office of the Assistant Secretary for Health at the Department of Health and Human Services (HHS). Drafts were refined through successive rounds of review by the Steering Committee, Domestic Policy Council, inter-departmental clearance, and the White House.

Table A.1. Composition of NHAS Federal Steering Committee

Federal Departments and Agencies	HHS Agencies/Offices	
• Department of Agriculture • Department of Defense • Department of Education • Department of Justice • Equal Employment Opportunity Commission • Department of Health and Human Services • Department of Housing and Urban Development • Department of Labor • Department of Veterans Affairs	• Administration for Community Living • Agency for Healthcare Research and Quality • Centers for Disease Control and Prevention • Centers for Medicare & Medicaid Services • Food and Drug Administration • Health Resources and Services Administration • Indian Health Service	• National Institutes of Health • Office for Civil Rights • Office of the Assistant Secretary for Health • Office of the National Coordinator for Health Information Technology • Substance Abuse and Mental Health Services Administration

IDENTIFICATION OF PRIORITY POPULATIONS BASED ON NATIONAL-LEVEL DATA

ONAP maintained in this Strategy the priority populations designated in the HIV National Strategic Plan. Priority populations are disproportionately affected populations, which are defined as groups of people with a higher burden of disease than others. HIV testing, prevention, care, and treatment interventions and resources can be delivered to priority populations for the greatest impact. An Indicators Subcommittee of the Steering Committee that developed

the HIV National Strategic Plan reviewed national HIV surveillance data available in 2020 to identify priority populations. In developing this Strategy, ONAP reviewed the most recent data and determined that it continued to support the designation of the identified priority populations.

Table A.2. Priority Populations and Summary National-Level Data, Calendar Year 2019 (unless otherwise indicated)

Gay, Bisexual, and Other Men Who Have Sex with Men (MSM)

- Gay, bisexual, and other men who have sex with men are the population most affected by HIV in the United States. At the end of 2019, an estimated 1,189,700 people had HIV in the United States. Of those, 692,900 (58%) were gay and bisexual men.¹¹
- In 2019, adult and adolescent gay and bisexual men represented 66% (23,100) of the 34,800 new HIV infections in the United States.¹¹
- The incidence of many STIs in gay, bisexual, and other men who have sex with men—including primary and secondary syphilis and antimicrobial-resistant gonorrhea—is greater than that reported in women and men who have sex with women only.¹⁵² Having another STI can greatly increase the chance of getting or transmitting HIV. Of new HIV infections among men who have sex with men, 10% are estimated to be attributable to gonorrhea and chlamydia, equating to 2,600 HIV infections each year.⁵¹

Black MSM

- Black gay, bisexual, and other men who have sex with men are more affected by HIV than any other group in the United States.
- In 2019, Black gay and bisexual men accounted for 26% (8,900) of the 34,800 new HIV infections and 39% of the 23,100 new infections among all gay and bisexual men in the United States.¹¹
- Of the 36,337 new HIV diagnoses among adolescents and adults ≥13 years in the United States and dependent areas in 2019, 25% were among Black gay and bisexual men.³
- From 2015 to 2019, HIV infections remained stable among Black gay and bisexual men overall. By age group, the annual number of new HIV infections declined in Black gay and bisexual men aged 13–24, while the number of new infections remained stable among all other age groups of Black gay and bisexual men.¹¹ In 2019 the largest percentage of new HIV infections among Black/African American gay and bisexual men was among those aged 25–34 years (46%), followed by those aged 13–24 years (33%).¹¹
- Along the HIV care continuum, compared to all people with diagnosed HIV in 41 states and the District of Columbia, Black gay and bisexual men have lower viral suppression rates.⁷ (See Figure A.1.)

Latino MSM

- Latino gay, bisexual, and other men who have sex with men are heavily affected by HIV. In 2019, adult and adolescent Latino gay and bisexual men comprised 23% (7,900) of the 34,800 new HIV infections in the United States and 34% of 23,100 new HIV infections among all gay and bisexual men in the United States.¹¹
- Of the 36,337 new HIV diagnoses among adolescents and adults ≥13 years in the United States and dependent areas in 2019, 22% were among Latino gay and bisexual men.³
- From 2015 to 2019, the annual number of new HIV infections declined in Hispanic/Latino gay and bisexual men aged 13–24, while the number of new infections remained stable among all other age groups of Hispanic/Latino gay and bisexual men.¹¹ In 2019 the largest percentage of HIV infections among Hispanic/Latino gay and bisexual men was among those aged 25–34 years (44%), followed by those aged 13–24 years (23%).¹¹

American Indian/Alaska Native MSM

- American Indian/Alaska Native men who have sex with men are disproportionately affected by HIV. In 2019, 62% (126/209) of diagnoses among adolescents and adults ≥13 years occurring among American Indian/Alaska Native people were among men who have sex with men.³
- HIV diagnoses among American Indian/Alaska Native gay and bisexual men increased 15% between 2015–2019, while diagnoses among gay and bisexual men of other races/ethnicities were either stable or declined.¹²⁵

Black Women

- Although data show a 22% decrease in new HIV infections among Black women between 2010 and 2019, among all women in the United States, Black women account for the largest share of 6,400 new HIV infections (3,400 or 53%) in 2019.^{4, 11}
- The rate of new HIV infections among Black women (18.9 per 100,000) is nearly 11 times as high as the rate among White women (1.8 per 100,000) and nearly 4 times as high as the rate among Latinas (4.9 per 100,000).¹¹

Transgender Women

- A 2019 systematic review and meta-analysis found that an estimated 14% of transgender women have HIV.¹⁴
- By race/ethnicity, an estimated 44% of Black transgender women, 26% of Latina transgender women, and 7% of White transgender women have HIV.^{2, 3, 153}
- Among the 3 million HIV testing events reported to CDC in 2017, the percentage of transgender people who received a new HIV diagnosis was three times the national average.¹⁵⁴

Youth Aged 13–24 Years

- In 2019, youth aged 13–24 years accounted for 21% (7,200) of the 34,800 new HIV infections in the United States and dependent areas. Most new HIV diagnoses among youth were among young gay and bisexual men.
- Only 9% of high school students have been tested for HIV and therefore do not know their HIV status. Among male students who had sexual contact with other males, only 15% have ever been tested for HIV.¹⁵⁵
- In 2019, youth with diagnosed HIV were also the least likely of any age group to be linked to care within 1 month of diagnosis (79%).² Further, compared to all people with HIV, youth have the lowest rates of viral suppression. For every 100 youth with HIV, 45 received some HIV care, 33 were retained in care, and 35 were virally suppressed.²
- People aged 15–24 years account for approximately 50% of the 20 million new STIs in the United States each year, yet approximately 25% of the sexually active population.¹⁵² Having another STI can greatly increase the chance of getting or transmitting HIV.

People Who Inject Drugs (PWID)

- People who inject drugs are at high risk for getting HIV and/or HCV if they use and share needles, syringes, or other drug injection equipment that someone with HIV has used.
- New HIV infections among people who inject drugs have increased 8.7% in recent years (from 2,300 infections in 2015 to 2,500 infections in 2019) in the United States and dependent areas.¹¹
- Although HIV incidence among people who inject drugs has declined substantially over many years, the ongoing use of opioids and other frequently injected substances including cocaine and methamphetamine are threatening this HIV prevention success. HIV diagnoses among people who inject drugs increased by 11% nationally from 2016 to 2018, with more pronounced increases among adults younger than age 40 and non-Hispanic White adults.¹²⁵ Injection drug use has contributed to multiple recent clusters and outbreaks of new HIV infections among people who inject drugs.¹⁵⁶
- Among people with HIV who inject drugs, 62–81% were also living with hepatitis C.¹⁵⁷ People with HIV also living with hepatitis B or hepatitis C have higher liver-related morbidity and mortality, and higher overall mortality than patients only living with hepatitis B or hepatitis C.¹⁵⁸⁻¹⁶⁰

Figure A.1 depicts the subpopulations (defined by race, ethnicity, and gender) with the most new HIV diagnoses in 2019.

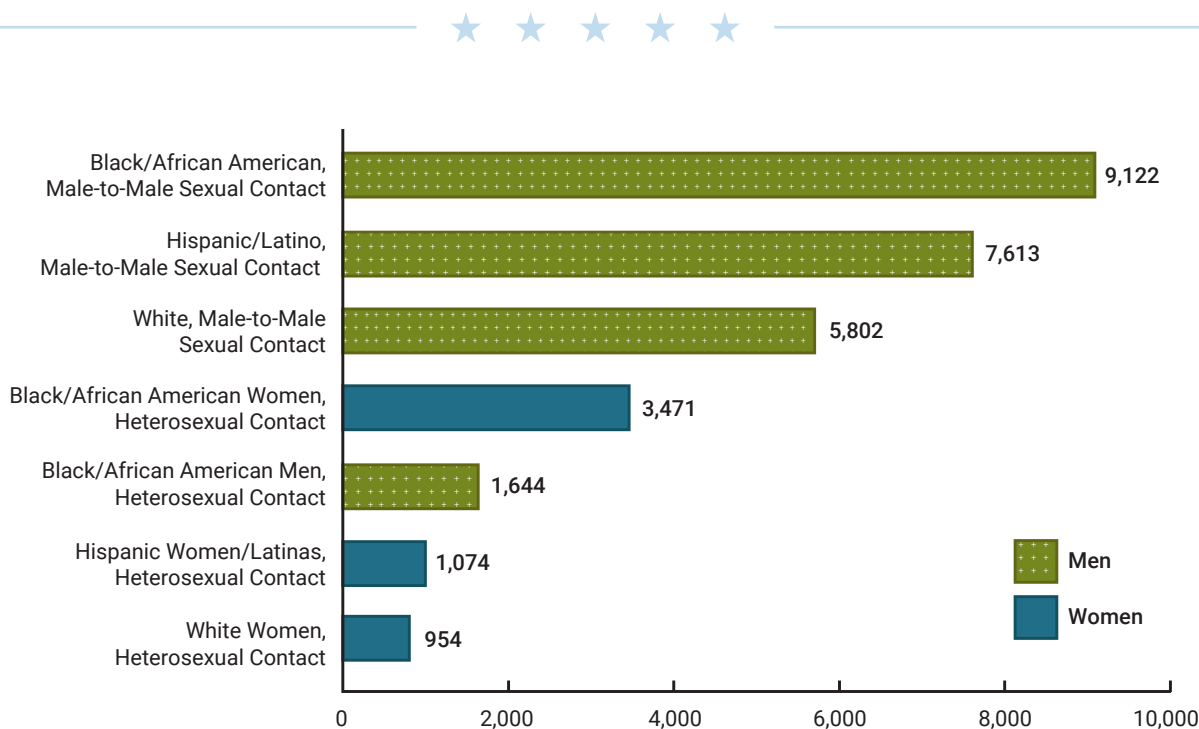


Figure A.1. New HIV diagnoses in the United States and dependent areas for the most-affected subpopulations, 2019

Notes: Black refers to people having origins in any of the Black racial groups of Africa. African American is a term often used for Americans of African descent with ancestry in North America. Hispanics/Latinos can be of any race. Subpopulations representing 2.0% or less of all people who received an HIV diagnosis in 2018 are not represented in this chart. Source: Centers for Disease Control and Prevention.¹⁶¹

The Strategy recognizes the importance of providing HIV services to all populations with or who experience risk for HIV. Therefore, even though they were not designated as priority populations, the Strategy discusses the importance of addressing the unique needs of other groups, such as long-term survivors and older people with HIV or people experiencing unstable housing or homelessness.

INDICATORS TO MEASURE PROGRESS FOR THE NATIONAL HIV/AIDS STRATEGY

The Strategy includes 9 core indicators to monitor annual progress toward achieving Goals 1, 2, and 3. In addition, one of the core indicators is stratified by each of the priority populations to measure progress toward reducing disparities.

For each indicator, baseline measurements (2017) and targets for 2025 are provided. Indicators 1–6 are aligned with the EHE initiative and *Healthy People 2030* objectives. Alignment of the indicators between the HIV Plan and EHE allows for consistency and reduced burden on local and state health departments that report data as well as on federal partners who monitor and report on progress in measuring and reporting results across the indicators.

The methods for measuring progress and specifications for each of the indicators is detailed below.

METHODS

CDC's National Center for Health Statistics describes the “percent of targeted change achieved,” which quantifies progress for *Healthy People 2020* indicators that are moving toward their targets. The methods are described in full by Talih and Huang¹⁶² and may be used for measuring progress in *Healthy People 2030*. To align methods for measuring progress across HHS, the percentage of targeted change achieved method is adapted for use to measure national progress annually for the National HIV/AIDS Strategy.

METHODS

The “percent of targeted change achieved” used in *Healthy People 2020* is the difference between the baseline and the midcourse value as a percent of the targeted change between the baseline value and the *Healthy People 2020* target. To adapt for use in the National HIV/AIDS Strategy, annual results and National HIV/AIDS Strategy targets are used. This method also provides a way to compare percent of targeted change achieved by National HIV/AIDS Strategy indicator and highlights areas on which to focus. The formula is as follows:

$$\text{Percent of targeted change achieved} = \frac{\text{Annual result} - \text{Baseline result} \times 100}{2025 \text{ target} - \text{Baseline result}}$$

The magnitude of change for percent of targeted change achieved may be evaluated using statistical significance testing for indicators that are estimated.

An *example* using hypothetical data is provided below to illustrate the calculations for the percent of targeted change achieved for linkage to care within 1 month and viral suppression.

Table A.3. Hypothetical Data for Linkage to Care and Viral Suppression Calculations

Indicator	2017	2023	2025 Target
Linkage to Care within 1 Month	78.4%	82.3%	95%
Viral Suppression	54.4%	65.5%	95%

Percent of targeted change achieved for *linkage to care within 1 month*:

$$= \frac{82.3\% - 78.4\%}{95\% - 78.4\%} = \frac{3.9}{16.6} = 23.5\%$$

Achieving the 95% target for linkage to care within 1 month is 100% of the targeted change needed by 2025.

Interpretation: By 2023, almost one-quarter or 23.5% of the targeted change has occurred for linkage to care within 1 month.

Percent of targeted change achieved for *viral suppression*:

$$= \frac{65.5\% - 54.4\%}{95\% - 54.4\%} = \frac{11.1}{40.6} = 27.3\%$$

Achieving the 95% target for viral suppression is 100% of the targeted change needed by 2025. *Interpretation:* By 2023, a little more than one-quarter or 27.3% of the targeted change has occurred for viral suppression.

Indicators that met or exceeded their targets

When the desired direction is increase, an indicator has met or exceeded the target if the annual result is greater than or equal to the 2025 target.

$$\text{Annual result} \geq 2025 \text{ target}$$

When the desired direction is a decrease, an indicator has met or exceeded the target if the annual result is less than or equal to the 2025 target or the 2030 target.

$$\text{Annual result} \leq 2025 \text{ target}$$

Statistical significance is not factored into the determination of the target met or exceeded status.

Indicators moving toward their targets

For indicators that had not already met or exceeded their targets at baseline and are *moving toward* their 2025 targets, the percent of targeted change achieved measures the extent of movement toward the target. The formula is the same as that presented above and is calculated by:

$$\text{Percent of targeted change achieved} = \frac{\text{Annual result} - \text{Baseline result} \times 100}{2025 \text{ target} - \text{Baseline result}}$$

When the desired direction is an increase (i.e., increase to 95%), an indicator is *moving toward* its target when the most recent *annual result is higher than the baseline value but less than the 2025 target*.

Baseline result < Annual result < 2025 target

When the desired direction is a decrease (i.e., decrease by 75%), an indicator is *moving toward* its target when the most recent *annual result is less than the baseline value but greater than the 2025 target*.

Baseline result > Annual result > 2025 target

Indicators moving away from their targets

For indicators that had not already met or exceeded their targets at baseline and are moving away from their 2025 targets, the percent of targeted change achieved measures the extent of movement away from the target and is calculated by:

$$\text{Magnitude of percent change from baseline} = \frac{|\text{Annual result} - \text{Baseline result}| \times 100}{\text{Baseline result}}$$

The absolute value of the percent change from baseline is used to measure movement in this instance. When indicator results are moving away from the 2025 targets, the indicator results will need to make up the deficit from the baseline (i.e., get back to baseline value). Additional work would be needed to see desired targeted change once the baseline value is regained.

INDICATOR SPECIFICATIONS FOR THE NATIONAL HIV/AIDS STRATEGY

Indicator 1: Increase knowledge of status

- Definition:
 - ◊ Numerator: Number of persons aged ≥13 years living with diagnosed HIV at end of a measurement year.
 - ◊ Denominator: Estimated number of persons aged ≥13 years living with diagnosed or undiagnosed HIV at the end of a measurement year.
- Baseline year: 2017
- Baseline result: 85.8%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).¹¹ NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.

Indicator 2: Reduce new HIV infections

- Definition: Incidence is the estimated number of new HIV infections among persons aged ≥ 13 years that occurred in the measurement year and includes diagnosed and undiagnosed infections.
- Baseline year: 2017
- Baseline result: 37,000
- Targets: By 2025, reduce incidence by 75% from baseline. By 2030, reduce incidence by 90% from baseline.
- Data source: National HIV Surveillance System (NHSS).¹¹ NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.

Indicator 3: Reduce new HIV diagnoses

- Definition: Number of persons ≥ 13 years who have received laboratory or clinical confirmation of HIV in a measurement year.
- Baseline year: 2017
- Baseline result: 38,351
- Targets: By 2025, reduce diagnoses by 75% from baseline. By 2030, reduce diagnoses by 90% from baseline.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.³
- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Notes: Provisional annual data (annual data with ≥ 12 months of reporting delay) will be used to measure progress.

Indicator 4: Increase PrEP coverage

- Definition:
 - ◊ Numerator: Number of persons ≥ 16 years who were classified as having been prescribed PrEP in a measurement year.
 - ◊ Denominator: Estimated number of persons with indications for PrEP in a measurement year.
- Baseline year: 2017
- Baseline result: 13.2%
- Target: By 2025, increase to 50%.
 - ◊ Numerator: IQVIA Real-World Longitudinal Prescriptions database
 - ◊ Denominator: Uses three data sources:
 1. The American Community Survey from U.S. Census is used to estimate the number of men who have sex with men (MSM) in a jurisdiction.¹⁶³
 2. Behavioral data from the National Health and Nutrition Examination Survey (NHANES) are used to estimate the proportion of HIV-negative MSM with indications for PrEP.¹⁶⁴
 3. The National HIV Surveillance System (NHSS) diagnoses data are used.² The number of HIV-negative MSM with indications for PrEP are multiplied by the ratio of percentage of HIV diagnoses during the specified year attributed to persons who inject drugs (PWID) and heterosexual transmission risk groups compared to the percentage among MSM. The estimated number of persons with indications

for PrEP in the three major transmission risk groups (MSM, heterosexuals, PWID) in each jurisdiction are then summed to yield national estimates.

- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Note: Prescriptions for PrEP or having indications for PrEP are not reportable conditions and therefore are not reported through the National HIV Surveillance System. Annual data will be used to measure progress.

Indicator 5: Increase linkage to care

- Definition:
 - ◊ Numerator: Number of persons aged ≥ 13 years with HIV diagnosed in a measurement year and who had ≥ 1 viral load (VL) or CD4 test ≤ 1 month after HIV diagnosis.
 - ◊ Denominator: Number of persons aged ≥ 13 years with HIV infection diagnosed during a measurement year.
- Baseline year: 2017
- Baseline result: 77.8%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.²
- Data availability: Data are published annually. Preliminary data are also available quarterly.
- Notes: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results to CDC. The number of jurisdictions may vary each year. Provisional annual data (annual data with ≥ 12 months of reporting delay) will be used to measure progress.

Indicator 6: Increase viral suppression

- Definition:
 - ◊ Numerator: Number of persons aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of persons aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Example: Denominator for 2019 viral suppression is the number of persons aged ≥ 13 years living with diagnosed HIV by the end of 2018 and alive at the end of 2019.
- Baseline year: 2017
- Baseline result: 63.1%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS). NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.²
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results to CDC and with complete death ascertainment. The number of jurisdictions may vary each year.

Indicator 7: Decrease stigma

- Definition: The median score of a 10-item stigma scale, ranging from 0 (no stigma) to 100 (high stigma), measured among persons aged > 18 years living with diagnosed HIV infection living in the United States and Puerto Rico.

- Note: The stigma scale was revised for the 2018 data collection cycle and includes three questions with a 12-month reference period to allow participants to provide experiences in a defined and more recent period of time for one domain of stigma (personalized stigma).
- Baseline year: 2018
- Baseline result: 31.2 median score
- Target: By 2025, decrease by 50%.
- Data source: Medical Monitoring Project (MMP). MMP is a cross-sectional, nationally representative, complex sample survey that assesses the behavioral and clinical characteristics of adults with diagnosed HIV infection in the United States. MMP also provides information on behaviors and clinical outcomes affecting the risk of HIV transmission, morbidity, and mortality. In 2015, MMP sampling and weighting methods were revised to include all adults with diagnosed HIV infection regardless of HIV care status.
- Data availability: Data are published annually.

Indicator 8: Reduce homelessness

- Definition:
 - ◊ Numerator: Number of persons aged ≥ 18 years living with diagnosed HIV in a measurement year and report having been homeless during the 12 months prior to interview. Homelessness is defined as living on the street, living in a shelter, living in a single-room-occupancy hotel, or living in a car.
 - ◊ Denominator: A sample of persons aged ≥ 18 years living with diagnosed HIV in a measurement year, as documented in the medical record.
- Baseline year: 2017
- Baseline result: 9.1%
- Target: By 2025, reduce by 50%.
- Data source: Medical Monitoring Project (MMP). MMP is a cross-sectional, nationally representative, complex sample survey that assesses the behavioral and clinical characteristics of adults with diagnosed HIV infection in the United States. MMP also provides information on behaviors and clinical outcomes affecting the risk of HIV transmission, morbidity, and mortality. In 2015, MMP sampling and weighting methods were revised to include all adults with diagnosed HIV infection regardless of HIV care status.
- Data availability: Data are published annually.

Indicator 9: Increase LGBTQ-supportive school policies and practices

- Definition: This indicator is the median percentage of secondary schools that are implementing at least four of seven school policies and practices that are known to improve health outcomes for both LGBTQ youth and all students: (1) having a Gay/Straight Alliance (GSA) or similar club, (2) identifying safe spaces, (3) prohibiting harassment based on sexual orientation or gender identity, (4) encouraging staff to attend professional development; (5) facilitating access to out-of-school health service providers, (6) facilitating access to out-of-school social and psychological service providers, and (7) providing LGBTQ-relevant curricula or supplementary materials.
- Baseline year: 2018
- Baseline result: 59.8%
- Targets: By 2025, increase the median percentage of secondary schools that are implementing at least four of seven LGBTQ-supportive policies and practices to 65% from a 2018 baseline of 59.8%. By 2030, increase the median percentage of secondary schools to 68.7%.

- Data source: CDC School Health Profiles. The School Health Profiles is a system of surveys assessing school health policies and practices in states, large urban school districts, and territories.
- Data availability: Data are published bi-annually.

Disparities Indicators

To monitor our progress in addressing HIV disparities, the viral suppression indicator is monitored for the following priority populations.

MSM

- Definition:
 - ◊ Numerator: Number of persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 66.1%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Black/African American MSM

- Definition:
 - ◊ Numerator: Number of Black/African American persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of Black/African American persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 58.4%
- Target: By 2025, increase to 95%.
- Data availability: Data are published annually.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Hispanic/Latino MSM

- Definition:
 - ◊ Numerator: Number of Hispanic/Latino persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of Hispanic/Latino persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 64.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

American Indian/Alaska Native MSM

- Definition:
 - ◊ Numerator: Number of American Indian/Alaska Native persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of American Indian/Alaska Native persons with male-to-male sexual contact (MSM) aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 67.3%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Black Women

- Definition:
 - ◊ Numerator: Number of Black/African American females aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of Black/African American females aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 59.3%

- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Transgender Women in HIV Medical Care

- Definition:
 - ◊ Numerator: Number of transgender women living with HIV ≥ 13 years who received from a Ryan White HIV/AIDS Provider at least one outpatient ambulatory health care (OAHC) visit and had at least one viral load test during the measurement year who was virally suppressed. Viral suppression was defined as the most recently reported HIV test result of < 200 copies/mL.
 - ◊ Denominator: Number of transgender women living with HIV ≥ 13 years who received from a Ryan White HIV/AIDS Provider at least one outpatient ambulatory health care (OAHC) visit and had at least one viral load test during the measurement year.
- Baseline year: 2017
- Baseline result: 80.5%
- Target: By 2025, increase to 95%.
- Data source: Ryan White HIV/AIDS Program Services Report⁵
- Data availability: Data are published annually.

People Who Inject Drugs (PWID)

- Definition:
 - ◊ Numerator: Number of persons who inject drugs aged ≥ 13 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of persons who inject drugs aged ≥ 13 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.
- Baseline year: 2017
- Baseline result: 54.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Data availability: Data are published annually.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Youth 13–24 years

- Definition:
 - ◊ Numerator: Number of persons aged 13–24 years living with diagnosed HIV and have a viral load test result < 200 copies/mL at the most recent viral load test during a measurement year.
 - ◊ Denominator: Number of persons aged 13–24 years living with diagnosed HIV by the end of the year prior to the measurement year and alive at the end of the measurement year.

- Baseline year: 2017
- Baseline result: 54.9%
- Target: By 2025, increase to 95%.
- Data source: National HIV Surveillance System (NHSS).² NHSS is the primary source for monitoring trends in HIV in the United States. It is the data source for incidence, diagnoses, and other HIV care continuum data.
- Note: Data are reported for jurisdictions with complete laboratory reporting of CD4 and viral load test results and with complete death ascertainment. The number of jurisdictions may vary each year.

Developmental Indicator—Quality of life for people with HIV

In addition, one key issue, quality of life for people with HIV, was designated as the subject for a “developmental indicator,” meaning that data sources, measures, and targets will be identified, and progress monitored thereafter. Potential data sources and measures exist for this indicator, but further work must be done to assess them and craft the specifications for this developmental indicator. Working with parties and organizations, the federal government will develop an indicator.

APPENDIX B: ACRONYMS

AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
CDC	Centers for Disease Control and Prevention (HHS)
COVID-19	coronavirus disease 2019
EHE	Ending the HIV Epidemic in the U.S.
FDA	Food and Drug Administration (HHS)
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HOPWA	Housing Opportunities for Persons With AIDS
HRSA	Health Resources and Services Administration (HHS)
IHS	Indian Health Service (HHS)
MSM	men who have sex with men
NHAS	National HIV/AIDS Strategy
NIH	National Institutes of Health
OASH	Office of the Assistant Secretary for Health (HHS)
OIDP	Office of Infectious Disease and HIV/AIDS Policy (HHS)
ONAP	Office of National AIDS Policy (White House)
PEP	post-exposure prophylaxis
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RWHAP	Ryan White HIV/AIDS Program (HRSA)
SAMHSA	Substance Abuse and Mental Health Services Administration (HHS)
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SSP	syringe services program
STI	sexually transmitted infection
U=U	Undetectable = Untransmittable
USPSTF	U.S. Preventative Services Task Force

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EXHIBIT O



HRSA
@HRSAgov



ICYMI [#HRSA](#)'s [#RyanWhite](#) HIV/AIDS Program released a letter reaffirming the importance of providing gender affirming [#HIV](#) care & treatment services to transgender people w/HIV to reduce barriers, ensure access to medication & improve health outcomes. bit.ly/35reCDX



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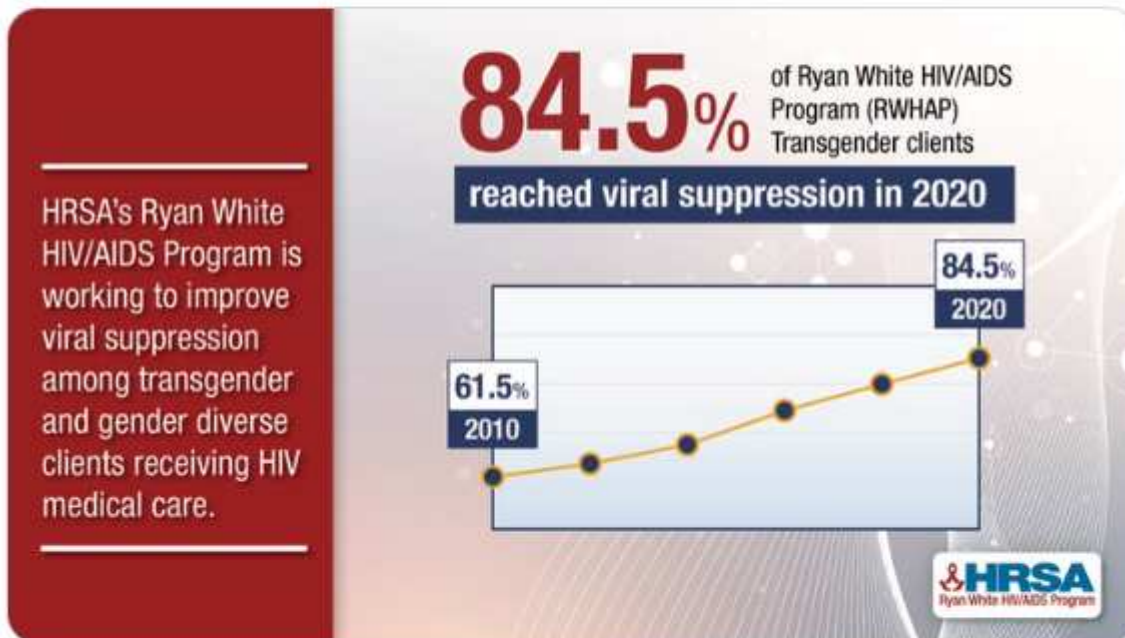
EXHIBIT P



HRSA
@HRSAgov



ICYMI - #HRSA's #RyanWhite HIV/AIDS Program released a letter reaffirming the importance of providing gender affirming #HIV care & treatment services to transgender people w/HIV to reduce barriers, ensure access to medication & improve health outcomes:
bit.ly/3DdwY88



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4



EXHIBIT Q

Presidential Documents

Executive Order 14183 of January 27, 2025

Prioritizing Military Excellence and Readiness

By the authority vested in me as President by the Constitution and the laws of the United States of America, and as Commander in Chief of the Armed Forces of the United States, and to ensure the readiness and effectiveness of our Armed Forces, it is hereby ordered:

Section 1. Purpose. The United States military has a clear mission: to protect the American people and our homeland as the world's most lethal and effective fighting force. Success in this existential mission requires a singular focus on developing the requisite warrior ethos, and the pursuit of military excellence cannot be diluted to accommodate political agendas or other ideologies harmful to unit cohesion.

Recently, however, the Armed Forces have been afflicted with radical gender ideology to appease activists unconcerned with the requirements of military service like physical and mental health, selflessness, and unit cohesion. Longstanding Department of Defense (DoD) policy (DoD Instruction (DoDI) 6130.03) provides that it is the policy of the DoD to ensure that service members are "[f]ree of medical conditions or physical defects that may reasonably be expected to require excessive time lost from duty for necessary treatment or hospitalization." As a result, many mental and physical health conditions are incompatible with active duty, from conditions that require substantial medication or medical treatment to bipolar and related disorders, eating disorders, suicidality, and prior psychiatric hospitalization.

Consistent with the military mission and longstanding DoD policy, expressing a false "gender identity" divergent from an individual's sex cannot satisfy the rigorous standards necessary for military service. Beyond the hormonal and surgical medical interventions involved, adoption of a gender identity inconsistent with an individual's sex conflicts with a soldier's commitment to an honorable, truthful, and disciplined lifestyle, even in one's personal life. A man's assertion that he is a woman, and his requirement that others honor this falsehood, is not consistent with the humility and selflessness required of a service member.

For the sake of our Nation and the patriotic Americans who volunteer to serve it, military service must be reserved for those mentally and physically fit for duty. The Armed Forces must adhere to high mental and physical health standards to ensure our military can deploy, fight, and win, including in austere conditions and without the benefit of routine medical treatment or special provisions.

Sec. 2. Policy. It is the policy of the United States Government to establish high standards for troop readiness, lethality, cohesion, honesty, humility, uniformity, and integrity. This policy is inconsistent with the medical, surgical, and mental health constraints on individuals with gender dysphoria. This policy is also inconsistent with shifting pronoun usage or use of pronouns that inaccurately reflect an individual's sex.

Sec. 3. Definitions. The definitions in the Executive Order of January 20, 2025 (Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government) shall apply to this order.

Sec. 4. Implementation. (a) Within 60 days of the date of this order, the Secretary of Defense (Secretary) shall update DoDI 6130.03 Volume 1 (Medical Standards for Military Service: Appointment, Enlistment, or Induction

(May 6, 2018), Incorporating Change 5 of May 28, 2024) and DoDI 6130.03 Volume 2 (Medical Standards for Military Service: Retention (September 4, 2020), Incorporating Change 1 of June 6, 2022) to reflect the purpose and policy of this Order.

(b) The Secretary shall promptly issue directives for DoD to end invented and identification-based pronoun usage to best achieve the policy outlined in section 2 of this order.

(c) Within 30 days of the date of this order, the Secretary shall:

(i) identify all additional steps and issue guidance necessary to fully implement this order; and

(ii) submit to the President through the Assistant to the President for National Security Affairs a report that summarizes these steps.

(d) Absent extraordinary operational necessity, the Armed Forces shall neither allow males to use or share sleeping, changing, or bathing facilities designated for females, nor allow females to use or share sleeping, changing, or bathing facilities designated for males.

(e) Within 30 days of the issuance of the respective updates, directives, and guidance under subsections (a), (b), and (c) of this section, the Secretary of Homeland Security shall, with respect to the Coast Guard, issue updates, directives, and guidance consistent with the updates, directives, and guidance issued under subsections (a), (b), and (c) of this section.

Sec. 5. *Implementing the Revocation of Executive Order 14004.* (a) Pursuant to the Executive Order of January 20, 2025 (Initial Rescissions of Harmful Executive Orders and Actions), Executive Order 14004 of January 25, 2021 (Enabling All Qualified Americans To Serve Their Country in Uniform), has been revoked. Accordingly, all policies, directives, and guidance issued pursuant to Executive Order 14004 shall be rescinded to the extent inconsistent with the provisions of this order.

(b) The Secretary and, with respect to the Coast Guard, the Secretary of Homeland Security, shall take all necessary steps to implement the revocations described in subsection (a) of this section and ensure that all military departments and services fully comply with the provisions of this order.

Sec. 6. *Severability.* If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected thereby.

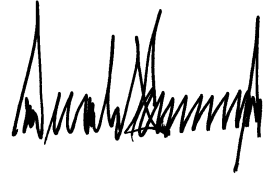
Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be a stylized representation of a name, possibly "Donald Trump", written in a cursive, somewhat jagged style.

THE WHITE HOUSE,
January 27, 2025.

EXHIBIT R

Presidential Documents

Executive Order 14187 of January 28, 2025

Protecting Children From Chemical and Surgical Mutilation

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Policy and Purpose.* Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions. This dangerous trend will be a stain on our Nation's history, and it must end.

Countless children soon regret that they have been mutilated and begin to grasp the horrifying tragedy that they will never be able to conceive children of their own or nurture their children through breastfeeding. Moreover, these vulnerable youths' medical bills may rise throughout their lifetimes, as they are often trapped with lifelong medical complications, a losing war with their own bodies, and, tragically, sterilization.

Accordingly, it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called "transition" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

Sec. 2. *Definitions.* For the purposes of this order:

(a) The term "child" or "children" means an individual or individuals under 19 years of age.

(b) The term "pediatric" means relating to the medical care of a child.

(c) The phrase "chemical and surgical mutilation" means the use of puberty blockers, including GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions. This phrase sometimes is referred to as "gender affirming care."

Sec. 3. *Ending Reliance on Junk Science.* (a) The blatant harm done to children by chemical and surgical mutilation cloaks itself in medical necessity, spurred by guidance from the World Professional Association for Transgender Health (WPATH), which lacks scientific integrity. In light of the scientific concerns with the WPATH guidance:

(i) agencies shall rescind or amend all policies that rely on WPATH guidance, including WPATH's "Standards of Care Version 8"; and

(ii) within 90 days of the date of this order, the Secretary of Health and Human Services (HHS) shall publish a review of the existing literature on best practices for promoting the health of children who assert gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion.

(b) The Secretary of HHS, as appropriate and consistent with applicable law, shall use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion, or who otherwise seek chemical or surgical mutilation.

Sec. 4. *Defunding Chemical and Surgical Mutilation.* The head of each executive department or agency (agency) that provides research or education grants to medical institutions, including medical schools and hospitals, shall, consistent with applicable law and in coordination with the Director of the Office of Management and Budget, immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end the chemical and surgical mutilation of children.

Sec. 5. *Additional Directives to the Secretary of HHS.* (a) The Secretary of HHS shall, consistent with applicable law, take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions, which may involve the following laws, programs, issues, or documents:

- (i) Medicare or Medicaid conditions of participation or conditions for coverage;
- (ii) clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs;
- (iii) mandatory drug use reviews;
- (iv) section 1557 of the Patient Protection and Affordable Care Act;
- (v) quality, safety, and oversight memoranda;
- (vi) essential health benefits requirements; and
- (vii) the Eleventh Revision of the International Classification of Diseases and other federally funded manuals, including the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

(b) The Secretary of HHS shall promptly withdraw HHS's March 2, 2022, guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and, in consultation with the Attorney General, issue new guidance protecting whistleblowers who take action related to ensuring compliance with this order.

Sec. 6. *TRICARE.* The Department of Defense provides health insurance, through TRICARE, to nearly 2 million individuals under the age of 18. As appropriate and consistent with applicable law, the Secretary of Defense shall commence a rulemaking or sub-regulatory action to exclude chemical and surgical mutilation of children from TRICARE coverage and amend the TRICARE provider handbook to exclude chemical and surgical mutilation of children.

Sec. 7. *Requirements for Insurance Carriers.* The Director of the Office of Personnel Management, as appropriate and consistent with applicable law, shall:

- (a) include provisions in the Federal Employee Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) programs call letter for the 2026 Plan Year specifying that eligible carriers, including the Foreign Service Benefit Plan, will exclude coverage for pediatric transgender surgeries or hormone treatments; and
- (b) negotiate to obtain appropriate corresponding reductions in FEHB and PSHB premiums.

Sec. 8. *Directives to the Department of Justice.* The Attorney General shall:

- (a) review Department of Justice enforcement of section 116 of title 18, United States Code, and prioritize enforcement of protections against female genital mutilation;
- (b) convene States' Attorneys General and other law enforcement officers to coordinate the enforcement of laws against female genital mutilation across all American States and Territories;
- (c) prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the Food, Drug, and Cosmetic Act by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation;

(d) in consultation with the Congress, work to draft, propose, and promote legislation to enact a private right of action for children and the parents of children whose healthy body parts have been damaged by medical professionals practicing chemical and surgical mutilation, which should include a lengthy statute of limitations; and

(e) prioritize investigations and take appropriate action to end child-abusive practices by so-called sanctuary States that facilitate stripping custody from parents who support the healthy development of their own children, including by considering the application of the Parental Kidnaping Prevention Act and recognized constitutional rights.

Sec. 9. *Enforcing Adequate Progress.* Within 60 days of the date of this order, the heads of agencies with responsibilities under this order shall submit a single, combined report to the Assistant to the President for Domestic Policy, detailing progress in implementing this order and a timeline for future action. The Assistant to the President for Domestic Policy shall regularly convene the heads of agencies with responsibilities under this order (or their designees) to coordinate and prepare for this submission.

Sec. 10. *Severability.* If any provision of this order, or the application of any provision to any person or circumstances, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

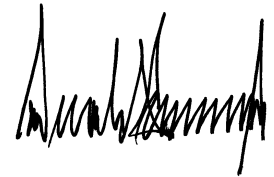
Sec. 11. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 28, 2025.

EXHIBIT S

Presidential Documents

Executive Order 14190 of January 29, 2025

Ending Radical Indoctrination in K–12 Schooling

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose and Policy. Parents trust America’s schools to provide their children with a rigorous education and to instill a patriotic admiration for our incredible Nation and the values for which we stand.

In recent years, however, parents have witnessed schools indoctrinate their children in radical, anti-American ideologies while deliberately blocking parental oversight. Such an environment operates as an echo chamber, in which students are forced to accept these ideologies without question or critical examination. In many cases, innocent children are compelled to adopt identities as either victims or oppressors solely based on their skin color and other immutable characteristics. In other instances, young men and women are made to question whether they were born in the wrong body and whether to view their parents and their reality as enemies to be blamed. These practices not only erode critical thinking but also sow division, confusion, and distrust, which undermine the very foundations of personal identity and family unity.

Imprinting anti-American, subversive, harmful, and false ideologies on our Nation’s children not only violates longstanding anti-discrimination civil rights law in many cases, but usurps basic parental authority. For example, steering students toward surgical and chemical mutilation without parental consent or involvement or allowing males access to private spaces designated for females may contravene Federal laws that protect parental rights, including the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA), and sex-based equality and opportunity, including Title IX of the Education Amendments of 1972 (Title IX). Similarly, demanding acquiescence to “White Privilege” or “unconscious bias,” actually promotes racial discrimination and undermines national unity.

My Administration will enforce the law to ensure that recipients of Federal funds providing K–12 education comply with all applicable laws prohibiting discrimination in various contexts and protecting parental rights, including Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.*; Title IX, 20 U.S.C. 1681 *et seq.*; FERPA, 20 U.S.C. 1232g; and the PPRA, 20 U.S.C. 1232h.

Sec. 2. Definitions. As used herein:

(a) The definitions in the Executive Order “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government” (January 20, 2025) shall apply to this order.

(b) “Discriminatory equity ideology” means an ideology that treats individuals as members of preferred or disfavored groups, rather than as individuals, and minimizes agency, merit, and capability in favor of immoral generalizations, including that:

(i) Members of one race, color, sex, or national origin are morally or inherently superior to members of another race, color, sex, or national origin;

(ii) An individual, by virtue of the individual’s race, color, sex, or national origin, is inherently racist, sexist, or oppressive, whether consciously or unconsciously;

(iii) An individual's moral character or status as privileged, oppressing, or oppressed is primarily determined by the individual's race, color, sex, or national origin;

(iv) Members of one race, color, sex, or national origin cannot and should not attempt to treat others without respect to their race, color, sex, or national origin;

(v) An individual, by virtue of the individual's race, color, sex, or national origin, bears responsibility for, should feel guilt, anguish, or other forms of psychological distress because of, should be discriminated against, blamed, or stereotyped for, or should receive adverse treatment because of actions committed in the past by other members of the same race, color, sex, or national origin, in which the individual played no part;

(vi) An individual, by virtue of the individual's race, color, sex, or national origin, should be discriminated against or receive adverse treatment to achieve diversity, equity, or inclusion;

(vii) Virtues such as merit, excellence, hard work, fairness, neutrality, objectivity, and racial colorblindness are racist or sexist or were created by members of a particular race, color, sex, or national origin to oppress members of another race, color, sex, or national origin; or

(viii) the United States is fundamentally racist, sexist, or otherwise discriminatory.

(c) "Educational service agency" (ESA) has the meaning given in 20 U.S.C. 1401(5), and the terms "elementary school," "local educational agency" (LEA), "secondary school," and "state educational agency" (SEA) have the meanings given in 34 CFR 77.1(c).

(d) "Patriotic education" means a presentation of the history of America grounded in:

(i) an accurate, honest, unifying, inspiring, and ennobling characterization of America's founding and foundational principles;

(ii) a clear examination of how the United States has admirably grown closer to its noble principles throughout its history;

(iii) the concept that commitment to America's aspirations is beneficial and justified; and

(iv) the concept that celebration of America's greatness and history is proper.

(e) "Social transition" means the process of adopting a "gender identity" or "gender marker" that differs from a person's sex. This process can include psychological or psychiatric counseling or treatment by a school counselor or other provider; modifying a person's name (e.g., "Jane" to "James") or pronouns (e.g., "him" to "her"); calling a child "nonbinary"; use of intimate facilities and accommodations such as bathrooms or locker rooms specifically designated for persons of the opposite sex; and participating in school athletic competitions or other extracurricular activities specifically designated for persons of the opposite sex. "Social transition" does not include chemical or surgical mutilation.

Sec. 3. *Ending Indoctrination Strategy.* (a) Within 90 days of the date of this order, to advise the President in formulating future policy, the Secretary of Education, the Secretary of Defense, and the Secretary of Health and Human Services, in consultation with the Attorney General, shall provide an Ending Indoctrination Strategy to the President, through the Assistant to the President for Domestic Policy, containing recommendations and a plan for:

(i) eliminating Federal funding or support for illegal and discriminatory treatment and indoctrination in K–12 schools, including based on gender ideology and discriminatory equity ideology; and

(ii) protecting parental rights, pursuant to FERPA, 20 U.S.C. 1232g, and the PPRA, 20 U.S.C. 1232h, with respect to any K–12 policies or conduct implicated by the purpose and policy of this order.

(b) The Ending Indoctrination Strategy submitted under subsection (a) of this section shall contain a summary and analysis of the following:

(i) All Federal funding sources and streams, including grants or contracts, that directly or indirectly support or subsidize the instruction, advancement, or promotion of gender ideology or discriminatory equity ideology:

(A) in K–12 curriculum, instruction, programs, or activities; or

(B) in K–12 teacher education, certification, licensing, employment, or training;

(ii) Each agency’s process to prevent or rescind Federal funds, to the maximum extent consistent with applicable law, from being used by an ESA, SEA, LEA, elementary school, or secondary school to directly or indirectly support or subsidize the instruction, advancement, or promotion of gender ideology or discriminatory equity ideology in:

(A) K–12 curriculum, instruction, programs, or activities; or

(B) K–12 teacher certification, licensing, employment, or training;

(iii) Each agency’s process to prevent or rescind Federal funds, to the maximum extent consistent with applicable law, from being used by an ESA, SEA, LEA, elementary school, or secondary school to directly or indirectly support or subsidize the social transition of a minor student, including through school staff or teachers or through deliberately concealing the minor’s social transition from the minor’s parents.

(iv) Each agency’s process to prevent or rescind Federal funds, to the maximum extent consistent with applicable law, from being used by an ESA, SEA, LEA, elementary school, or secondary school to directly or indirectly support or subsidize:

(A) interference with a parent’s Federal statutory right to information regarding school curriculum, records, physical examinations, surveys, and other matters under the PPRA or FERPA; or

(B) a violation of Title VI or Title IX; and

(v) A summary and analysis of all relevant agency enforcement tools to advance the policies of this order.

(c) The Attorney General shall coordinate with State attorneys general and local district attorneys in their efforts to enforce the law and file appropriate actions against K–12 teachers and school officials who violate the law by:

(i) sexually exploiting minors;

(ii) unlawfully practicing medicine by offering diagnoses and treatment without the requisite license; or

(iii) otherwise unlawfully facilitating the social transition of a minor student.

(d) The Assistant to the President for Domestic Policy shall regularly convene the heads of the agencies tasked with submitting the Ending Indoctrination Strategy under subsection (a) of this section to confer regarding their findings, areas for additional investigation, the modification or implementation of their respective recommendations, and such other policy initiatives or matters as the President may direct.

Sec. 4. Reestablishing the President’s Advisory 1776 Commission and Promoting Patriotic Education. (a) The President’s Advisory 1776 Commission (“1776 Commission”), which was created by Executive Order 13958 of November 2, 2020, to promote patriotic education, but was terminated by President Biden in Executive Order 13985 of January 20, 2021, is hereby reestablished. The purpose of the 1776 Commission is to promote patriotic education and advance the purposes stated in section 1 of Executive Order 13958, as well as to advise and promote the work of the White House Task Force on Celebrating America’s 250th Birthday (“Task Force 250”) and the United States Semiquincentennial Commission in their efforts to

provide a grand celebration worthy of the momentous occasion of the 250th anniversary of American Independence on July 4, 2026.

(b) Within 120 days of the date of this order, the Secretary of Education shall establish the 1776 Commission in the Department of Education.

(c) The 1776 Commission shall be composed of not more than 20 members, who shall be appointed by the President for a term of 2 years. The 1776 Commission shall be made up of individuals from outside the Federal Government with relevant experience or subject-matter expertise.

(d) The 1776 Commission shall have a Chair or Co-Chairs, at the President's discretion, and a Vice Chair, who shall be designated by the President from among the Commission's members. An Executive Director, designated by the Secretary of Education in consultation with the Assistant to the President for Domestic Policy, shall coordinate the work of the 1776 Commission. The Chair (or Co-Chairs) and Vice Chair shall work with the Executive Director to convene regular meetings of the 1776 Commission, determine its agenda, and direct its work, consistent with this order.

(e) The 1776 Commission shall:

(i) facilitate the development and implementation of a "Presidential 1776 Award" to recognize student knowledge of the American founding, including knowledge about the Founders, the Declaration of Independence, the Constitutional Convention, and the great soldiers and battles of the American Revolutionary War;

(ii) in coordination with the White House Office of Public Liaison, coordinate bi-weekly lectures regarding the 250th anniversary of American Independence that are grounded in patriotic education principles, which shall be broadcast to the Nation throughout calendar year 2026;

(iii) upon request, advise executive departments and agencies regarding their efforts to ensure patriotic education is appropriately provided to the public at national parks, battlefields, monuments, museums, installations, landmarks, cemeteries, and other places important to the American founding and American history, as appropriate and consistent with applicable law;

(iv) upon request, offer advice and recommendations to, and support the work of Task Force 250 and the United States Semiquincentennial Commission regarding their plans to celebrate the 250th anniversary of American Independence; and

(v) facilitate, advise upon, and promote private and civic activities nationwide to increase public knowledge of and support patriotic education surrounding the 250th anniversary of American Independence, as appropriate and consistent with applicable law.

(f) The Department of Education shall provide funding and administrative support for the 1776 Commission, to the extent permitted by law and subject to the availability of appropriations.

(g) Members of the 1776 Commission shall serve without compensation but, as approved by the Department of Education, shall be reimbursed for travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707).

(h) Insofar as chapter 10 of title 5, United States Code (commonly known as the Federal Advisory Committee Act), may apply to the 1776 Commission, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Education, in accordance with the guidelines issued by the Administrator of General Services.

(i) The 1776 Commission shall terminate 2 years from the date of this order, unless extended by the President.

Sec. 5. Additional Patriotic Education Measures. (a) All relevant agencies shall monitor compliance with section 111(b) of title I of Division J of

Public Law 108–447, which provides that “[e]ach educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students served by the educational institution,” including by verifying compliance with each educational institution that receives Federal funds. All relevant agencies shall take action, as appropriate, to enhance compliance with that law.

(b) All relevant agencies shall prioritize Federal resources, consistent with applicable law, to promote patriotic education, including through the following programs:

(i) the Department of Education’s American History and Civics Academies and American History and Civics Education-National Activities programs;

(ii) the Department of Defense’s National Defense Education Program and Pilot Program on Enhanced Civics Education; and

(iii) the Department of State’s Bureau of Educational and Cultural Affairs and Fulbright, U.S. Speaker, and International Visitor Leadership programs, as well as the American Spaces network.

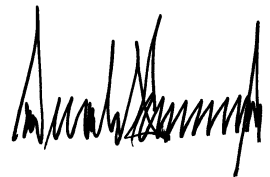
Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 29, 2025.

EXHIBIT T

Presidential Documents

Executive Order 14201 of February 5, 2025

Keeping Men Out of Women's Sports

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to protect opportunities for women and girls to compete in safe and fair sports, it is hereby ordered:

Section 1. *Policy and Purpose.* In recent years, many educational institutions and athletic associations have allowed men to compete in women's sports. This is demeaning, unfair, and dangerous to women and girls, and denies women and girls the equal opportunity to participate and excel in competitive sports.

Moreover, under Title IX of the Education Amendments Act of 1972 (Title IX), educational institutions receiving Federal funds cannot deny women an equal opportunity to participate in sports. As some Federal courts have recognized, "ignoring fundamental biological truths between the two sexes deprives women and girls of meaningful access to educational facilities." *Tennessee v. Cardona*, 24-cv-00072 at 73 (E.D. Ky. 2024). See also *Kansas v. U.S. Dept. of Education*, 24-cv-04041 at 23 (D. Kan. 2024) (highlighting "Congress' goals of protecting biological women in education").

Therefore, it is the policy of the United States to rescind all funds from educational programs that deprive women and girls of fair athletic opportunities, which results in the endangerment, humiliation, and silencing of women and girls and deprives them of privacy. It shall also be the policy of the United States to oppose male competitive participation in women's sports more broadly, as a matter of safety, fairness, dignity, and truth.

Sec. 2. *Definitions.* The definitions in Executive Order 14168 of January 20, 2025 (Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government), shall apply to this order.

Sec. 3. *Preserving Women's Sports in Education.* (a) In furtherance of the purposes of Title IX, the Secretary of Education shall promptly:

(i) in coordination with the Attorney General, continue to comply with the vacatur of the rule entitled "Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance" of April 29, 2024, 89 FR 33474, see *Tennessee v. Cardona*, 24-cv-00072 at 13-15 (E.D. Ky. 2025), and take other appropriate action to ensure this regulation does not have effect;

(ii) take all appropriate action to affirmatively protect all-female athletic opportunities and all-female locker rooms and thereby provide the equal opportunity guaranteed by Title IX of the Education Amendments Act of 1972, including enforcement actions described in subsection (iii); to bring regulations and policy guidance into line with the Congress' existing demand for "equal athletic opportunity for members of both sexes" by clearly specifying and clarifying that women's sports are reserved for women; and the resolution of pending litigation consistent with this policy; and

(iii) prioritize Title IX enforcement actions against educational institutions (including athletic associations composed of or governed by such institutions) that deny female students an equal opportunity to participate in sports and athletic events by requiring them, in the women's category, to compete with or against or to appear unclothed before males.

(b) All executive departments and agencies (agencies) shall review grants to educational programs and, where appropriate, rescind funding to programs that fail to comply with the policy established in this order.

(c) The Department of Justice shall provide all necessary resources, in accordance with law, to relevant agencies to ensure expeditious enforcement of the policy established in this order.

Sec. 4. *Preserving Fairness and Safety in Women's Sports.* Many sport-specific governing bodies have no official position or requirements regarding trans-identifying athletes. Others allow men to compete in women's categories if these men reduce the testosterone in their bodies below certain levels or provide documentation of "sincerely held" gender identity. These policies are unfair to female athletes and do not protect female safety. To address these concerns, it is hereby ordered:

(a) The Assistant to the President for Domestic Policy shall, within 60 days of the date of this order:

(i) convene representatives of major athletic organizations and governing bodies, and female athletes harmed by such policies, to promote policies that are fair and safe, in the best interests of female athletes, and consistent with the requirements of Title IX, as applicable; and

(ii) convene State Attorneys General to identify best practices in defining and enforcing equal opportunities for women to participate in sports and educate them about stories of women and girls who have been harmed by male participation in women's sports.

(b) The Secretary of State, including through the Bureau of Educational and Cultural Affairs' Sports Diplomacy Division and the Representative of the United States of America to the United Nations, shall:

(i) rescind support for and participation in people-to-people sports exchanges or other sports programs within which the relevant female sports category is based on identity and not sex; and

(ii) promote, including at the United Nations, international rules and norms governing sports competition to protect a sex-based female sports category, and, at the discretion of the Secretary of State, convene international athletic organizations and governing bodies, and female athletes harmed by policies that allow male participation in women's sports, to promote sporting policies that are fair, safe, and in furtherance of the best interests of female athletes.

(c) The Secretary of State and the Secretary of Homeland Security shall review and adjust, as needed, policies permitting admission to the United States of males seeking to participate in women's sports, and shall issue guidance with an objective of preventing such entry to the extent permitted by law, including pursuant to section 212(a)(6)(C)(i) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(6)(C)(i)).

(d) The Secretary of State shall use all appropriate and available measures to see that the International Olympic Committee amends the standards governing Olympic sporting events to promote fairness, safety, and the best interests of female athletes by ensuring that eligibility for participation in women's sporting events is determined according to sex and not gender identity or testosterone reduction.

Sec. 5. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

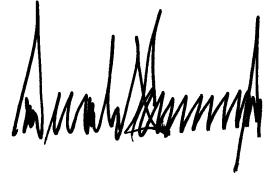
(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party

against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected thereby.

A handwritten signature in black ink, appearing to be a stylized name, possibly "Donald Trump", written in a cursive, slanted style.

THE WHITE HOUSE,
February 5, 2025.

EXHIBIT U



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Supreme Court Bolsters President Trump's Push to Eliminate Transgender Insanity

The White House

June 30, 2026

Today, the Supreme Court affirmed President Donald J. Trump's longstanding commitment to protect women and girls, ruling that states may reserve female athletic competition for biological females.

The Court's decision is a landmark victory for common sense, biological reality, and for the millions of women and girls who deserve a level playing field. By upholding laws protecting female athletic competition, the Court confirmed that states may preserve the fairness, safety, and equal opportunities that Title IX was enacted to guarantee.

This ruling is the latest affirmation of President Trump's efforts to restore biological reality throughout the federal government and protect the rights of women and girls. Since returning to office, President Trump has taken a series of decisive actions to advance those goals, including:

- Barring men from competing in women's sports, resulting in athletic organizations such as the NCAA, International Olympic Committee, and World Athletics Council realigning their policies with biological reality.
- Cracking down on athletic organizations that refuse to comply with President Trump's commonsense Executive Order by launching Title IX investigations across the country, including four in the past week alone.
- Restoring biological reality as the official policy of the federal government by recognizing that there are only two immutable sexes: male and female.
- Restoring biological sex as the sole markers for official federal documents, including passports.
- Banning federal funding, sponsorship, and promotion of child gender mutilation in more than 40 hospitals and health systems across the country stopping and mutilation programs.



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- Ordering the Department of Health and Human Services to perform a comprehensive review of best practices for children and adolescents, ultimately confirming the complete absence of scientific evidence supporting child gender mutilation.
- Terminating federal support for “gender ideology” and “equity” curricula, forcing states to halt the indoctrination of children with woke ideology or risk losing federal funding.
- Cutting billions of dollars in federal funding for the proliferation of radical gender ideology.
- Prioritizing military readiness over radical gender ideology by requiring troops to serve according to their biological sex, and barring so-called transgender individuals from military service.
- Ending all funding for sex change surgeries at the Department of War and Department of Veterans Affairs.
- Eliminating radical gender ideology from U.S. service academies and training programs.
- Protecting women’s spaces, including bathrooms, locker rooms, and shelters.

President Trump and his entire Administration will continue safeguarding women’s sports, shielding children from radical gender ideology, and restoring biological truth throughout the federal government, just as he promised on the campaign trail.

Related

President Trump Ended Democrats’ “Transgender for Everybody” Insanity

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Fact Sheet: President Donald J. Trump Protects Safety, Fairness, and Dignity in Women’s Sports

Fact Sheets | February 5, 2025

Keeping Men Out of Women’s Sports

Presidential Actions | February 5, 2025

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EXHIBIT V



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President Trump Ended Democrats' "Transgender for Everybody" Insanity

The White House

March 31, 2026

Two years ago today, the Biden Administration desecrated Easter Sunday with a “transgender” message that elevated radical leftist ideology over faith, family, and biological truth. This Easter season, the Trump Administration is celebrating a decisive victory: the swift and unrelenting dismantling of subversive, woke policies that endangered children, eroded women’s rights, assaulted common sense, and dragged America toward moral and cultural decline.

Under President Trump, the era of government-sanctioned delusion is over:

- President Trump declared it the official policy of the U.S. Government that there are only two immutable sexes: male and female.
- President Trump banned federal funding, sponsorship, or promotion of the chemical and surgical mutilation of minors — protecting children from irreversible harm and directing agencies to defund institutions engaged in these practices.
 - As a result, more than three dozen health systems across the country — including Kaiser Permanente, Children’s Hospital Los Angeles, Children’s Minnesota, Denver Health, Lurie Children’s Hospital of Chicago, Stanford Medicine, NYU Langone, and many others — announced they are stopping or suspending child mutilation programs.
- The Trump Administration ended the un-American indoctrination of schoolchildren by terminating federal support for “gender ideology” and “equity” curricula — enforcing parental rights and putting states on notice to remove such content or lose funding.
- President Trump ended the unfair, demeaning practice of forcing women to compete against biological men in sports — which resulted in both the NCAA and the International Olympic Committee, as well as multiple state high school athletics associations, to realign with biological reality.



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- The Department of War reinstated standards requiring service members to serve according to their biological sex, banned transgender individuals from military service where it conflicts with readiness and cohesion, and prohibited taxpayer funds for sex change procedures — restoring the military’s focus on excellence, not ideology.
- The Department of Health and Human Services conducted a comprehensive review of so-called “gender-affirming care” and confirmed the lack of medical or scientific evidence supporting its irreversible effects on minors.
- The Trump Administration — including across the Department of War and the Department of Veterans Affairs — ceased all funding for sex change surgeries and related procedures.
- President Trump eliminated radical gender ideology from U.S. service academies and training programs.
- President Trump directed enforcement to protect single-sex spaces designed for women and girls — including bathrooms, locker rooms, and shelters — based on biological sex.
- The Trump Administration axed billions of dollars in grants that had been used by states to perpetuate radical gender ideology and related propaganda.
- The Trump Administration ended the practice of allowing gender self-identification on federal documents — including passports — restoring biological sex as the sole basis for official records.

These bold actions have shattered years of Democrat extremism, rescued a generation of children from irreversible harm, restored biological truth, and reclaimed America’s commitment to fairness, science, and sanity.

In the Trump Administration, truth, strength, and moral clarity are once again guiding our nation forward.

Related

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EXHIBIT W

Presidential Documents

Proclamation 10911 of April 3, 2025

National Child Abuse Prevention Month, 2025

By the President of the United States of America

A Proclamation

America's children are the foundation of our families, the heirs of our freedom, and the stewards of our national promise. This National Child Abuse Prevention Month, we commit to empowering every child in America to lead a fulfilling life of dignity and love—and we pledge to bring every abuser, predator, and evildoer who threatens the health and safety of our children to swift justice.

As citizens, each of us is entrusted with the sacred responsibility of caring for the most vulnerable among us, especially children uniquely at risk of trauma and abuse. My Administration recognizes that the most powerful safeguard against child abuse is a stable family with loving parents, and that there is no substitute for a strong mother and father. For this reason, I am working every day to fortify our families and embolden our Nation's children to live their lives full of happiness, health, and success that they so dearly deserve. I call on every American to take steps to prevent child abuse and neglect before it occurs. By doing so, we can reduce the risk of depression, suicide, substance abuse, and developmental challenges in our youth.

Sadly, one of the most prevalent forms of child abuse facing our country today is the sinister threat of gender ideology. Proponents of the gender ideology movement are outrageously indoctrinating our children with the devastating lie that they are trapped in the wrong body—and that the only way they can be truly happy is to alter their sex with hormone therapy, puberty blockers, and sexual mutilation surgery. The evil and backwards lies of gender insanity are robbing our children of their happiness, health, and freedom, while imposing unimaginable heartbreak on parents and families. As I stated during my Joint Address to the Congress last month, my message to every American child is simple: you are perfect exactly the way God made you.

As President, I proudly signed Executive Order 14187 prohibiting public schools from indoctrinating our children with transgender ideology, while also taking action to cut off all taxpayer funding to any institution that engages in the sexual mutilation of our youth. To further protect our children, I have taken historic action to secure our southern border and end child trafficking—and am working diligently to make our young people healthy again.

This National Child Abuse Prevention Month, we pledge to stop the atrocity of child abuse in all its forms. We affirm that every perpetrator who inflicts violence on our children will be punished to the fullest extent of the law. Above all, we vow to give our children the tools they need to fully embrace God's gift of life, and to carry that radiant torch of American Liberty generations into the future.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2025 as National Child Abuse Prevention Month. I call upon all Americans to invest in the lives of our Nation's children, to be aware of their safety and well-

being, and to support efforts that promote their psychological, physical, and emotional development.

IN WITNESS WHEREOF, I have hereunto set my hand this third day of April, in the year of our Lord two thousand twenty-five, and of the Independence of the United States of America the two hundred and forty-ninth.

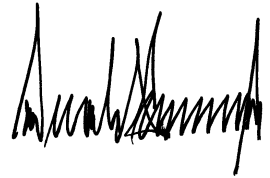
A handwritten signature in black ink, appearing to be a stylized name, possibly "Donald Trump", written in a cursive script.

EXHIBIT X



The Director

UNITED STATES OFFICE OF PERSONNEL MANAGEMENT
Washington, DC 20415

MEMORANDUM

TO: Heads and Acting Heads of Departments and Agencies

FROM: Charles Ezell, Acting Director, U.S. Office of Personnel Management

DATE: January 29, 2025

RE: Initial Guidance Regarding President Trump's Executive Order *Defending Women*.

Pursuant to its authority under 5 U.S.C. § 1103(a)(1) and (a)(5), the U.S. Office of Personnel Management (OPM) is providing the following initial guidance to agencies regarding the President's Executive Order entitled *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government (Defending Women)*.

Steps to End Federal Funding of Gender Ideology: In light of *Defending Women*, each agency should take prompt actions to end all agency programs that use taxpayer money to promote or reflect gender ideology as defined in Section 2(f) of *Defending Women*. Specifically, agency heads should take the following steps:

1. No later than **5:00 p.m. EST on Friday, January 31, 2025**
 - a. Send an email to all agency employees announcing that the agency will be complying with *Defending Women* and this guidance.
 - b. Review all agency programs, contracts, and grants, and terminate any that promote or inculcate gender ideology.
 - c. Review all agency position descriptions and send a notification to all employees whose position description involves inculcating or promoting gender ideology that they are being placed on paid administrative leave effective immediately as the agency takes steps to close/end all initiatives, offices, and programs that inculcate or promote gender ideology.
 - d. Take down all outward facing media (websites, social media accounts, etc.) that inculcate or promote gender ideology.
 - e. Review agency email systems such as Outlook and turn off features that prompt users for their pronouns.

- f. Withdraw any final or pending documents, directives, orders, regulations, materials, forms, communications, statements, and plans that inculcate or promote gender ideology.
 - g. Cancel any trainings that inculcate or promote gender ideology or have done so in the past.
 - h. Disband or cancel any employee resource groups or special emphasis programs that inculcate or promote gender ideology or have done so in the past.
 - i. Review all agency forms that require entry of an individual's sex and ensure that all list male or female only, and not gender identity. Remove requests for "gender" and substitute requests for "sex."
 - j. Ensure that all applicable agency policies and documents, including forms, use the term "sex" and not "gender."
 - k. Ensure that intimate spaces designated for women, girls, or females (or for men, boys, or males) are designated by biological sex and not gender identity.
2. No later than **12:00 p.m. EST on Friday, February 7, 2025**, report to OPM on all steps taken to implement this guidance, including:
- a. a complete list of actions taken in response to this guidance and *Defending Women*; and
 - b. any agency plans to fully comply with this guidance and *Defending Women*.

Please contact OPM at defendingwomen@opm.gov if you have any questions regarding this guidance. Please send any reports requested by this guidance to defendingwomen@opm.gov.

cc: Chief Human Capital Officers (CHCOs), Deputy CHCOs, Human Resources Directors, and Chiefs of Staff

EXHIBIT Y



THE DIRECTOR

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

January 27, 2025

M-25-13

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Matthew J. Vaeth, Acting Director, Office of Management and Budget 

SUBJECT: Temporary Pause of Agency Grant, Loan, and Other Financial Assistance Programs

The American people elected Donald J. Trump to be President of the United States and gave him a mandate to increase the impact of every federal taxpayer dollar. In Fiscal Year 2024, of the nearly \$10 trillion that the Federal Government spent, more than \$3 trillion was Federal financial assistance, such as grants and loans. Career and political appointees in the Executive Branch have a duty to align Federal spending and action with the will of the American people as expressed through Presidential priorities. Financial assistance should be dedicated to advancing Administration priorities, focusing taxpayer dollars to advance a stronger and safer America, eliminating the financial burden of inflation for citizens, unleashing American energy and manufacturing, ending “wokeness” and the weaponization of government, promoting efficiency in government, and Making America Healthy Again. The use of Federal resources to advance Marxist equity, transgenderism, and green new deal social engineering policies is a waste of taxpayer dollars that does not improve the day-to-day lives of those we serve.

This memorandum requires Federal agencies to identify and review all Federal financial assistance¹ programs and supporting activities consistent with the President’s policies and requirements.² For example, during the initial days of his Administration, President Donald J. Trump issued a series of executive orders to protect the American people and safeguard valuable taxpayer resources, including *Protecting the American People Against Invasion* (Jan. 20, 2025), *Reevaluating and Realigning United States Foreign Aid* (Jan. 20, 2025), *Putting America First in International Environmental Agreements* (Jan. 20, 2025), *Unleashing American Energy* (Jan. 20, 2025), *Ending Radical and Wasteful Government DEI Programs and Preferencing* (Jan. 20,

¹ 2 CFR 200.1 defines Federal financial assistance to mean “[a]ssistance that recipients or subrecipients receive or administer” in various forms, but this term does not include assistance provided directly to individuals. For the purposes of this memorandum, Federal financial assistance includes: (i) all forms of assistance listed in paragraphs (1) and (2) of the definition of this term at 2 CFR 200.1; and (ii) assistance received or administered by recipients or subrecipients of any type except for assistance received directly by individuals.

² Nothing in this memo should be construed to impact Medicare or Social Security benefits.

2025), *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government* (Jan. 20, 2025), and *Enforcing the Hyde Amendment* (Jan. 24, 2025). These executive orders ensure that Federal funds are used to support hardworking American families.

To implement these orders, each agency must complete a comprehensive analysis of all of their Federal financial assistance programs to identify programs, projects, and activities that may be implicated by any of the President's executive orders. In the interim, to the extent permissible under applicable law, Federal agencies **must temporarily pause** all activities related to obligation or disbursement of all Federal financial assistance, and other relevant agency activities that may be implicated by the executive orders, including, but not limited to, financial assistance for foreign aid, nongovernmental organizations, DEI, woke gender ideology, and the green new deal.

This temporary pause will provide the Administration time to review agency programs and determine the best uses of the funding for those programs consistent with the law and the President's priorities. The temporary pause will become effective on January 28, 2025, at 5:00 PM. Even before completing their comprehensive analysis, Federal agencies must immediately identify any legally mandated actions or deadlines for assistance programs arising while the pause remains in effect. Federal agencies must report this information to OMB along with an analysis of the requirement. OMB also directs Federal agencies to pause all activities associated with open NOFOs, such as conducting merit review panels.

No later than February 10, 2025, agencies shall submit to OMB detailed information on any programs, projects or activities subject to this pause. Each agency must pause: (i) issuance of new awards; (ii) disbursement of Federal funds under all open awards; and (iii) other relevant agency actions that may be implicated by the executive orders, to the extent permissible by law, until OMB has reviewed and provided guidance to your agency with respect to the information submitted.

OMB may grant exceptions allowing Federal agencies to issue new awards or take other actions on a case-by-case basis. To the extent required by law, Federal agencies may continue taking certain administrative actions, such as closeout of Federal awards (2 CFR 200.344), or recording obligations expressly required by law.

Additionally, agencies must, for each Federal financial assistance program: (i) assign responsibility and oversight to a senior political appointee to ensure Federal financial assistance conforms to Administration priorities; (ii) review currently pending Federal financial assistance announcements to ensure Administration priorities are addressed, and, subject to program statutory authority, modify unpublished Federal financial assistance announcements, withdraw any announcements already published, and, to the extent permissible by law, cancel awards already awarded that are in conflict with Administration priorities, and; (iii) ensure adequate oversight of Federal financial assistance programs and initiate investigations when warranted to identify underperforming recipients, and address identified issues up to and including cancellation of awards.

EXHIBIT Z

Directive on NIH Priorities

Agency: National Institutes of Health

Office of the Director

Action: Directive

FOR FURTHER INFORMATION CONTACT:

National Institutes of Health

Office of the Director

EFFECTIVE DATE: February 21, 2025

Restoring Scientific Integrity and Protecting the Public Investment in NIH Awards

The National Institutes of Health (NIH) is the largest public funder of biomedical and behavioral research in the world. The public trusts NIH with substantial funds to foster creative discoveries that will improve health and prevent disease in this Country. Accordingly, NIH is committed to promoting only the highest level of scientific integrity, public accountability, and social responsibility in the programs it funds. And NIH promises to prioritize the funding of projects that will generate a high return on the public's investment, so that taxpayer dollars are not going to waste. Every dollar should be used to make Americans live longer, healthier lives.

This mission requires NIH to ensure that it is not supporting low-value and off-mission research programs, including but not limited to studies based on diversity, equity, and inclusion (DEI) and gender identity. While this description of NIH's mission is consistent with recent Executive Orders issued by the President, I issue this directive based on my expertise and experience; consistent with NIH's own obligation to pursue effective, fiscally prudent research; and pursuant to NIH authorities that exist independently of, and precede, those Executive Orders.

Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, DEI studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Likewise, research programs based on gender identity are often unscientific, have little identifiable return on investment, and do nothing to enhance the health of many Americans. Many such studies ignore, rather than seriously examine, biological realities. It is the policy of NIH not to prioritize these research programs either.

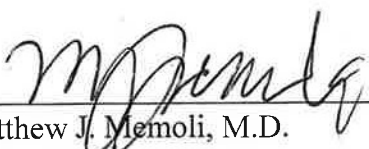
For these reasons and pursuant to, among other authorities, 42 U.S.C. § 282(b) and 45 C.F.R. Part 75 (45 C.F.R. §§ 75.207, 75.210, 75.371–373),¹ the Director of NIH hereby directs:

NIH personnel shall conduct an internal review of all contract solicitations and notices of funding opportunities; applications pending Type 1 and Type 2 awards; existing awards; cooperative agreements; and other transactions. Such review shall be aimed at ensuring NIH grants, contracts, cooperative agreements, and other transactions do not fund or support low-value and off-mission research activities or projects – including DEI and gender identity research activities and programs. NIH personnel should also ensure grants, contracts, cooperative agreements, and other transactions are free from fraud, abuse, and duplication, and are being implemented consistent with federal law.

This Directive shall be implemented by all relevant NIH personnel, including but not limited to those in the Office of Extramural Research, Office of Intramural Research, and the Division of Program Coordination, Planning, and Strategic Initiatives. Grants, contracts, cooperative agreements, and other transactions deemed inconsistent with NIH's mission may, where permitted by applicable law, be subject to funding restrictions, terminated or partially terminated, paused, and/or not continued or renewed, in compliance with all procedural requirements.

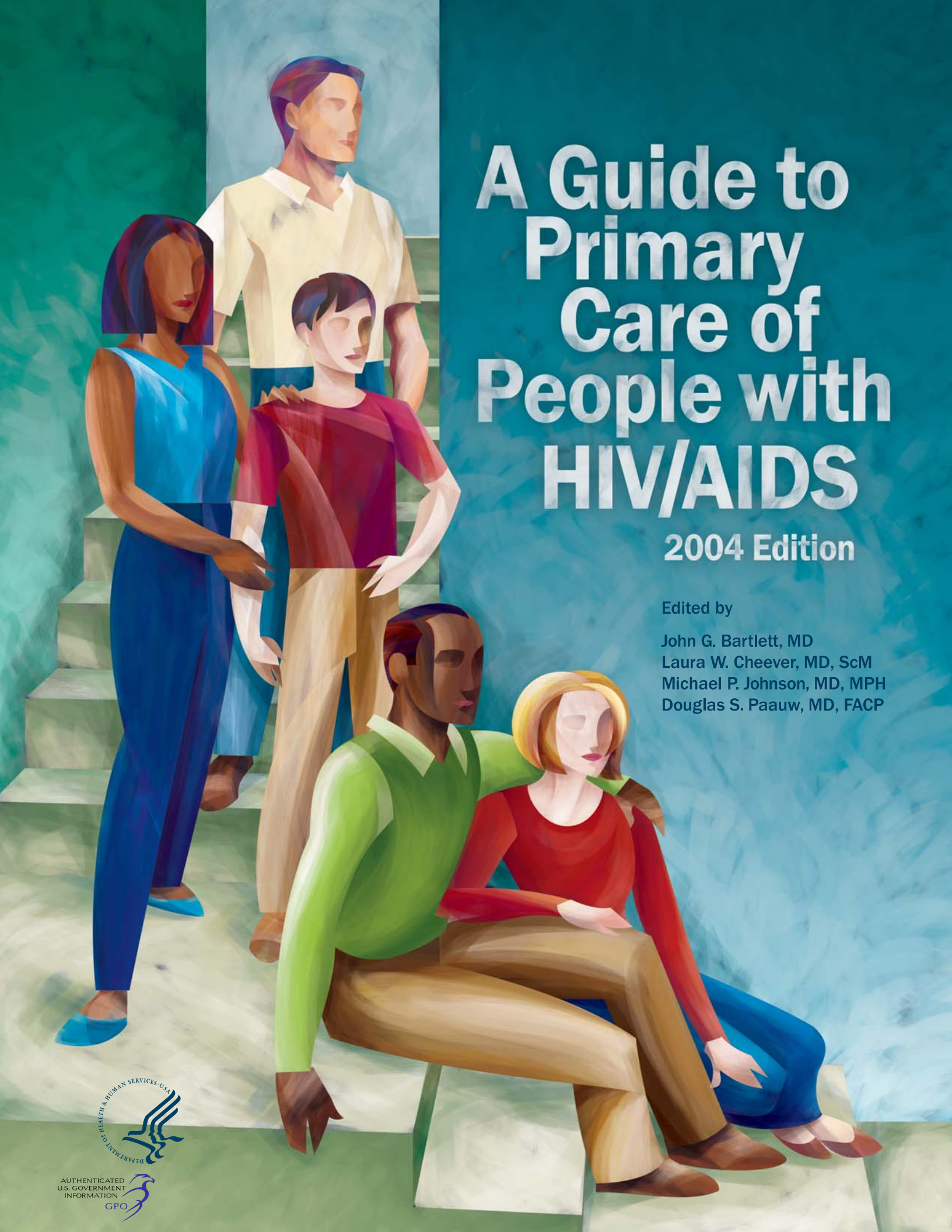
Notwithstanding this Directive, and consistent with any court orders that may apply, no open award disbursements may be paused in reliance upon Office of Management and Budget Memorandum M-25-13 or any Executive Order underlying that Memorandum. Previous instructions ordering the immediate release of such funds remain in effect. Also, consistent with any court orders that may apply, this Directive does not instruct personnel to condition or withhold federal funding pursuant to Section 4 of Executive Order 14,187 (Protecting Children from Chemical and Surgical Mutilation) based on the fact that a healthcare entity or health professional provides care or treatment.

Dated: February 21, 2025


Matthew J. Memoli, M.D.
Acting Director of NIH

¹ To be clear, these citations are illustrative, not exhaustive. Further explanation of the range of statutory and regulatory authorities that support actions taken pursuant to this Directive will be issued as appropriate.

EXHIBIT AA

A stylized, low-poly illustration of five diverse people standing and sitting on a set of stairs. The background is a textured blue. The people are rendered in various colors: a man in a yellow shirt and blue pants, a woman in a blue dress, a man in a red shirt and tan pants, a man in a green sweater and tan pants, and a woman in a red shirt and blue pants.

A Guide to Primary Care of People with HIV/AIDS

2004 Edition

Edited by

John G. Bartlett, MD

Laura W. Cheever, MD, ScM

Michael P. Johnson, MD, MPH

Douglas S. Paauw, MD, FACP



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INFORMATION
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2004 Edition

A Guide to Primary Care of People with HIV/AIDS

EDITORS

John G. Bartlett, MD

*Professor of Medicine, Chief, Division of Infectious Diseases, and
Director, AIDS Service
The Johns Hopkins University School of Medicine
Baltimore, Maryland*

Laura W. Cheever, MD, ScM

*Deputy Associate Administrator and Chief Medical Officer
HIV/AIDS Bureau
Health Resources and Services Administration
Rockville, Maryland*

Michael P. Johnson, MD, MPH

*Director, Office of Global AIDS
Office of Global Health Affairs, Office of the Secretary
Department of Health and Human Services
Washington, D.C.*

Douglas S. Paauw, MD, FACP

*Professor of Medicine and Rathmann Family Foundation
Endowed Chair for Patient-Centered Clinical Education
University of Washington School of Medicine
Seattle, Washington*

Dedication

A Guide to Primary Care of People with HIV/AIDS is dedicated to all the men and women working in the Ryan White CARE Act programs. Their commitment and dedication to serving people living with HIV and AIDS makes these programs possible.

Acknowledgments

Helen Schietinger managed the development and production of the guide. Joan Holloway oversaw its conception and execution.

Cover design and layout was done by Laura Spofford.

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Frances Porcher and Helen Schietinger copyedited the text, and Bill Todd created the index.

Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau
Parklawn Building, Room 7-05
5600 Fishers Lane
Rockville MD 20857
301-443-1993

Publication date 2004

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Contributing Authors

Bruce D. Agins, MD, MPH

*Medical Director
New York State Department of Health AIDS Institute
New York, New York*

Carla S. Alexander, MD

*Assistant Professor of Medicine
Medical Director of Palliative Care
Institute of Human Virology
University of Maryland School of Medicine
Baltimore, Maryland*

John G. Bartlett, MD

*Professor of Medicine
Chief, Division of Infectious Diseases
Director, AIDS Service
The Johns Hopkins University School of Medicine
Baltimore, Maryland*

Constance A. Benson, MD

*Professor of Medicine
Division of Infectious Diseases
University of Colorado Health Sciences Center
Denver, Colorado*

Kennita R. Carter, MD

*Clinical Assistant Professor
Department of Hematology/Oncology
Veterans Administration Medical Center
Baltimore, Maryland*

Gloria A. Casale, MD, MSPH

*Adjunct Professor, University of St. Francis
Adjunct Professor, University of New Mexico
School of Medicine
Albuquerque, New Mexico*

Laura W. Cheever, MD, ScM

*Deputy Associate Administrator
Chief Medical Officer
HIV/AIDS Bureau
Health Resources and Services Administration
Rockville, Maryland*

Jonathan Allen Cohn, MD, MS, FACP

*Associate Professor of Medicine
Wayne State University School of Medicine
Detroit, Michigan*

Niccolo D. Della Penna, MD

*Department of Psychiatry and Behavioral Sciences
The Johns Hopkins University School of Medicine
Baltimore, Maryland*

Henry Francis, MD

*Director, Center on AIDS and Other Medical
Consequences of Drug Abuse
National Institute on Drug Abuse
National Institutes of Health
Rockville, Maryland*

Linda Frank, PhD, MSN, ACRN

*Assistant Professor
Graduate School of Public Health
University of Pittsburgh
Pittsburgh, Pennsylvania*

Michael P. Johnson, MD, MPH

*Director, Office of Global AIDS
Office of Global Health Affairs, Office of the Secretary
Department of Health and Human Services
Washington, DC*

Contributing Authors (continued)

John McNeil, MD

*Chief, Infectious Diseases
Howard University Hospital
Washington, DC*

José Rafael Morales, MD, FACOG

*Associate Director for Clinical Affairs
Division of Community Based Programs
HIV/AIDS Bureau
Health Resources and Services Administration
Rockville, Maryland*

Tara Evans Nysoe, MD

*Department of Medicine
University of Washington School of Medicine
Seattle, Washington*

Douglas S. Paauw, MD, FACP

*Professor of Medicine
Rathmann Family Foundation Endowed Chair for
Patient-Centered Clinical Education
Division of General Internal Medicine
University of Washington School of Medicine
Seattle, Washington*

María del Carmen Ríos, MD, MPH

*Acting Chief, Northeastern Regional Branch
Division of Community Based Programs
HIV/AIDS Bureau
Health Resources and Services Administration
Rockville, Maryland*

John V. L. Sheffield, MD

*Associate Professor of Medicine
Division of General Internal Medicine
University of Washington School of Medicine
Seattle, Washington*

Renslow Sherer, MD

*Director, Coordinated HIV Services
The CORE Center
Cook County Hospital
Chicago, Illinois*

David H. Spach, MD

*Associate Professor of Medicine
Division of Infectious Diseases
Department of Medicine
University of Washington Medical Center
Seattle, Washington*

Caroline J. Teter, PA-C, MPH

*Project Coordinator
AIDS Education and Training Center
National Resource Center
Cook County Hospital
Chicago, Illinois*

Glenn J. Treisman, MD, PhD

*Associate Professor
Department of Psychiatry
The Johns Hopkins University School of Medicine
Baltimore, Maryland*

Abbreviations

ALT: alanine aminotransferase

anti-HBc: hepatitis B core antibody

ART: antiretroviral therapy, highly active antiretroviral therapy

bid: twice a day

c/mL: copies of virus per mL

DSP: distal symmetrical polyneuropathy

DRESS: drug rash with eosinophilia and systemic symptoms

FTA-ABS: fluorescent treponemal antibody absorption test for syphilis

HAART: highly active antiretroviral therapy (see ART)

INH: isoniazid

HCV: hepatitis C virus

IVIG: intravenous immune globulin

LDL: low-density lipoprotein

LFT: liver function test

MAC: *Mycobacterium avium* complex

nPEP: nonoccupational postexposure prophylaxis

NRTI: nucleoside reverse transcriptase inhibitor, nucleoside

NNRTI: non-nucleoside reverse transcriptase inhibitor

OD: opportunistic disease

OI: opportunistic infection

po: per os, by mouth

PI: protease inhibitor

PPD: purified protein derivative of tuberculin

qd: every day

qhs: every night

qam: every morning

RPR: rapid plasma regain test for syphilis

SSRI: selective serotonin reuptake inhibitor

STD: sexually transmitted disease

STI: sexually transmitted infection

TB: tuberculosis

VDRL: Venereal Disease Research Laboratory serologic test for syphilis

VL: viral load

Glossary of Antiretroviral Drugs

Generic name	Abbreviation	Trade name	Class
abacavir	ABC	Ziagen	nucleoside
amprenavir	APV	Agenerase	PI
atazanavir	ATV	Reyataz	PI
delavirdine	DLV	Rescriptor	NNRTI
didanosine	ddI	Videx	nucleoside
efavirenz	EFV	Sustiva	NNRTI
emtricitabine	FTC	Emtriva	nucleoside
enfuvirtide	T-20	Fuzeon	fusion inhibitor
fosamprenavir	FPV	Lexiva	PI
indinavir	IDV	Crixivan	PI
lamivudine	3TC	Epivir	nucleoside
lopinavir + ritonavir	LPV/r	Kaletra	PIs
nelfinavir	NFV	Viracept	PI
nevirapine	NVP	Viramine	NNRTI
ritonavir	RTV	Norvir	PI
saquinavir	SQV soft gel cap	Fortovase	PI
saquinavir	SQV hard gel cap	Invirase	PI
stavudine	d4T	Zerit	nucleoside
tenofovir	TDF	Viread	nucleotide
zalcitabine	ddC	Hivid	nucleoside
zidovudine	AZT, ZDV	Retrovir	nucleoside
zidovudine + lamivudine	AZT + 3TC	Combivir	nucleosides
zidovudine + lamivudine + abacavir	AZT + 3TC + ABC	Trizivir	nucleosides

PI: protease inhibitor

NNRTI: non-nucleoside reverse transcriptase inhibitor

nucleoside: nucleoside reverse transcriptase inhibitor
(NRTI)

Chapter 1:

Primary Care as Chronic Care

1*John G. Bartlett, MD**Laura W. Cheever, MD, ScM**Michael P. Johnson, MD, MPH**Douglas S. Paauw, MD, FACP*

What is a primary care approach to the treatment of HIV/AIDS, and why is it important?

People with HIV/AIDS can live longer, healthier lives because of advances in treatment of HIV infection. However, longer lives are associated with increased prevalence of 1) adverse effects of HIV infection, 2) adverse effects of the drugs used to treat HIV, and 3) concurrent medical conditions that would occur in the absence of HIV. These long-term complications have put HIV infection in the realm of chronic diseases rather than of infectious diseases, which usually respond to short-term clinical interventions.

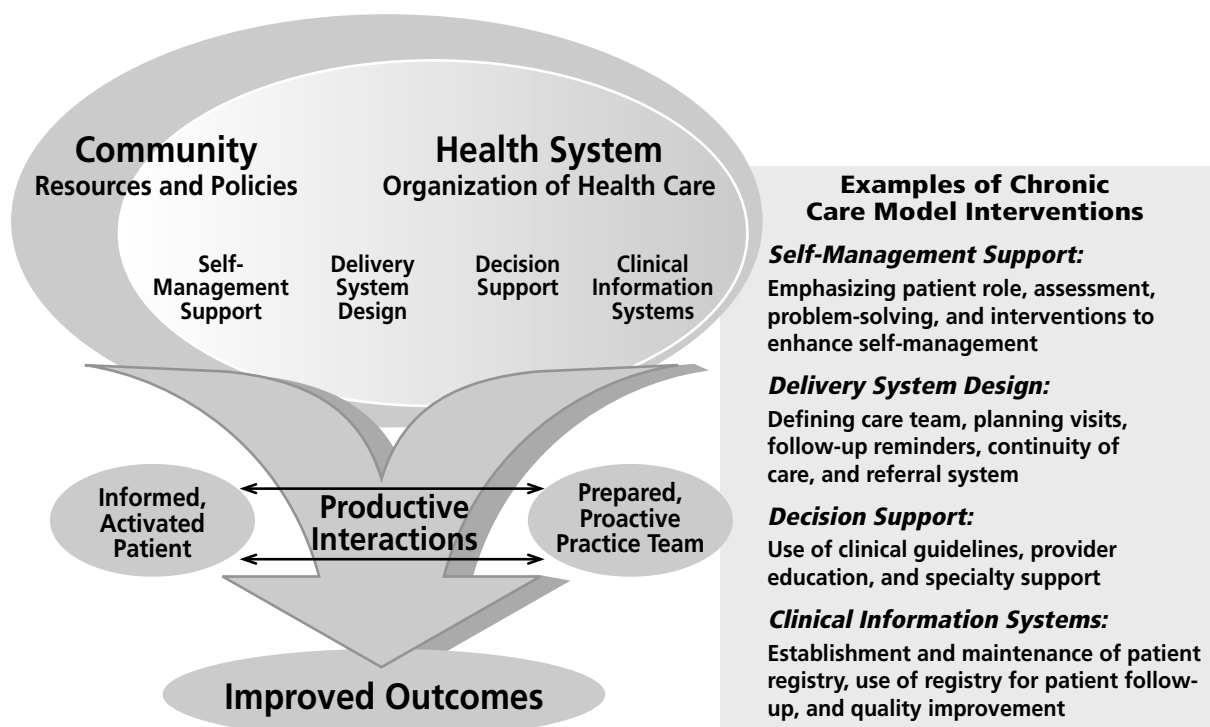
Effective management of chronic diseases in the primary care setting requires the coordination of interventions that occur at the level of the clinical services, the community supports for those clinical services, and the individual patient. While clinical services begin in the primary care clinic, community supports are needed, and the patient must be engaged to enhance self-management. The coordinated interventions together contribute to the desired clinical outcomes. The Chronic Care Model, which is used in the design and quality improvement activities of clinical services, conceptualizes how these factors impact the clinical outcome of chronic disease management (see Figure 1-1).

What is the purpose of this guide?

This book addresses several important aspects of HIV/AIDS care and treatment in a concise, accessible format; it is not meant to be a comprehensive reference book. Recommended references and citations are provided for the reader to be able to access in-depth information on topics that are particularly important and/or controversial. Appropriate use of antiretroviral drugs, treatment of opportunistic infections, symptom management, treatment of concurrent medical conditions, and other specific interventions to treat HIV disease and its complications are addressed.

The format of this guide is designed to provide practical information for the common questions that arise in the care of patients with HIV infection. Recognizing the broader array of best practices that contribute to effective clinical outcomes among patients with a complex array of service needs, the authors also address patient evaluation, adherence, mental health, substance abuse, overall clinic management, and other factors that lead to improved patient outcomes according to the Chronic Care Model. Last, because the authors recognize the challenges of maintaining clinical practices in the face of rapidly changing and ever more complex treatment interventions, a chapter on sources for updated and in-depth clinical information is provided. Pediatric HIV/AIDS treatment is not addressed in this book.

Figure 1-1. The Chronic Care Model



Source: Adapted from Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? *Effective Clinical Practice*. 1998;1:2-4. Reprinted with permission. The Chronic Care Model was developed by Ed Wagner, MD, MPH, Director of the MacColl Institute for Healthcare Innovation, Group Health Cooperative of Puget Sound, and colleagues with support from The Robert Wood Johnson Foundation. Further details can be found at www.ihl.org.

Who is the target audience?

The target audience is providers of primary medical care, such as physicians, physician assistants, and nurse practitioners, who are taking care of a small but perhaps an increasing number of HIV-infected persons but who are not experts in HIV care. Parts of this book will also be useful for nurses, counselors, pharmacists, and others seeking specific, concise information about the treatment of HIV-infected persons. Last, specific chapters on clinic management and quality improvement are relevant for those responsible for the administration of clinical sites treating patients with HIV/AIDS. Clinicians with small numbers of patients with HIV/AIDS are encouraged to seek appropriate expert consultation when complex clinical situations arise. Provider expertise in HIV care is essential in many treatment decisions. In fact, patient outcome is correlated with the number of patients with HIV a provider has treated. For more information, see Suggested Resources in Chapter 18 on Keeping Up-to-Date: Sources of Information for the Practicing Clinician.

What is the purpose of the pocket guide contained within the book?

The guide is a pocket-sized quick reference that provides a summary of all Federal guidelines dealing with HIV, including antiretroviral therapy (ART), prevention of opportunistic infections (OIs), management of class adverse reactions, treatment of tuberculosis (TB) and hepatitis C (HCV), laboratory testing, prevention after occupational exposure, and HIV management in pregnancy. It is presented in a format that is intended for point-of-care decision making: it can be carried in the clinic and at the bedside to rapidly access needed information for patient treatment.

The pocket guide will be updated more frequently than the book to meet rapid changes in HIV medication options and recommendations.

How will the book keep pace with the rapidly changing field of HIV/AIDS treatment?

The book details principles and major recommendations for the treatment of persons with HIV/AIDS that will remain, for the most part, relevant for the coming 2 or 3 years. However, the field of HIV treatment is very fluid, and specific drugs and drug combinations evolve rapidly. For this reason, such information has been consolidated in the pocket guide, which will be revised, with updates available in the on-line version on the HIV/AIDS Bureau (HAB) website. Revisions of the pocket guide will include new drugs, new treatment guidelines, and new side effects as well as new drug interactions. In addition to the pocket guide, information on other useful websites is provided to help with keeping up-to-date.

KEY POINTS

HIV is now a chronic disease requiring ongoing primary care management.

The chronic care model uses coordinated interventions at the clinic, community, and individual levels.

A Guide to Primary Care of People with HIV/AIDS is for primary care providers who are taking care of a small number of patients with HIV but who are not experts in HIV care.

The Pocket Guide provides easy reference to rapidly changing treatment guidelines for point-of-care decision making.

Chapter 2:**Approach to the Patient**

John V. L. Sheffield, MD
Gloria A. Casale, MD, MSPH

BASIC ELEMENTS OF CARE
STIGMA AND DISCRIMINATION
CONFIDENTIALITY AND DISCLOSURE
PATIENT EDUCATION
RISK ASSESSMENT AND COUNSELING
KEY POINTS
SUGGESTED RESOURCES

2**BASIC ELEMENTS OF CARE****What are the special challenges of caring for patients with HIV/AIDS?**

Providers need to be mindful of several special issues:

- Patients infected with HIV face a complex array of medical, psychological, and social challenges. A strong provider-patient relationship, the assistance of a multidisciplinary care team, and frequent office visits are usually required to provide excellent care.
- The stigma associated with HIV/AIDS places a major psychological burden on patients. Confidentiality is critical, as is a careful assessment of each patient's emotional support system.
- Ethnic minorities are over-represented among people with HIV. Efforts to understand and acknowledge the beliefs of patients from a variety of cultural backgrounds are necessary to establish trust between providers and patients.
- Providers play a key role in the public health system's HIV prevention strategy. Disease reporting, partner notification, and risk assessment are important aspects of care.
- Many patients have inaccurate AIDS information that can heighten their anxiety, sabotaging treatment adherence and appropriate prevention behaviors. They need assurance that HIV is a treatable disease and that with successful treatment, patients may live indefinitely. They also need to hear explicitly that HIV is transmitted through sexual contact, intravenous drug use, and blood contact (perinatal or other) and how they can prevent transmission to others.

What are the important components of good HIV care?

The elements that ensure good care for people with HIV/AIDS include mechanisms for coordination and communication of care:

- Clinics must offer a nonjudgmental and supportive environment because of the sensitive nature of issues that must be discussed.

- A multidisciplinary approach, utilizing the special skills of nurses, pharmacists, nutritionists, social workers, and case managers is highly desirable to help physicians address patients' needs regarding housing, medical insurance, emotional support, financial benefits, substance abuse counseling, and legal issues.
- Providers and other clinic staff should be prepared to conduct appropriate interventions and make timely referrals to community resources and institutions.
- The primary provider should coordinate care, with close communication among providers across disciplines.
- Individual office visits should be long enough to allow a thorough evaluation.
- Providers must be able to see patients frequently for good continuity of care, and clinic scheduling should be flexible so that patients with acute problems can be seen quickly.
- A range of medical resources, including providers with subspecialties and laboratory expertise, must be in place (see Chapter 16: Clinic Management).
- Patient education is a vital aspect of care that begins during the initial evaluation and continues throughout the course of care (see section on Patient Education below).

What steps can providers take to enhance care?

Providing comprehensive care for patients infected with HIV requires a lot of time, attention to detail, and a strong patient-provider relationship. Specifically, the provider should do the following:

- Discuss issues in a straightforward fashion to foster trust and openness.
- Be realistic about the seriousness of HIV disease and yet, to instill hope, be optimistic about the potential to restore health and to provide comfort. Give accurate information regarding prognosis and the real hope that antiretrovirals provide.
- Encourage patients to learn all they can about their condition and take an active role in decisions regarding their care.

- Anticipate that significant time will be required for patient education (see section on Patient Education below).
- Explicitly outline clinic operations and expectations for provider-patient communication.
- Plan to see patients often and communicate regularly between visits to answer questions, assess treatment effectiveness, and manage side effects.
- Arrange to see patients with acute problems quickly.

How can providers help patients with HIV/AIDS cope with the emotional issues they face?

Patients coming to terms with HIV infection often experience a range of emotions, including anger, fear, shock, disbelief, sadness, and depression. Loss is a major issue for patients with HIV disease because health, employment, income, relationships with friends, lovers, and family, and hope may all be threatened. Many patients feel overwhelmed, and providers need to recognize that a patient's emotional state affects the ability to solve problems and attend to important medical or social issues. Even patients who seem to be adjusting reasonably well can find it difficult to keep all of the appointments that are scheduled as they initiate care. Providers can do the following:

- Assess each patient's emotional state and the availability of friends and family for emotional support. Patients may feel hesitant about seeking emotional support, and some will need counseling to help them decide whether to disclose their diagnosis to friends, family, or employers.
- Deliver important information in easily understood terms and in small amounts. Reassess patient understanding of crucial information at subsequent visits, and repeat important information as necessary.
- Screen for anxiety, depression (including suicidal ideation), and substance use.
- Refer patients to community resources for crisis counseling, support groups, and, if appropriate, psychiatric treatment to help them achieve emotional stability (see also Chapter 14: Mental Health Disorders).
- Assign a case manager who can help reduce anxiety about keeping life in order.

STIGMA AND DISCRIMINATION

Why is stigma associated with HIV/AIDS?

Stigma is founded on fear and misinformation. Theodore de Bruyn has observed that stigma is associated with HIV/AIDS because "it is a life-

threatening disease; people are afraid of contracting HIV; it is associated with behaviors that are considered deviant; a belief that HIV/AIDS has been contracted due to unacceptable lifestyle choices; and, some believe it is the result of a moral fault which deserves punishment" (de Bruyn, Theodore. Paper prepared for the Canadian HIV/AIDS Legal Network. 1999).

Stigma can adversely affect how patients are perceived by others and how they view themselves. The stigma associated with HIV/AIDS is such that individuals known to be or suspected of being infected with HIV may be excluded from community activities and suffer isolation or abandonment. Some patients may feel ambivalent about seeking medical care if by doing so they risk disclosing their condition. Others may have learned from experience to expect rejection and are therefore untrusting of all care providers. It is essential for providers to be supportive of patients dealing with the burden of stigma.

How can providers support patients facing the stigma of fear of contagion?

The clinic must be inviting, and *all* staff members must model behavior in this area. For example, gloves should be worn only as appropriate during physical exams and as consistent with universal precautions. There should not be separate facilities or procedures for HIV-infected patients. Patients and their families are often unaware that routine household contact with a person with HIV poses no risk of contagion. They should be educated about this but also taught what to do in situations that do pose risk, such as bleeding.

How can providers support patients who face stigma associated with being gay, lesbian, bisexual, or transgender?

Demonstrating respect and providing excellent care to patients with various cultural backgrounds, beliefs, and sexual orientations define professionalism. Providers should approach patients in an open and nonjudgmental fashion and be familiar with medical management issues unique to these populations, such as STD screening for men who have sex with men (MSM) and high-dose hormonal treatment for transgender male-to-female patients. Clinic staff members must also be respectful and supportive; having staff who are familiar with gay and lesbian culture is a natural way to create a welcoming environment. Providers and social workers should be aware of community agencies with resources available to people who are gay, lesbian, or transgender. In addition, providers and clinic staff should be aware of special legal issues that affect these populations. For

example, designating a durable power of attorney for medical decision making can be particularly important in states that do not recognize same-gender partners as legal next of kin.

What other special cultural issues affect patients infected with HIV?

Minorities are disproportionately affected by HIV, and many people of color with HIV disease have major socioeconomic problems such as poverty, homelessness, lack of medical insurance, lack of acculturation, and undocumented immigration status. All of these can make accessing health care difficult and attending to health problems less of a priority. A patient's cultural background influences health beliefs and behaviors, and the effectiveness of provider-patient communication may affect compliance with therapy. In addition, prior adverse experiences may make some patients distrustful of medical care. For all of these reasons, providers should do the following:

- Carefully explore what each patient believes about his or her health, what would be appropriate treatment, and who should be involved in medical decision making.
- Use professional interpreters to help overcome language barriers.
- Use case managers to help overcome social barriers.

CONFIDENTIALITY AND DISCLOSURE

Why is confidentiality especially important for patients with HIV disease?

Confidentiality of medical information is always mandatory, but the stakes are particularly high for patients infected with HIV, who risk losing medical insurance, employment, or the support of friends or family if the wrong individuals learn of their diagnosis. Unfortunately, fear and ignorance persist regarding HIV transmission; people with HIV disease may be shunned because of the incorrect belief that HIV can be transmitted via casual contact. Although people with HIV disease are protected against discrimination under provisions of the Americans with Disabilities Act, discrimination can be difficult to prove, and there are strict time limits after which charges of discrimination can no longer be made.

What steps should providers take to protect patient confidentiality?

By adhering to the newly implemented Health Insurance Portability and Accountability Act (HIPAA) regulations, providers are protecting patient confidentiality. Personnel policies should reinforce measures such as requiring that papers and computer screens containing patient identifying information not be left unattended and documenting whether phone messages can be left for the patient, and if they can, with whom.

How can providers help patients decide whom to disclose their HIV status to?

Patients with a support network function better than those who are isolated. However, patients' fear of disclosure is often well founded, and providers must find a balance between accepting patients' unwillingness to disclose and the need to develop support networks. Patients may find support groups or individual psychotherapy sessions beneficial in deciding to whom and when to disclose.

The sex and needle-sharing partners of people with HIV need to be informed about their possible exposure to HIV. The local health department should be able to either assist patients in making these disclosures or provide anonymous partner notification for them.

What public health role do providers play in the HIV epidemic?

Primary care providers must also consider their public health role in curbing the spread of HIV. The nationwide increase in the incidence of syphilis and gonorrhea, especially among MSM, suggests that the advent of potent antiretroviral therapy has resulted in relaxed adherence to safer sex recommendations. All patients with a diagnosis of AIDS and, in many states, those with a positive HIV test must be reported to the State health department. Laws vary by state regarding reporting requirements and subsequent notification of potentially exposed individuals, but the name of the source contact is never divulged to the person being notified. Providers should become familiar with the laws of their jurisdiction by contacting their health departments. (The Association of State and Territorial Health Officers provides links to all State health departments at: <http://www.astho.org>.) Providers are required to do the following:

- Inform patients whose positive HIV or AIDS status must be reported to the State health department, tell them if partner notification is required, and explain what they should expect regarding efforts that must be made by the patient, provider, or health department to notify sex partners or individuals who may have been exposed to HIV through their needle sharing. Assure them that the patient's name is always kept confidential, and is never given to potentially exposed individuals by the Health Department.
- Carefully assess patients' risk-taking behaviors, educate them regarding HIV transmission, and perform STD screening (see question on STD screening in this chapter).
- Provide counseling to encourage safer sexual practices (see section on Risk Assessment and Counseling below) and make referrals to drug rehabilitation or needle exchange centers (see Chapter 13: Management of Substance Abuse).

The recently released Federal guidelines on prevention for persons living with HIV, which contain recommendations for providers, are listed in the Suggested Resources below. (See also Chapter 4: Prevention of HIV in the Clinical Care Setting.)

PATIENT EDUCATION

What does patient education involve?

The provider should assess the patient's understanding of HIV disease and begin patient education at the initial evaluation. To make sound decisions regarding treatment, the patient must understand certain medical information, including:

- The critical role of the patient in his or her own care
- Natural history of HIV disease and consequences of immune system destruction
- How HIV is transmitted
- The meaning of the viral load and CD4 count
- The beneficial impact of antiretroviral drugs
- Early signs and symptoms of opportunistic illnesses
- The role of prophylactic agents

What should patients understand before beginning antiretroviral therapy?

Before initiating antiretroviral therapy, patients must be fully aware of:

- The importance of adhering completely to the treatment regimen
- The possibility of drug resistance and loss of treatment options
- The proper timing of pills and coordinating pill-taking with meals
- Possible side effects and long-term drug toxicities
- The option to stop treatment at any time

In addition, patients should express a commitment to adhere to treatment before providers initiate any form of treatment. (For more on adherence, see Chapter 7: Adherence.)

How should providers incorporate patient education into care?

Patient education is so important that entire clinic visits are often devoted to a discussion of key concepts. Providers should use easily understood language and confirm the patient's understanding of medical terms and concepts. During these discussions, it is helpful for providers to be flexible, acknowledging that uncertainties exist regarding optimal medical management of HIV disease.

Because patient education is time-consuming, many HIV specialty clinics utilize staff other than the primary care provider, such as nurses and nurse practitioners who specialize in HIV clinical care, physician's assistants, pharmacists, and trained peer educators. This interdisciplinary team approach can supplement the limited time primary care providers often have with patients.

What information resources are available for patients?

Clinics can provide patient education materials and make referrals to social workers, nutritionists, pharmacists, and financial advisers who serve as first-line sources of information about medical issues and social services available in the community. At the regional level, community-based HIV/AIDS organizations and county and State public health departments offer information about medical care and facilitate access to legal aid, financial assistance, low-income housing, support groups, and other social services. At the national level, many organizations provide comprehensive information about HIV/AIDS. Table 2-1 lists recommended resources to which providers can refer patients for information and support.

Table 2-1. Information Resources for Patients

Internet Sites		
Agency	Topics	Web address (accessed 4/04)
AIDS Education Global Information System	Daily briefing; key topics; basics; fact sheets	http://www.aegis.com
AIDS Gateway to the Internet	Fact sheets; conferences; news; community	http://www.aids.org
AIDS Info	Resource for federally and privately funded clinical trials	http://www.aidsinfo.nih.gov/
AIDSmeds.com	Extensive treatment information	http://www.aidsmeds.com
American Association of Family Practice	Health topics	http://familydoctor.org
Centers for Disease Control and Prevention	Health topics; traveler's health	http://www.cdc.gov
Guides for Living	Database of social service organizations	http://www.guides4living.com
HIV InSite	Comprehensive site for providers and patients	http://hivinsite.ucsf.edu/
Johns Hopkins AIDS Service	Comprehensive site for providers and patients; expert Q & A; resources	http://www.hopkins-aids.edu/
New Mexico AIDS Info	Fact sheets; internet bookmarks	http://www.aidsinonet.org
Project Inform	Fact sheets; outreach and education; publications	http://www.projectinform.org
San Francisco AIDS Foundation	AIDS 101; treatment; prevention	http://www.sfaf.org
The Body	Comprehensive AIDS and HIV information resource	http://www.thebody.com
The Well Project	Resource for HIV positive women	http://www.thewellproject.com
Phone Numbers		
Agency	Topics	Phone number(s)
AIDS Clinical Trials Information Service	Clinical trials information	1-800-874-2572
CDC National AIDS Hotline	General AIDS information, local resources for HIV testing and services	English 1-800-342-2437 (24/7) Spanish 1-800-344-7432 (8 am - 2 am EST) TTY 1-800-243-7889
Guides for Living	National resource directory	1-303-702-1254
Social Security Benefits	How to apply for social security benefits	1-800-772-1213
Project Inform	Treatment information	1-800-822-7422
AIDS Treatment Information Service	Treatment information	1-800-448-0440
Direct Access Alternative Information Resources	Alternative Treatments	1-888-951-5433 NYC: 1-212-725-6994

RISK ASSESSMENT AND COUNSELING

What risk-taking behaviors should be reviewed with patients?

Patients infected with HIV who practice unsafe sex or inject drugs can infect others, be reinfected themselves with new HIV strains, or contract STDs, viral hepatitis, or other infections. Abuse of alcohol or illicit drugs is directly harmful and may affect adherence to a complicated medical regimen. Accordingly, providers need a detailed understanding of their patients' risk-taking behaviors to guide patient education and counseling efforts and to assess the advisability of initiating antiretroviral treatment.

Table 2-2 lists specific risk-taking behaviors to review with patients. See also Chapter 4: Prevention of HIV in the Clinical Care Setting and Chapter 13: Management of Substance Abuse.

Table 2-2. Risk-Taking Behaviors to Review with Patients Infected with HIV

Sexual Practices

Number and gender of partners

Specific sexual practices

Frequency

Condom use

HIV status of partners and disclosure of patient's HIV status

Anonymous partners

Association with drug use

Prior STDs

Genital ulcer disease

Drugs

Substances used

Routes of administration

Tolerance and history of withdrawal

History of drug treatment

How should one ask about risk-taking behaviors?

Explaining the rationale for reviewing risk-taking behaviors, informing patients that such a review is routine, and asking for a patient's permission to discuss these topics is a good way to initiate the conversation.

Projecting comfort with the subject material and proceeding in a poised, professional, nonjudgmental, and supportive fashion will engender trust and help patients feel safe enough to discuss their behavior. With regard to sexual behavior, asking "Do you have sex with men, women, or both?" indicates the provider's openness to all sexual orientations. Making a comment that many men who have sex with men, particularly in certain cultures, do not self-identify as gay assures patients that discussing their behavior will not cause the provider to categorize them without their consent. Providers should also explore factors associated with sexual abstinence.

At the same time, it is important for providers to be realistic. Wanting a satisfying sex life is a reasonable desire; the goal is to minimize risk associated with sex. Similarly, changing addictive behavior is extremely difficult and often requires several attempts. Discussing realistic goals will enhance a provider's credibility and minimize a patient's resistance to discussing these subjects. The goal of this initial survey is to learn what patients are doing, not to draw battle lines.

What are effective counseling strategies to help patients decrease their risk taking?

When discussing risk-taking behaviors, a key first goal is to assess a patient's state of preparedness for change. Some patients with newly diagnosed HIV come to care motivated to make healthy lifestyle changes. For these individuals, an enhanced understanding of the risks associated with certain behaviors in conjunction with a provider's strong recommendation to modify behavior may suffice. Providers should also be prepared to offer appropriate medications (e.g., to assist with smoking cessation) or referrals for drug and alcohol abuse counseling. For patients with complicating factors such as severe mental illness, substance abuse, domestic violence, or sexual abuse, referral and close linkages with specialty care are essential.

What if a patient is not prepared to make lifestyle changes?

Providers should deliver a clear, unequivocal message regarding the risks to patients and others associated with unsafe sex and ongoing drug use and advise patients of ways, such as safer sexual practices and needle exchange programs, to reduce risk. It should be kept in mind, however, that pushing patients unprepared for behavioral change may lead to animosity and resistance and that direct advice alone is unlikely to result in immediate or sustained behavioral change. For example, advice to stop smoking generally results in 12-month success rates of 5% -

10%. For patients unprepared to alter their risk-taking behavior, a longer-term strategy is required, and a nonconfrontational approach such as motivational interviewing is recommended (see Table 2-3).

When working with a patient over time to support behavioral change, it is crucial for the provider to be a consistent source of support, hope, and optimism. By acknowledging positive efforts even when initial attempts to modify behavior fail, by continuing to offer encouragement, and by supporting even small progress, the provider can help bolster a patient's resolve and sense of control over his or her actions.

Table 2-3. Motivational Interviewing

Basic Steps:

- Seek to understand the patient's experience through careful and reflective listening.
- Help the patient voice his or her own reasons for change.
- Recognize and accept resistance to change.
- Affirm the patient's ability to control his or her own actions.

In this patient-centered approach, the provider seeks an accurate understanding of the patient's unique experience with certain behaviors. The interviewer listens carefully to the patient's thoughts about his or her behavior, monitors readiness for change, clarifies what the patient believes to be obstacles to change, identifies the patient's own self-motivational statements, and selectively reinforces these expressions of desire, intent, and ability to change. In this manner, the provider yields the role of "expert" and offers affirmation and support for the patient's ability to control his or her own behavior.

Principles to Remember:

- For most people, motivation for change must come from within. Direct persuasion does not often result in sustained behavioral change.
- It is the patient's task to articulate resolve and ambivalence.
- When patients voice resistance to change, it is preferable to recognize and accept a lack of readiness than to press for immediate change. Timing is important.
- Patients must understand that resolutions to change often slip, and failure should not become a reason to avoid contact with the provider.

KEY POINTS

Caring for patients with HIV/AIDS requires a strong provider-patient relationship, a multidisciplinary care team, and frequent office visits.

Stigma and discrimination must be addressed through strong confidentiality protections, emotional support, and cultural sensitivity.

Patient education about the disease process, treatment, and community resources is a vital component of care.

The primary care provider plays a key role in risk assessment and counseling for all patients with HIV.



SUGGESTED RESOURCES

Aranda-Naranjo B, Davis R. Psychosocial and cultural considerations. In: *A Guide to the Clinical Care of Women with HIV/AIDS*, 1st ed. Washington: US Department of Health and Human Services, HRSA, HIV/AIDS Bureau; 2001. Available at <http://www.hab.hrsa.gov>.

Centers for Disease Control and Prevention. Incorporating HIV prevention into the medical care of persons living with HIV. *MMWR Recommendations and Reports*, (July 18, 2003; 52(RR12);1-24.

Hecht FM, Wilson IB, Wu AW, Cook RL, Turner BJ. Society of General Internal Medicine AIDS Task Force. Optimizing care for persons with HIV infection. *Ann Intern Med*. 1999;131:136-143.

Positive Living. A practical guide for people with HIV. Seattle: Public Health–Seattle & King County, HIV/AIDS Program; 1999.

Rollnick S, Miller WR. What is motivational interviewing? *Behavioral and Cognitive Psychotherapy*. 1995;23:325-334.

Chapter 3:

Core Elements of HIV Primary Care

John McNeil, MD
John V. L. Sheffield, MD
John G. Bartlett, MD

INITIAL EVALUATION
ONGOING CARE
KEY POINTS
SUGGESTED RESOURCES

3

INITIAL EVALUATION

What are the goals of the initial evaluation?

The goals will depend to a large extent on why the patient is being seen by the primary care provider, which may be because of symptoms, the need for evaluation after a positive HIV test, referral, for a consultation, etc. The initial evaluation should be tailored to the patient's specific need, but the following are the usual goals of the initial evaluation:

- Evaluate HIV-related complaints that require immediate intervention
- Establish a strong patient-provider relationship with clear lines of communication
- Initiate a complete medical database (Table 3-1)
- Assess the patient's understanding of HIV disease
- Identify health needs for current medical problems, including those associated with mental health, substance abuse, hepatitis, and hypertension
- Assess the need for social and psychological intervention
- Assess the need for consultants for medical, social, or psychiatric care
- Describe HIV disease in lay terms, including natural history, laboratory tests (CD4 cell count and viral load), complications, treatment, and outcome
- Describe methods of transmission and of prevention

This is a large menu, and there may need to be several "first visits."

What are the important aspects of the initial evaluation in patients with symptoms?

It is critical to learn quickly if the patient has any HIV-related complications that indicate advanced disease and may require rapid intervention. The most common presentations related to earlier HIV disease are thrush, weight loss, skin lesions of Kaposi's sarcoma, *Pneumocystis carinii* pneumonia (PCP), and fever. Patients with HIV can also have medical conditions that stem from other causes, such as headaches, upper respiratory infections (URI), gastroesophageal reflux disease (GERD), hypertension, diabetes, or heart disease. Distinction between these and conditions that are HIV-related may be obvious, but when not, the best laboratory test is a CD4 cell count, which represents the barometer of immune function with HIV infection. Nearly all HIV-related complications occur when the CD4 cell count is $< 200/\text{mm}^3$. It may take 2-3 days for the laboratory to report the CD4 cell count, but clues to late-stage disease include evidence of chronic illness with weight loss and/or fever, and/or a total lymphocyte count of $< 1,000/\text{mL}$ which is readily available from a stat complete blood count (WBC x % lymphocytes). Late-stage HIV also is an indication of some urgency to initiate antiretroviral therapy. Some patients present with late complications such as PCP, cryptococcal meningitis, toxoplasmosis, or cytomegalovirus (CMV) retinitis. When these are in the differential diagnosis, the workup may require hospitalization, consultation, extensive testing, and frequent followup by telephone or clinic visit. These are medical emergencies – all are ultimately lethal and all are treatable.

Table 3-1. Initial History and Physical Examination: Key Areas for Patients with HIV/AIDS

History	
Emotional reaction to HIV diagnosis	Availability of friends and family for support
HIV-specific information	First known positive HIV test Documentation of positive HIV test Possible timing and risk factors for HIV infection Opportunistic illnesses Prior CD4 counts, viral load measurements, and resistance tests Prior antiretroviral therapy and side effects Understanding of HIV disease Transmission, natural history of immune-response destruction and opportunistic infections, significance of CD4 counts and viral load, and antiretroviral therapy
Risk assessment	Risk category Sexual behavior history (see Table 2-2) Current sexual activity History of syphilis and other STDs Substance abuse history Intravenous and other substance abuse Rehabilitation and interest in rehabilitation
Past medical history	Use of alternative medicine Mental health history Reproductive history, including pregnancies since becoming HIV positive, and plans for pregnancy Tuberculosis history History of positive PPD test, TB disease, or treatment of latent TB infection Concurrent medical conditions (diabetes, coronary artery disease, hypertension, etc.) Hospitalizations
Social history	Housing Food sources, 3-day diet history Income, employment, and insurance Emergency contacts Legal issues Living will and durable power of attorney for medical decisions Permanency planning for dependent children
Physical Examination	
Vital signs, weight, height	
Skin	Dermatitis, folliculitis, fungal infections, molluscum, and Kaposi sarcoma
HEENT	Retinal exam (with CD4 < 200/mm ³) Oropharynx: oral hairy leukoplakia, candidiasis, dentition
Lymph nodes	Cervical, axillary, inguinal
Abdomen	Liver and spleen
Neurologic status	Special focus on mental status and sensation
Genital and rectal findings	Discharges, ulcers, and warts

What are important aspects of the initial history in asymptomatic patients?

The encounters should be tailored to the idiosyncrasies of the individual patient's needs supplemented with the collection of some routine information about their HIV and general health status. The patient's most pressing concern may require confirming the diagnosis, addressing denial, dealing with "HIV hysteria," evaluating conditions unrelated to HIV, or evaluating for antiretroviral therapy (ART). For patients with prior medical treatment for HIV infection, the previous records are often critical for efficiency in time and cost. When possible, these should be brought by the patient or sent in advance of the visit. The type of information that is particularly useful is the record of CD4 cell counts and viral loads, HIV-related complications, current and prior medications, including information about tolerance, toxicity, and adherence (see Table 3-1).

What information do patients need to know about HIV?

HIV is a chronic infection, which will be lifelong, and its outcome will depend to a large extent on the patient's understanding of the disease process and management. Parallels with type 1 diabetes are clear. With this in mind, it is very important that the patient have access to information to advance his or her understanding of the disease. Essential knowledge includes:

- **Transmission** Sex, injection drug use, and perinatal transmission are the "big 3" and have accounted for virtually all cases in the United States since blood began being screened in 1985.
- **Natural history** Explain the 5 stages: 1) acute HIV, 2) seroconversion, 3) long period with no symptoms and decreasing CD4 cell count, 4) complications when the CD4 cell count is $< 200/\text{mm}^3$, and 5) lethal outcome. Emphasize that without therapy the average untreated patient survives about 10 years from HIV acquisition to death, but there is a great deal of individual variation.
- **What does the CD4 cell count mean?** This is the cell that becomes infected with HIV, it is also the quarterback of the immune system, and the count is a barometer of immunosuppression. Normal is $> 500/\text{mm}^3$; a count of $< 200/\text{mm}^3$ is the definition of AIDS.
- **What does the viral load mean?** This indicates the amount of HIV in the blood. The average is about 30,000 copies per ml (c/ml), but again there is a great deal of individual variation. When it is high, the CD4 cell count tends to decline rapidly (negative CD4 slope). The goal of therapy is to reduce the viral load to undetectable levels, and with this the CD4 cell count usually increases 100-150 cells/ mm^3 each year.

- **Therapy** Potent antiretroviral therapy (ART, also called highly active antiretroviral therapy, or HAART) has revolutionized the course of this disease. Although a miraculous development, HAART is also terribly demanding for the patient in terms of adherence, and some patients have big problems with side effects that are either short-term (eg, nausea, rash, asthenia) or long-term (eg, fat redistribution, hyperlipidemia, peripheral neuropathy). The benefits clearly outweigh the risks, and HIV is no longer an inevitably progressive disease, but is a chronic condition such as hypertension or diabetes that requires continual observation and care.
- **Cure** No cure yet and unlikely to be with any of the current medications.
- **Prevention** See discussion below.

For more information, see Chapter 2: Approach to the Patient (section on Patient Education, especially Table 2-1, Information Resources for Patients).

How should prevention be addressed?

Prevention needs to be addressed early and frequently, usually at every encounter. Nearly all adults who acquired HIV after 1985 did so by sexual exposure or needle sharing in the context of injection drug use. Patients in HIV clinics now constitute an important source for HIV transmission by the same mechanisms. Health care providers are now considered essential in risk reduction with a 3-part responsibility:

- **Risk behavior screening** Patients need to be screened for risk behaviors. The screening includes a history of sexual practices and a clinical assessment for evidence of sexually transmitted diseases (STDs). The history of sexual practices can be taken before patients are seen by the primary care provider, either by another staff member or by having patients complete questionnaires. A component of the assessment includes evaluation for STDs because having STDs is associated with a 5-fold increase in the risk of transmitting HIV and also indicates high-risk sexual activities. Women under 25 years old should be screened for cervical *Chlamydia trachomatis*, all symptomatic patients should be evaluated for gonococcal and chlamydia infection, and asymptomatic patients should be considered for screening for these pathogens. Screening is now facilitated by the use of urine specimens for nucleic acid amplification tests (NAAT) for both *N. gonorrhoeae* and *C. trachomatis*.
- **Risk reduction counseling** The second component of prevention is risk reduction counseling, which may be done in the office or through referral. It is critical that patients be fully informed about how HIV is and is not transmitted and that they be counseled about how they can reduce the risk of transmitting HIV to others.

- **Partner referral** The third component, partner referral, involves asking patients to identify persons whom they have placed at risk through sexual or drug-using behaviors. These persons are then referred to a “Partner Counseling and Referral Service” (PCRS) without identifying the source of the information. The PCRS provides public health resources for confidentially informing partners that they have been exposed to HIV and need HIV counseling and testing.

For more information on prevention, see Chapter 2: Approach to the Patient (section on Risk Assessment and Counseling), Chapter 4: Prevention of HIV in the Clinical Care Setting, and Chapter 13: Management of Substance Abuse .

What are common patient questions?

Patients have many questions when they are newly diagnosed with HIV.

- **What will happen to me?** Patients need to know the facts of HIV regarding prognosis, but emphasis should be placed on the extraordinary benefits of therapy, which, for many, may mean a normal lifespan.
- **Can HIV be cured?** Not with current drugs (but it can be contained).
- **Will I need to take medicine forever?** Patients who respond well to therapy will probably be able to discontinue treatment periodically, but regularly scheduled treatment interruptions generally result in poor long-term control of HIV.
- **Would alternative medicine help me?** Probably not, but some patients seem to think it does. Patients should be encouraged to report any alternative medicines they are taking because some of them are problematic in combination with ART.
- **Will I give HIV to the people I live with?** Patients can give HIV to anyone they have sex with or share needles with; however, they also need to understand that people who live in the same household without that kind of contact are not at risk. It is probably best for people with HIV to have their own toothbrushes and razors and not to share eating utensils that have not been washed, even though HIV is not generally transmitted that way.
- **Are pets a problem for me?** Pets don’t give or get HIV. Occasionally cats will become the source of *Toxoplasma gondii* or *Bartonella*, but this is rare; patients should wash their hands after handling pets and especially before eating, avoid contact with cat stool to prevent toxoplasmosis, and avoid cat bites and scratches and fleas to avoid bartonellosis.
- **Should I have a special diet?** Nutrition is important, but there is nothing idiosyncratic about the needs of people with HIV (see Table 2-1 in Chapter 2 for nutrition resources). With late-stage disease, it might be smart to avoid ingesting lake water because of *Cryptosporidium parvum*, which is commonly present and can cause chronic disease.

- **Can I travel?** Certain vaccines required for travel to developing countries are best avoided by people with suppressed immune systems, but vaccines rarely interfere with travel. The biggest problem may be access to good health care and the usual conditions such as traveler’s diarrhea that can affect any traveler.
- **What will happen if I am around someone with a cold or some other common infection?** This type of exposure would probably cause nothing more than an ordinary cold. People with HIV infection do not become susceptible to infectious complications until the CD4 cell count is low. Then they become vulnerable to a very specific menu of infectious disease complications that are extremely rare in the general public. The infections that are common, such as upper respiratory infections or gastroenteritis, are generally no worse in a person with advanced HIV disease than in a healthy person.
- **My cousin has a newborn infant that I want to visit. Is this a good idea?** There should be no reservations here and no reason to talk about HIV infection. It’s okay to hold, kiss, and hug the child; patients should just obey the simple rules of hygiene that they would under ordinary circumstances.
- **Who should I tell?** People who have been placed at risk either sexually or through drug use need to know, and either the patient can tell them or health department staff can do it. The reason is that they need to be tested so that if they are infected they do not transmit HIV to others, and they also need to gain access to care, which is critical. Beyond that, patients should be counseled to be very careful who they tell about the diagnosis.
- **Do I need to tell people at work?** Generally no. HIV is not transmitted by HIV-infected workers in the work place. A rare exception is some health care workers who could conceivably transmit HIV infection during surgery. Most institutions have policies about health care workers who perform invasive procedures, and these need to be followed. Otherwise, there are no other circumstances in which anyone needs to know unless the symptoms of HIV interfere with effective performance.

What should be covered in the physical exam?

Everything, but special attention should be paid to scrutiny of the vital signs, enlargement of lymph nodes, skin lesions, enlargement of liver or spleen, and mental status (see Table 3-1).

What are the initial laboratory tests to order?

Standard laboratory testing should be done to stage the HIV disease, determine the general health status, and identify the presence of concurrent conditions, and baseline tests should be done on patients who are candidates for ART (see Table 3-2). In general, the CD4 cell count identifies the need to treat with antiretroviral drugs, and the viral load is the major indicator of therapeutic response.

Table 3-2 Laboratory Testing in HIV Primary Care			
(Revised 10/8)			
Test	Baseline	Repeat	Comment
Confirmation of Positive HIV Status			
Standard HIV serologic test	Either copy of prior lab results or new tests		Make sure there is a confirmed positive result with standard HIV serologic test
HIV Staging			
CBC	Yes	Repeat at 3-6 month intervals	Repeat more often with some drugs or abnormalities
CD4 count	Yes	Repeat at 3-6 month intervals	Evaluates immune status
HIV viral load	Yes	Repeat at 3-month intervals	Prognostic indicator Repeat more frequently with initiation of ART
Health Status Evaluation			
Chemistry panel	Yes	Repeat annually	Repeat more frequently with abnormalities
Pap smear	Yes	Repeat at 6 months and then annually	
PPD	Yes if no history of TB or a prior positive test	Repeat if initial test was negative and patient was exposed, or if CD4 count increased to > 200/mm ³	
Hepatitis screen			
HAV	Optional		Screen once to identify candidates for HAV vaccine
HBsAg			Test if abnormal liver function tests
anti-HBc or anti-HBs	Yes		Identify candidates for HBV vaccine
HCV	Yes		Screen especially if liver disease present
STDs			
VDRL or RPR	Yes	Repeat annually in sexually active patients	Syphilis screen
Urine nucleic acid amplification test (NAAT) for <i>N. gonorrhoeae</i> and <i>C. trachomatis</i>	Consider for sexually active patients	Consider annual testing or more frequently if at high risk	First-catch urine or urethral (male)/cervical (female) specimen
Chest x-ray	Optional		Must do if positive PPD or chest symptoms
<i>Toxoplasma gondii</i> IgG	Yes		Consider repeating if there are typical symptoms and negative prior test
Baseline for HAART			
Fasting glucose	Yes		
Fasting lipids	Yes		

ONGOING CARE

After the initial evaluation is completed, how often do patients need to be seen?

In general, patients with early-stage disease are seen at 3-month intervals to undergo routine medical evaluation and monitoring of CD4 cell count, viral load, and CBC. During the initial evaluation more frequent visits are common because there is so much information to transmit. Visits should also be more frequent when therapy is introduced and when the CD4 cell count is $< 200/\text{mm}^3$ because complications are more likely. It is very important for the primary care provider to thoroughly understand HIV and its complications. In general, the patients are in 4 categories with some overlap: 1) those with a CD4 cell count of $> 200/\text{mm}^3$, whose complaints are rarely due to HIV or its complications, 2) patients with a CD4 cell count of $< 200/\text{mm}^3$, whose new complaints usually reflect an HIV-related complication which is usually both potentially serious and treatable, 3) patients from either group who are receiving ART and other medications, in which case the side effects of the drugs must be considered, and 4) patients with other medical problems, which is actually the rule rather than the exception because of the high frequency of concurrent conditions.

How can one provider take care of all of the problems?

HIV is generally a complex disease in patients with complicated lives, lifestyles, and concurrent conditions. They are best served by a multidisciplinary team with ancillary services for support regarding case management, mental health, substance abuse treatment, transportation, and housing assistance, using the chronic disease model of care. Another model of care emphasizes patient self-management, with the patient as the principal caregiver supported by a well-prepared practice team with a clear division of labor. The patient is linked not only to the provider unit (the clinic) but also to community-based resources and support from the larger health care organization.

What needs to be done in the follow-up evaluations?

Follow-up evaluations are important to document disease trends and response to therapy and to assess high-risk behavior. This includes history, physical exam, and lab tests (see Tables 3-1 and 3-2). In general, the review needs to be tailored to the specific needs of the patient. Sometimes the major issue is a concurrent condition such as hepatitis C, mental illness, or substance abuse requiring resources that are best achieved with a multidisciplinary approach. For patients who are receiving ART and prophylactic drugs to prevent opportunistic infections, heavy emphasis needs to be placed on adherence and drug-related toxicities as discussed in Chapter 7 or on symptoms related to HIV complications as discussed in Chapters 8, 9, and 10. Under all circumstances, it is important to periodically assess the patient's knowledge of HIV since misconceptions are common and patients are often reluctant to ask the questions that bother them most. In virtually all encounters, it is important to emphasize prevention.

In patients at highest risk for STDs (multiple or anonymous partners, sex in conjunction with illicit drug use, patients whose partners participate in these activities, high prevalence of STDs in the area or in the patient population), STD screening is recommended more frequently than annually (see Chapter 4).

KEY POINTS

The focus of the first visit is determined by the patient's most immediate needs.

The initial evaluation is complex and usually requires several visits.

An important aspect of primary care is answering the patient's questions to ensure that he or she understands the HIV disease process and treatment.

While patients with early-stage HIV disease can be seen at 3-month intervals for routine medical evaluation, those receiving ART or with more advanced disease must be seen more frequently.

A multidisciplinary team approach with the patient as primary caregiver is the best approach to care.



SUGGESTED RESOURCES

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Centers for Disease Control and Prevention. Incorporating HIV Prevention into the Medical Care of Persons Living with HIV. *MMWR*. 52(RR12):1-24. July 18, 2003. Available at: <http://www.cdc.gov/hiv/pubs/guidelines.htm#prevention>.

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Nerad J, Romeyn M, Silverman E, et al. General nutrition management in patients infected with human immunodeficiency virus. *Clinical Infect Dis*. 2003;36(Suppl. 2):S52-62.

Sande MA, Volberding PA, Eds. *The Medical Management of AIDS* – 6th ed. Philadelphia, PA: WB Saunders; 1999.



WEBSITES

AIDSInfo: <http://www.aidsinfo.com>
Accessed 9/03.

AIDS Education Global Information System:
<http://www.aegis.com> Accessed 9/03.

Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention: <http://www.cdc.gov/hiv/dhap.htm> Accessed 10/03.

HIVInsite: <http://www.hivinsite.ucsf.edu>
Accessed 10/03.

Johns Hopkins AIDS Service: <http://www.hopkins-aids.edu> Accessed 10/03.

STD/HIV Prevention Training Centers: <http://depts.washington.edu/nnptc/> Accessed 10/03.

Chapter 4:

Prevention of HIV in the Clinical Care Setting

*Michael P. Johnson, MD, MPH**RATIONALE FOR HIV PREVENTION IN PRIMARY CARE**INTERVENTIONS FOR HIV PREVENTION**KEY POINTS**SUGGESTED RESOURCES**REFERENCES***4**

RATIONALE FOR HIV PREVENTION IN PRIMARY CARE

Why is HIV prevention important in the HIV clinical care setting?

*Why rob banks?...**Because that is where the money is!*

There is growing awareness that the majority of people living with HIV are having sex and that active substance abuse, often with needle-sharing behavior, remains common in the setting of HIV infection (see Chapter 13: Management of Substance Abuse). The HIV clinical care setting provides an opportunity to work with patients to reduce their risk of transmitting HIV to others. Studies are under way to measure the effectiveness of comprehensive clinical care in preventing the spread of HIV. Until those results are available, one should assume that interventions to reduce HIV concentrations in the body through antiretroviral therapy (ART) combined with behavioral counseling to reduce high-risk sexual behaviors and, when indicated, drug abuse treatment are important approaches to decreasing the incidence of HIV infection.

Do most primary care providers incorporate HIV prevention into their care?

Experienced providers, and even HIV specialists, often do not conduct screening and assessment of behavioral risk or offer prevention counseling for their HIV-infected patients. The degree to which these are neglected is startling. Nationwide, approximately a third of HIV-infected patients report that their providers have never counseled them about HIV prevention; in some settings as many as three quarters of HIV medical care providers do not ask about sexual behavior and as many as half do not ask about drug use (Marks et al, 2002; Natter et al,

2002). Results of an unpublished study suggest that HIV specialists are less likely than primary care physicians to engage clients in discussions about sexual and drug-using behaviors. Barriers of time, training, and comfort level contribute to this missed opportunity for HIV prevention.

What factors are associated with high-risk behaviors of people living with HIV?

People living with HIV often practice high-risk sexual and drug-using behaviors in association with poor adherence to clinical care in general and to ART regimens in particular (Wilson et al, 2002). This is of particular concern given the risk of viral resistance with poor medication adherence, which may subsequently result in transmission of resistant viral strains to others. Also, both adherence to HIV prevention practices and adherence to medication regimens appear to be related to mental health problems, which are common among people with HIV (Kalichman et al, 2002). In particular, depression and anxiety disorders are common and should be assessed in patients who report continued high-risk sexual and drug-using behaviors. Any of these conditions should alert the provider to probe for problems in the other conditions or behaviors; addressing underlying issues can lead to improvements in several important behaviors.

What behavioral interventions work to prevent people living with HIV from transmitting HIV?

The earliest behavioral interventions provided factual information and generated fear of AIDS to motivate people to reduce high-risk behavior. Most experts now agree that these interventions do not effectively reduce high-risk behaviors of persons at greatest risk for acquiring HIV, and that generating fear of AIDS most likely increases stigmatization of people living with HIV infection.

A number of counseling interventions have been found to be more effective than providing knowledge alone. Among these effective approaches are brief, provider-delivered counseling messages, which can be delivered within the context of a clinical encounter (Kamb et al, 1998; CDC, 2001). Several theoretical behavioral models have been used to guide counseling interventions. Some common elements of these theory-based counseling approaches include:

- Establishing dialogue and rapport with the client and providing ongoing services in an understanding and nonjudgmental manner, often with the support of trained peers to supplement the provider-based counseling
- Understanding and addressing client needs, situations, and pressures for sexual and drug-using behavior (eg, mental health needs), with emphasis on issues that might be perceived by the client as more pressing than HIV prevention (eg, food, housing, employment), and external barriers to the adoption of safer behaviors (eg, domestic violence)
- Addressing the client's high-risk behavior in a step-wise manner, understanding the readiness and motivation for a change in each specific high-risk behavior, and building the client skills for implementing such changes

These elements are the basis for the assessment and counseling recommendations discussed below, which can be implemented in the clinical setting, along with planning and mobilization of supportive services.

What is the role of drug abuse treatment in preventing HIV transmission?

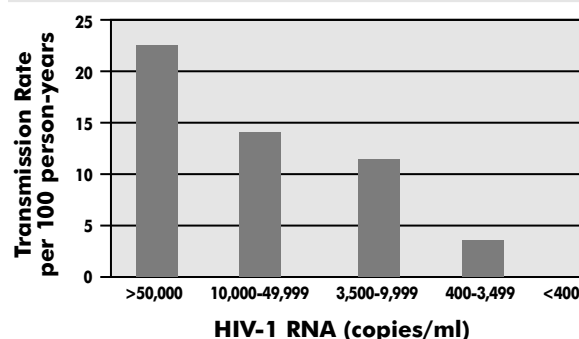
Sharing of drug-injection paraphernalia is directly related to HIV transmission through the transmission of infected blood. Drug and/or alcohol abuse indirectly lead to HIV transmission through the exchange of sex for drugs and enhanced sexual risktaking under the influence of these substances. Drug abuse treatment is an important intervention in the setting of HIV clinical care (see Chapter 13) and should be considered as an important and effective means of HIV prevention among persons with HIV who abuse drugs and/or alcohol.

What is known about the role of antiretroviral therapy in preventing HIV transmission?

Effective ART leads to a decline in plasma viral load, which reduces the risk of maternal-infant HIV transmission. The risk of sexual transmission of HIV is strongly correlated with plasma HIV levels (Quinn, 2000) (see Figure 4-1). There is also a strong correlation between changes in plasma viral load and the HIV

viral load in genital secretions (Ball et al, 1999); however, HIV can be present in genital secretions when plasma HIV is suppressed below the level of detection. While it is highly likely that effective ART leads to a significant reduction in HIV infectivity, from a behavioral standpoint an increase in high-risk sexual behavior because of a sense of lower risk to others has been observed in persons being treated with ART (Dukers, 2001; Scheer, 2001). For this reason, HIV prevention counseling remains important for those on effective ART, and it is particularly important when viral loads rise, eg, due to interruption of therapy and/or emergence of viral resistance.

Figure 4-1. Associations of HIV Plasma Viral Load and Sexual Transmission of HIV



Source: Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. *N Engl J Med*. 2000;342:921-929. Copyright 2000 Massachusetts Medical Society. All rights reserved. Reprinted with permission.

What is the role of nonoccupational postexposure prophylaxis (nPEP) in the prevention of HIV infection?

Nonoccupational postexposure prophylaxis (nPEP) refers to the use of ART to prevent HIV after a significant sexual exposure to HIV (eg, after sexual assault or condom breakage during intercourse between a discordant couple). A complete review of postexposure prophylaxis (PEP) can be found in Chapter 11: Postexposure Prophylaxis. In summary, a 28-day course of ART may be considered for prevention of nonoccupational HIV transmission if therapy is initiated within 72 hours after a significant exposure from a person with known or suspected HIV infection. This approach will be addressed in upcoming US Public Health Service (PHS) guidelines for nPEP (watch the AIDSInfo website listed in Suggested Resources for these guidelines).

INTERVENTIONS FOR HIV PREVENTION

What can the provider do to enhance prevention practice in the clinical setting?

Primary care interventions to assess and reduce the risk that HIV-infected persons will transmit the virus to others can be conducted at the level of 1) medical care, 2) other care (eg, case management, social services), and 3) clinic structure. Ideally, interventions at all 3 levels are combined to maximize the opportunities for HIV prevention, and each clinic will structure its interventions differently according to its configuration and resources. The following recommendations are directed primarily to the medical provider, although there are often other clinic staff members who support and reinforce these risk assessment and counseling interventions. Training can enhance the skills and motivation for providers to integrate these activities into their routine practice (see Suggested Resources and Chapter 18: Keeping Up-to-Date: Sources of Information for the Provider).

How can the provider identify a patient's risk behaviors?

A brief history should be taken at each regularly scheduled clinic visit to identify knowledge of HIV transmission, sexual and drug-using behavior, and symptoms of an STD (eg, urethral or vaginal burning or discharge, dysuria, genital or anal ulcers, inter-menstrual bleeding, or lower abdominal pain in women). History-taking methods include written, audio, and computerized questionnaires and face-to-face interviews, using either structured or open-ended questions (see examples in Table 4-1). Studies suggest that patients may provide more honest and detailed responses to questionnaires not administered face-to-face. Also, physicians trained in discussing sensitive sexual and drug-using issues are likely to perform better than those who are not. Providers should give positive reinforcement to patients when the screening questions indicate no high-risk sexual and drug-using behaviors. Conversely, indications of high-risk behavior should trigger a medical/laboratory evaluation for STDs, behavioral risk assessment and counseling interventions, and referral and contact notification, as indicated. For more detailed discussion, see the section on Risk Assessment and Counseling in Chapter 2: Approach to the Patient as well as the screening questions for drug abuse in Chapter 13: Management of Substance Abuse.

Table 4-1. Examples of Open- and Closed-ended Risk-screening Questions

Open-ended questions

What do you know about HIV transmission?

What, if anything, are you doing that could result in transmitting HIV to another person?

Tell me about any sexual activity since your last clinic visit.

What do you know about the HIV status of each sex partner?

Tell me about condom use during any sexual activity.

Tell me about any drug use or needle sharing since your last clinic visit.

Closed-ended questions

Do you know the facts about how HIV is and is not transmitted?

Have you had sex (vaginal, anal, or oral) with any partner since your last clinic visit?

For each of your partners, do you know if he/she has HIV infection, doesn't have HIV infection, or are you not sure?

Did you use a condom every time, from start to finish of each sexual encounter?

Have you shared drug injection equipment (including needle, syringe, cotton, cooker, water) with anyone?

Note: Symptoms of STDs (eg, urethral or vaginal burning or discharge, dysuria, genital or anal ulcers, inter-menstrual bleeding or lower abdominal pain among women) are asked in a closed-ended format, regardless of behavioral question format.

What medical and laboratory screening should be done?

Symptoms or signs of an STD or known exposure to STDs should prompt immediate physical and laboratory examinations. However, because STDs are often present without symptoms, every patient should be screened for laboratory evidence of syphilis, trichomonads (women only), gonorrhea, and chlamydia at the initial visit and at least annually (see Table 4-2). Some experts also recommend type-specific testing for herpes simplex virus type 2 because of its association with a higher risk of HIV transmission and possible need

for enhanced counseling. More frequent screening for STDs is appropriate with evidence or suspicion of high-risk sexual behavior (eg, sex with a new partner, sexual activity without consistent and correct condom use); however, there are no data to guide the precise frequency. More frequent screening might also be appropriate in asymptomatic men who have sex with men (MSM) and younger women because of a higher STD prevalence among these demographic groups. The local prevalence of these infections might guide frequency of screening. Laboratory screening for drug abuse is addressed in Chapter 13.

Table 4-2. Screening for Sexually Transmitted Diseases

STD	Recommended test
Syphilis	Non-treponemal serologic test (RPR, VDRL)
Gonorrhea	Nucleic acid amplification test (first-catch urine or urethral [male]/cervical [female] specimen) or culture (urethral [male]/cervical [female] specimen)
Chlamydia	Nucleic acid amplification test (first-catch urine or urethral [male]/cervical [female] specimen)
Trichomonas	Wet mount or culture (vaginal secretion)
Herpes simplex virus	Type-specific HSV-2 antibody testing

What behavioral assessment and counseling interventions should the provider implement?

Specific suggestions for assessment and counseling are presented in Table 4-3 and in Chapter 2. Each clinic must decide which aspects of HIV prevention assessment and counseling are best done by the primary provider, by other clinical providers with whom the patient interacts, or some combination of both. Brief interventions by physicians have been found to be effective with other conditions, including smoking cessation, improving dietary behavior, and reduction of alcohol consumption. Thus, while data are limited on the topic of HIV prevention, physicians should provide such counseling until studies suggest alternate and improved approaches.

How can clinic staff other than the primary medical provider enhance HIV prevention practice?

In most medium-sized and larger clinics, staff members other than the primary medical provider are responsible for referral, contact notification, and quality improvement, which can all be used to enhance prevention practice, as discussed below. In addition, specific structural interventions (eg, arranging client flow to ensure interaction with clinic staff who conduct prevention counseling, use of video, written handouts or other educational media, and distribution of condoms) can strengthen the role of other clinic staff in prevention activities.

What role does referral to community resources play in HIV prevention?

Some complex patient issues and conditions fall beyond the scope of a primary care clinic and must be addressed before risky behavior can be reduced or eliminated. These include drug abuse, mental health issues, domestic violence, and assistance with needs such as housing, food, and employment. Each clinic should have established relationships with community resources to address these issues, and staff members should have thorough knowledge of the available services as well as mechanisms in place to ensure that patients can access the services. Finally, followup should be done to be certain that the referrals are utilized and are effective for each patient. It is unlikely that persons at highest risk for transmitting HIV to others can effectively reduce such behavior without access to a comprehensive array of services and supports.

What are key elements of contact notification?

Contact notification is an effective way to identify additional HIV-infected persons through HIV counseling and testing, bring them into care, and provide support to help them avoid transmitting HIV to others. Health departments traditionally conduct contact notification; in some States providers are required by law to report to the health department known sexual or drug-equipment-sharing contacts of persons infected with HIV. The standard method is to inform the patient's contacts that they have been placed at risk and need HIV testing without identifying the source.

Table 4-3. Suggested Counseling Content for Behavioral Risk Reduction

Factual topics about HIV transmission	Suggested content
Relative risk of HIV transmission during sex	Most to least risky activities: receptive anal > receptive vaginal > insertive anal > insertive vaginal > receptive oral > insertive oral
Preventing HIV transmission during sexual activity	Abstinence (safest behavior) Correct condom use (latex or polyurethane condoms, used with water-based, not oil-based, lubricants, used from start to finish of any sexual penetration) Other means of reducing risk
Effect of drug use on sexual decisionmaking	Potential increase in sexual risk behavior following drug and/or alcohol use
Risk of HIV transmission when sharing drug-injection equipment	Highest risk for HIV transmission Risk of other disease transmission for either user Entire works (drug paraphernalia), not only needles, need to be clean
Impact of viral load level on HIV transmission risk	Greatest risk of HIV transmission when viral load is elevated (eg, when antiretroviral therapy is stopped or is ineffective) HIV transmission still possible during effective antiretroviral therapy (eg, there can be HIV in genital secretions even when plasma viral load is undetectable)
Components of assessment and counseling	Suggested content
Motivation for HIV prevention	Risk to self: acquiring non-HIV infectious agent and acquiring drug-resistant HIV strain Risk to others: transmitting HIV
Readiness and capacity for HIV prevention	Patient's belief about his/her desire, intent, and sense of capacity to adopt behaviors that prevent HIV transmission
Barriers to adopting safer sexual and drug-using behaviors	Identification of barriers, such as mental health needs, substance abuse, domestic violence, and other social and economic pressures that might impede the adoption of behaviors to prevent the transmission of HIV
Willingness to accept in-depth counseling and/or referral to overcome barriers to adopting safer behaviors	Identification of history of past efforts to address the issue impeding the adoption of safer behavior Encouragement and offering of assistance for more in-depth support through referral
Development of an HIV prevention plan	Creation of a plan mutually agreeable to patient and provider, written for both the medical record and the client
Discussion of reproductive intentions	Assessment of need for in-depth counseling with HIV-experienced obstetrician to address risks and benefits of conception

How can HIV prevention be made a part of routine clinic practice?

HIV prevention, often neglected as a component of HIV clinical care, is more likely to be a part of routine clinic practice if it is part of the clinical continuous quality improvement activities (see Chapter 17: Quality Improvement). While the most effective indicators for prevention practice in the clinical setting are not known, considerations include medical record documentation of risk assessment history, prevention counseling, medical/laboratory examination for STDs, establishment of a prevention plan, and completion of referrals. There should be regular assessment of whether such tasks are completed and regular feedback to staff members regarding the success rates of completing these interventions. Finally, training interventions should be guided by data from these quality improvement activities (see Chapter 18).

KEY POINTS

The HIV clinical care setting offers an ongoing opportunity to work with patients to reduce their risk of transmitting HIV to others.

Common elements of behavioral interventions to reduce HIV risktaking include establishing rapport with the patient, addressing immediate patient needs (eg, mental health problems, substance abuse, housing), and working in small steps to build motivation and skills for change.

A brief history of patient risk behaviors and HIV prevention counseling should be parts of each patient visit.

Besides HIV prevention counseling, the following are important components of HIV prevention in the clinical setting: contact notification, drug abuse treatment, screening for STDs, decreasing the patient's viral load through ART, and nPEP.

Structural interventions for HIV prevention include making available educational materials and condoms, establishing strong referral relationships with social service and substance abuse services, and incorporating prevention indicators into quality improvement activities.



SUGGESTED RESOURCES

Institute of Medicine/Committee on HIV Prevention Strategies in the United States. *No time to lose: getting more from HIV prevention*. Ruiz MS, Gable AR, Kaplan EH, Stoto MA, Fineberg HV, Trussell J, eds. Washington DC: National Academy Press. 2001.

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WEBSITES

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Accessed 11/03.

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Chapter 5:

Antiretroviral Therapy

*John G. Bartlett, MD**THE PRINCIPLES OF ANTIRETROVIRAL THERAPY (ART)**WHEN TO START THERAPY**WHAT TO START**WHEN TO CHANGE THERAPY**WHAT TO CHANGE TO**RESISTANCE TESTING**KEY POINTS**SUGGESTED RESOURCES**CASES*

THE PRINCIPLES OF ANTIRETROVIRAL THERAPY (ART)

What are the goals of therapy?

The overall objective of treatment for HIV disease, as with treatment for many other infectious diseases, is to control the putative agent with antimicrobial agents while providing other appropriate therapies for HIV-related complications. The single most important goal of HIV antiretroviral therapy is to reduce the HIV viral load to as low as possible for as long as possible. The 5 other goals of antiretroviral therapy (ART) are to

- Prevent HIV-associated complications
- Avoid the long-term and short-term adverse drug reactions associated with antiretroviral agents
- Prevent HIV transmission
- Avoid HIV resistance
- Preserve HIV treatment options

Does antiretroviral therapy work?

Treatment recommendations have evolved greatly since zidovudine (AZT), a nucleoside, was first tested in 1986. The strategy was revolutionized in 1996-97 with the introduction of protease inhibitors (PIs) and then subsequently non-nucleoside reverse transcriptase inhibitors (NNRTIs). Combined with AZT and other nucleosides (see Table 5-1), the result was potent combination ART (also referred to as highly active antiretroviral therapy, or HAART) that had an immediate and dramatic impact on the prognosis for HIV infection, in fact one of the most impressive changes in any disease since the introduction of penicillin in the 1940s. Within 2 years there was a 60%-80% decrease

in mortality, AIDS rates, and hospitalizations for HIV-associated complications. Nevertheless, this treatment was also associated with some disappointments: there is still no cure for HIV infection, many of the patients given ART develop serious side effects, and

drug resistance causes many patients to eventually have virologic failure so that long-term benefit may be difficult to sustain. Also, adherence has been shown to be critical to treatment success, and the level of adherence required is among the stiffest for the treatment of any disease in medicine.

See Glossary of Antiretroviral Drugs on page viii and the Pocket Guide

WHEN TO START THERAPY

What are the criteria for starting therapy?

The decision to start therapy, like most medical decisions, depends on the risk-to-benefit ratio of treatment. ART is given to control HIV replication and the consequent immune dysfunction, but therapy is also associated with the development of some substantial side effects and the risk of developing resistance that would limit future options. The reduction in CD4 cells is the pivotal event of HIV disease that renders the patient susceptible to the unique opportunistic infections (OIs) and tumors that have come to be known as AIDS-defining diagnoses (see Table 5-2). The patient becomes vulnerable to these diseases when the CD4 cell count decreases from normal levels (500-1500 cells/mm³) to <200 cells/mm³; the association with complications is the rationale for this CD4 cell threshold to be used by CDC to define AIDS.

Virtually all guidelines in the world have reached a consensus that a CD4 cell count of <200/mm³ is an indication for ART. The only question is the CD4 level above which treatment should be started. According to the DHHS Guidelines for the Use of Antiretroviral

Agents in HIV-Infected Adults and Adolescents (available at <http://www.aidsinfo.nih.gov>) the CD4 cell count range of 200-350/mm³ is also an indication for ART, but the decision is tempered by the viral load, the rapidity of the CD4 cell count decline (CD4 cell slope), and patient readiness. The role of viral load in this decision is based on 2 observations: 1) the viral load is an independent predictor of progression and 2) the CD4 decline slope is directly correlated with viral load. The implication is that a high viral load imparts a risk for more rapid progression to AIDS and a more rapid decline in the CD4 cell count. The threshold that appears important in the CD4 cell strata of 200-350 is $\geq 20,000$ copies of virus/mL (c/mL). Some authorities also treat patients with a viral load of 50,000-100,000 c/mL even when the CD4 cell count is $> 350/\text{mm}^3$, but there is no consensus here. It should be emphasized that multiple cohort studies involving thousands of patients clearly indicate that therapy is necessary when the CD4 cell count is $< 200/\text{mm}^3$; some of these studies also show a benefit when the CD4 cell count is 200-350/mm³, but these findings are somewhat inconsistent from study to study.

What patient factors influence this decision?

Patient readiness may be the most important factor in the decision to treat most patients. ART is never an emergency, although the CD4 cell count clearly indicates the magnitude of risk from waiting. Most experienced HIV providers will never start ART on the first patient visit, which is designed for evaluation and the initiation of patient education. The patient must understand not only the risks and benefits of HIV treatment, but also the critical role of adherence to what may be one of the most complicated medical treatment regimens for any disease (see Chapter 7: Adherence to HIV Therapies).

WHAT TO START

How do you suppress HIV replication?

The goal of treatment is to suppress HIV as much as possible for as long as possible. This requires 3-4 drugs in combinations that have been proven to have merit in clinical trials (see Table 5-1).

Do you ever start with 1 or 2 drugs?

No, with a rare exception; some providers treat pregnant women with a CD4 cell count of $> 350/\text{mm}^3$ and a viral load of $< 1,000$ c/mL with zidovudine (AZT) alone. With this exception, all patients should be treated with 3-4 drugs combined in a fashion that has established merit.

Table 5-1. Combination Antiretroviral Therapy

Standard initial regimens

- 2 nucleosides* and a protease inhibitor (PI)** or a ritonavir-boosted PI
- 2 nucleosides* and a non-nucleoside reverse transcriptase inhibitor (NNRTI)***

Classes

- * **Nucleosides:** zidovudine (AZT), didanosine (ddI), zalcitabine (ddC), stavudine (d4T), lamivudine (3TC), emtricitabine (FTC), abacavir (ABC), tenofovir (TDF) (tenofovir is actually a nucleotide rather than a nucleoside)
 - ** **Protease inhibitors (PI):** indinavir (IDV), ritonavir (RTV), nelfinavir (NFV), saquinavir (SQV; 2 formulations – Invirase and Fortovase), amprenavir (APV), fosamprenavir (FPV), lopinavir (LPV; co-formulated with ritonavir as LPV/r), and atazanavir (ATV)
 - *** **Non-nucleoside reverse transcriptase inhibitor (NNRTI):** efavirenz (EFV), nevirapine (NVP), and delavirdine (DLV)
- Fusion inhibitors** (used only for salvage): enfuvirtide (T20)

Table 5-2. When to Start Therapy

Patient status	Recommendation	Comment
Symptomatic HIV/AIDS	Treat	AIDS-defining diagnosis
Asymptomatic with CD4 cell count of $> 350/\text{mm}^3$	Defer therapy	Some authorities treat if viral load is $> 55,000$ c/mL
CD4 cell count of 200-350/mm ³	Treat or defer therapy	Influencing factors include • Patient readiness • CD4 slope (rate of decline) • Viral load ($< 20,000$ c/mL = low risk of progression) • Treatment-associated risks: heart disease, drug interactions
CD4 cell count of $< 200/\text{mm}^3$	Treat	Universally accepted CD4 threshold for initiating treatment in all guidelines

How do you decide on a specific regimen?

The selection of a regimen is based on the experience with completed trials and idiosyncrasies of the specific patients. No single regimen is appropriate for all patients, but virtually all experienced AIDS treaters have a few favorites. Most start with a 3- or 4-drug regimen that includes 1) an NNRTI combined with 2 nucleosides, 2) a PI either alone or boosted with ritonavir (RTV) plus 2 nucleosides, or 3) a 3-nucleoside regimen that includes abacavir (ABC), lamivudine (3TC), and zidovudine (combined as Trizivir). This last regimen has been popular for patients who struggle with complicated medical regimens because it is only 1 pill twice a day; however, the regimen is considered suboptimal compared with the PI- or NNRTI-based regimens.

Is once-a-day therapy possible?

This is now feasible and clearly preferred by some patients. The following drugs may be given once a day: tenofovir (TDF), lamivudine (3TC), emtricitabine (FTC), didanosine (ddI), stavudine (d4T), efavirenz (EFV), atazanavir (ATV), and amprenavir plus ritonavir (APV/r).

Table 5-3. Rationale for Changing Therapy

Problem	Definition	Intervention
Virologic failure	Failure to decrease viral load to <500 c/mL within 16-24 weeks or achieving that goal with subsequent elevation to >500 c/mL with at least 2 measurements Causes: non-adherence, resistance or pharmacologic issues (poor bioavailability, drug interaction, etc.) Consequences: viral replication with progression of immunodeficiency and accumulating resistance mutation	Change drugs, usually based on sensitivity tests
Drug toxicity	Side effects that may be 1) annoying (GI intolerance, asthenia), 2) life-threatening (pancreatitis, lactic acidosis, hypersensitivity, hepatic necrosis), 3) cosmetic (fat redistribution), or 4) pose ill-defined risks (hyperlipidemia)	Substitute a different drug

WHEN TO CHANGE THERAPY**When do you change therapy because of virologic failure?**

The goal of therapy is to reduce the viral load to undetectable levels. The expectation is a reduction by 1 log₁₀ c/mL within 1-4 weeks, a viral load of <500 c/mL at 16-24 weeks, and a viral load of <50 c/mL after 24 weeks. Viral load measurements are subsequently made at 3-month intervals and are expected to remain at <50 c/mL. Temporary increases above this level are sometimes called “blips.” Virologic failure is defined as 2 consecutive viral load counts of >500 c/mL (see Table 5-3).

What causes virologic failure?

There are 2 causes: 1) resistance, meaning that the strain of HIV is resistant to one or more of the drugs in the regimen, and 2) failure of the drug to reach the virus, which may be due to failure of adherence, drug interactions, or drug malabsorption. The most common cause is lack of adequate adherence.

What do you do when the patient has side effects or intolerance to the regimen?

Side effects of antiretroviral agents are common and highly variable in severity and implications. Nausea is particularly common and may become a huge impediment to adherence. Other side effects may be more serious in terms of specific medical consequences, including several that are potentially lethal: pancreatitis due to didanosine (ddI), hypersensitivity due to abacavir (ABC), Stevens-Johnson syndrome due to an NNRTI, nevirapine-associated hepatic necrosis, and lactic acidosis due to nucleosides, especially stavudine (d4T). If the side effect precludes adherence or is regarded as a serious consequence for adherence, the regimen must be changed. It is important to warn patients about common and serious side effects before treatment begins.

Are there other forms of treatment failure?

Immunologic failure, as opposed to virologic failure, is characterized by the failure of the CD4 count to rebound, and clinical failure is characterized by AIDS-defining events (see Table 5-4). Success in treatment is based on viral load response, and this dictates therapy decisions. No one knows what to do with immunologic or clinical failure if there is viral suppression.

Table 5-4. Definitions of Therapeutic Failure

Type	Definition
Virologic failure	Initial therapy: failure to decrease viral load by 1 log ₁₀ c/mL by 1-4 weeks, to <500 c/mL by 8-16 weeks, or to <50 c/mL by 16-24 weeks. Chronic therapy: viral load >400 c/mL with 2 measurements after achieving viral suppression.
Immunologic failure	Failure to increase CD4 to >25-50/mm ³ /year (this is an arbitrary definition; the average increase with viral suppression by the above definition is an increase of 100-150 c/mm ³ /year).
Clinical failure	HIV-related complication, usually an AIDS-defining condition after antiretroviral therapy for ≥3 months.

WHAT TO CHANGE TO

How do you address intolerance or serious side effects?

Assuming virologic control has been achieved, the goal is to find a substitute for the offending agent. In most cases, this is simply a single drug substitution using an agent in the same class with comparable potency. For example, for zidovudine (AZT) intolerance, stavudine (d4T) is commonly substituted. For indinavir-associated nephrolithiasis, the usual tactic is to reduce the dose, increase fluid intake, or substitute another PI for indinavir (IDV).

What is intensification?

Intensification is the addition of a drug, usually a single drug, to enhance antiretroviral activity in a patient who has a good but suboptimal response to therapy. This needs to be done at a time when the viral load has not increased to too high a level; for example, most authorities consider a viral load of > 5,000 c/mL to be an indication for a completely new regimen. Common ploys for intensification are the addition of tenofovir (TDF) or abacavir (ABC), or a boosting of a PI with ritonavir (RTV) if that was not done initially.

How do you deal with virologic failure?

The usual method is to measure HIV resistance. If the strain is sensitive, it is important to closely examine the adherence issue or look for drug interactions or some other reason that the antiretroviral agent does not reach the virus. If the virus is resistant, this information is used to select the next regimen as described below.

RESISTANCE TESTING

What are the tests?

There are 2 types of resistance tests: genotypic and phenotypic. Genotypic resistance measures mutations to the genes that are the target of antiretroviral drugs. These mutational changes predict resistance. Phenotypic resistance measures the activity of various drugs against the patient's virus compared with "wild type" virus (untreated HIV strains). These tests are quite different in method of performance, but there is no consensus regarding their relative merit. Many people use genotypic resistance testing most frequently because it is faster and cheaper. Under any circumstances, interpreting both tests requires substantial expertise. It should be emphasized that the testing is valid only for the drugs that are being given at the time the test is done; drugs discontinued > 2-6 weeks earlier may not be reliably tested because the resistant strains often become "minority species" when drug pressure is removed. Thus, a history of prolonged ART and virologic failure in the past often indicates resistance even if this is not revealed with the current test.

What are the indications and requirements for resistance testing?

The major indication for resistance testing is virologic failure, but testing is also sometimes done prior to initiation of therapy (see Table 5-5). The requirement for testing after virologic failure is an adequate viral load (usually > 1,000 c/mL) to do the test. For patients who have failed therapy it is standard practice to sample while the drugs of interest are being given. Resistance to drugs discontinued > 2-6 weeks before testing may not be expressed in the resistance testing, although this probably differs by individual patient and specific agent and has not been extensively studied.

Table 5-5. Resistance Testing		
Patient status	Recommendation	Comment
Primary HIV infection	Consider testing	There are no studies to show use in this setting alters outcome of therapy, but the viral population is presumed to be relatively homogeneous, giving theoretical reliability to testing.
Chronic infection – treatment-naïve	Consider testing	The concern is that resistant HIV may be archived making the test less reliable. Testing at this stage is best for predicting which agent will not work.
Chronic infection – treatment failure on therapy		
• First failure	Recommended if testing requirements are met	Need viral load of >1000 c/mL to do the test. Patient may need to be receiving the antiretrovirals that failed at the time of the test for resistance to be expressed.
• Multiple failures	Recommended if testing requirements are met	Resistant strains from prior therapy may not be expressed in the majority of strains tested; it is important to select next a regimen based on the current resistance test results, prior resistance tests, and treatment history.

How should you treat someone who has run out of options?

Extensive use of ART over several years combined with virologic failure and resistance leads to limited options for many patients. However, it appears that antiretroviral drugs are still beneficial in these patients because of reduced “fitness” of the virus. The implication is that the antiretroviral drugs force development and persistence of resistant mutations, and these mutated strains have reduced replicative capacity in vitro and presumably in vivo as well. Several studies show that discontinuation of ART is often followed after 4-8 weeks by a significant

increase in viral load and a very rapid decline in the CD4 cell count. Thus, the goal of therapy for heavily treated patients who have few therapeutic options is often to continue these drugs despite virologic failure with the hope of maintaining the CD4 cell count and preventing HIV-related complications. Virologic control would be nice, but may be impossible or unrealistic.

What is therapeutic drug monitoring (TDM)?

TDM is the measurement of serum concentrations of antiretroviral drugs to determine if there are adequate levels to assure antiviral activity or to account for toxicity. Relatively few laboratories offer the test, and interpretation is confounded by limited experience and great variability among laboratories testing the same samples. Nucleosides are not tested because this would require measuring intracellular concentrations. It is usually PIs, which may have marginal levels, and to a lesser extent NNRTIs that are tested. Although TDM is not common in clinical practice at present, many experts feel it may become a standard component of treatment in the future with better standardization and more information about how to use the tests. The anticipated use is in situations in which levels are difficult to predict, as in renal failure, hepatic failure, pregnancy, concurrent use of drugs with possible drug interactions, use of once-a-day PIs with concerns about trough levels, and the monitoring of adherence.

When is structured treatment interruption (STI) indicated?

Although there are 4 reasons to suspend treatment temporarily, pulse therapy appears to be the most promising.

- **Immunization** One rationale for STI, when used with patients who have prolonged virologic control, is to stop therapy to let the virus come back and “immunize” the patient in a fashion analogous to a vaccine. The theory seemed good, but has not proven successful, and most have abandoned this tactic except with the rare patient who was treated very early in the course of the disease.
- **Treatment failure** A rationale for discontinuing treatment when it has failed due to drug resistance is to allow growth of “wild type virus” that is sensitive to antiretroviral agents. The theory, that STI would permit a new round of therapy against sensitive virus, has not proven successful for possibly predictable reasons. In many or most patients, the resistant strains are minority species that quickly become the dominant strains under renewed antiviral pressure.

- **Intermittent therapy** The plan with intermittent therapy is to periodically discontinue treatment on a prearranged schedule, such as 1 week on and 1 week off or 5 days of treatment followed by a weekend off. The theory is that when therapy is discontinued there is usually sustained viral suppression for 10-14 days and treatment is restarted while the virus is still suppressed. This strategy could potentially reduce treatment-associated side effects and cost. Although the initial experience has been limited but promising, the strategy cannot be recommended until more substantial experience is gained.
- **Pulse therapy** With this strategy, therapy is discontinued when the CD4 cell count increases to a level that makes the patient and physician comfortable doing so and is restarted when the CD4 count declines to a worrisome level. Initial experience has generally been that the viral load returns within 2 weeks and the CD4 cell count declines rapidly and then plateaus. Most experts restart therapy when the CD4 cell count reaches $350/\text{mm}^3$, but this strategy has not been systematically studied. Nevertheless, it does appear that there is no penalty in terms of resistance and the period off therapy is often 1-2 years, depending to a large extent on the CD4 cell count at the time treatment is discontinued and on the pre-therapy CD4 nadir. The patient must be warned that viral loads will return to pre-therapy levels, with important implications for risk of HIV transmission to others.

KEY POINTS

The major indicator for the speed of progression in early stage disease is the viral load, which dictates the speed of CD4 cell decline. The major indicator for the risk of HIV-associated complications is the CD4 cell count.

ART is directed toward preventing HIV-associated complications and hospitalizations and improving quality of life and survival.

ART does not cure HIV infection, is expensive, is associated with substantial risks of short-term and long-term toxicity, and requires a level of adherence that is unmatched with any other antimicrobial therapy.

ART is recommended when there are HIV-associated symptoms or when the CD4 count is $< 200\text{-}350/\text{mm}^3$.

The standard of practice for ART is 3 or 4 drugs representing 2 classes.

The major objective of ART is to inhibit HIV as reflected by viral load. Successful antiviral therapy is defined as a viral load of $< 50\text{ c/mL}$ by 16-24 weeks, usually accompanied by an increase in the CD4 cell count of $100\text{-}150/\text{mm}^3/\text{year}$.

Failed therapy is defined as virologic (viral load $> 400\text{ c/mL}$ twice after 24 weeks), immunologic (CD4 count fails to increase by $> 25\text{-}50/\text{mm}^3$ at 6-12 months), or clinical (new AIDS-defining OI after > 3 months of therapy).

Treatment is changed for drug intolerance (substitution) or virologic failure (selection by resistance tests).

The 3 factors that consistently predict outcome are CD4 cell count, patient adherence, and provider experience.



SUGGESTED RESOURCES

Deeks SG, Hirschel B. Supervised interruptions of antiretroviral therapy. *AIDS*. 2002;16:S157-169.

Hirsch MS, Brun-Vezinet F, Clotet B, et al. Antiretroviral drug resistance testing in adults with Human Immunodeficiency Virus type 1: 2003 recommendations of an International AIDS Society – USA panel. *Clin Infect Dis*. 2003;37:113-128.

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Mellors JW, Munoz A, Giorgi JV, et al: Plasma viral load and CD4 + lymphocytes as prognostic markers of HIV-1 infection. *Ann Intern Med*. 1997;126:946-954.

Palella FJ, Delaney KM, Moorman AC, et al: Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. *N Engl J Med*. 1998;338:353-360.

Panel on Clinical Practices for Treatment of HIV Infection. *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*. Washington DC: U.S. Department of Health and Human Services. Nov 10, 2003. Available at <http://www.aidsinfo.nih.gov>.

Yeni PG, Hammer SM, Hirsch MS et al. Treatment for Adult HIV Infection: 2004 recommendations of the International AIDS Society–USA Panel. *JAMA*. 2004; 292:251-265.

Youle M. Strategies of HIV Management – When to start. *AIDS*. 2002;16:S145-149.



WEBSITES

AIDSInfo: <http://www.aidsinfo.nih.gov>
Accessed 11/03 (Several treatment guidelines are continuously updated at this U.S. Department of Health and Human Services website)

**AIDS information –
<http://www.aidsinfo.nih.gov>
for continuously updated
treatment guidelines**

CASES

1.

A 36-year-old woman is asymptomatic and has a CD4 cell count of $210/\text{mm}^3$ and a baseline viral load of $>750,000$ copies/mL. Other laboratory studies are unremarkable. She seeks your advice regarding management.

Question: What can you recommend?

- a. zidovudine (AZT) plus stavudine (d4T) plus efavirenz (EFV)
- b. lamivudine (3TC) plus zidovudine plus nelfinavir (NFV)
- c. Trizivir (AZT + 3TC + ABC) plus lopinavir/ritonavir (LPV/r)
- d. Trizivir
- e. lamivudine plus stavudine plus indinavir (IDV)

Answer:

Virtually all of these are feasible except option a, which combines zidovudine and stavudine, a combination that shows pharmacologic antagonism. The worrisome part of her presentation is that the CD4 cell count is quite low and approaching the threshold of vulnerability to opportunistic infections, and the viral load is very high, which poses substantial challenge to virologic control. The best drugs for baseline high viral load according to currently available data are 2 nucleosides combined with efavirenz or lopinavir/ritonavir. Thus, option c would be the best choice.

2.

A 42-year-old truck driver has HIV infection that was treated in 1999 with efavirenz (EFV), stavudine (d4T), and lamivudine (3TC). He subsequently did well and maintained a viral load of <50 c/mL, and the CD4 cell count increased from 250 to $450/\text{mm}^3$. He feels well, is fully adherent with his regimen by history, and has no complaints except that he is bothered by facial thinning (buccal cheek atrophy).

Question: Which of the following would you recommend?

- a. Discontinue treatment
- b. Change stavudine to abacavir (ABC)
- c. Switch efavirenz to indinavir (IDV) plus ritonavir (RTV)
- d. Switch stavudine to zidovudine
- e. Give zidovudine, lamivudine, and abacavir

Answer:

Discontinuing therapy is an option, although guidelines on when and how to do this are sparse because it has not been extensively studied. Anecdotal information suggests that this patient will have a sustained period with a CD4 cell count above the threshold for initiating treatment by current guidelines of $200\text{--}350/\text{mm}^3$. The best predictor of a prolonged drug-free interval is the baseline CD4 cell count, which in his case is low, but not severely low. The main problem is that the CD4 cell count at $450/\text{mm}^3$ is high, but possibly not high enough. The most likely cause of his change in face appearance is stavudine, but methods to reverse the change are not necessarily clear. If we stop stavudine, face thinning will not progress and some studies suggest there may be reversal after a prolonged period. Since this is important to the patient and this kind of change is relatively easy to make, we should probably do it, so the best answers are to use a potent regimen without stavudine treatment (options a, b, and d).

3.

A 36-year-old woman sees you for evaluation of HIV infection, which she has had since 1985. There have been multiple courses of treatment, including nucleosides in the period 1987 to 1996 and since then nucleosides combined with NNRTIs and PIs. The longest course of treatment was with zidovudine (AZT), lamivudine (3TC), and efavirenz (EFV), which produced a temporary period of virologic control but then failed. Currently she is receiving amprenavir (APV), lopinavir/ritonavir (LPV/r), and tenofovir (TDF). You perform a resistance test, which shows mutations on the reverse transcriptase gene at codons 41, 210, and 215 and mutations on the protease gene at 30 and 82. The conclusion is that HIV is resistant to some NRTIs and PIs. Her current numbers show a CD4 cell count of 87/mm³ and a viral load of 210,000 c/mL.

Question: What would you recommend?

- a. zidovudine plus lamivudine plus tenofovir plus efavirenz
- b. lopinavir/ritonavir plus efavirenz plus tenofovir
- c. AZT/3TC/ABC (Trizivir) plus lopinavir/ritonavir
- d. AZT/3TC/ABC plus tenofovir plus indinavir (IDV) plus ritonavir (RTV)
- e. enfurvirtide (T-20) plus atazanavir plus lamivudine plus tenofovir

Answer:

The tricky part of this question is the need to assume resistance to efavirenz and lamivudine despite the failure to demonstrate the associated mutations: 103 and 184 on the RT gene. This reflects the fact that these drugs were not being given at the time the test was done, but history suggests that resistance to these drugs occurred at the time of failure. The point is that interpretation of resistance tests must take into account both the current pattern and the history of drug exposure in terms of specific agent, duration, and virologic outcome. This patient is running low on options and low on CD4 cells. She does have some PI options, but the most predictable response would probably be a regimen with the fusion inhibitor enfurvirtide (option e).

4.

A 50-year-old secretary has just learned that he has HIV infection with a CD4 cell count of 49/mm³ and viral load of 280,000 c/mm³. He is quite shaken by this information, claims that he has never been able to take pills for anything and wants treatment, but wants it to be as simple as possible.

Question: What would you recommend?

- a. Delay therapy until the patient is ready
- b. AZT/3TC/ABC (Trizivir) plus efavirenz (EFV)
- c. tenofovir (TDF), lamivudine (3TC), plus efavirenz
- d. zidovudine (AZT), lamivudine, amprenavir (APV), and ritonavir (RTV)
- e. AZT/3TC/ABC (Trizivir)
- f. zidovudine plus efavirenz plus indinavir (IDV)

Answer:

This patient needs to be treated rapidly because he is highly vulnerable to major opportunistic infections. We emphasize the need for patient readiness, but this patient does not have much time to get ready. Training will take substantial effort as described in Chapter 7: Adherence to HIV Therapies. We would like potency plus convenience to facilitate adherence. The combination of lamivudine plus tenofovir plus efavirenz (option c) means 4 pills once a day, which could be taken, for example, when he shaves.

5.

A doctor telephones you about a patient who has read about structured treatment interruption for patients who have failed therapy. You are told this patient has extensive experience with antiretroviral treatment for over 10 years, a CD4 cell count of 80-100/mm³, and a viral load that is back to baseline at 420,000 c/mL.

Question: What would you recommend to the physician?

- a. Test resistance while receiving antiretroviral drugs and select the drugs based on the ART history and resistance tests
- b. Discontinue treatment, test the HIV strain at 12 weeks, and treat accordingly
- c. Continue therapy with same drugs
- d. Treat with lopinavir/ritonavir (LPV/r), Trizivir (AZT/3TC/ABC), tenofovir (TDF), and either efavirenz (EFV) or nevirapine (NVP)

Answer:

The experience with STI for virologic failure is that wild-type virus that is less resistant replaces the predominant strain after about 6-11 weeks, but the CD4 cell count drops rapidly during the period off treatment; after new treatment, the more completely resistant pre-STI strain returns. The largest experience indicates only about 10%-15% of these attempts have been judged successful. Therefore, STI for virologic failure has fallen into disfavor. Nevertheless, if you wanted to play long odds, the right time to do the testing is after there has been a sufficient interval for ingrowth of a new, more sensitive strain of HIV making option b the correct option. However, most would prefer option a with expert interpretation of the test results.

6.

Question: Which of the following patients is the best candidate for genotype resistance testing?

- a. A previously untreated pregnant woman with HIV
- b. A chronically infected, previously untreated man with a partner who is currently taking triple therapy with poor control
- c. A woman who has failed her initial treatment with a viral load of 7,000 c/mL after 1 year on indinavir (IDV), ritonavir (RTV), lamivudine (3TC), and stavudine (d4T)
- d. A 40-year-old man with good virologic control, but a need to change therapy because of AZT-induced anemia

Answer:

Recommendations for the use of resistance testing are somewhat arbitrary, but the highest priority according to virtually all guidelines is for patients who have failed treatment for the purpose of identifying the next regimen; therefore, option c is the best answer.

Chapter 6:

Metabolic Complications of Antiretroviral Therapy

*David H. Spach, MD**OVERVIEW**LIPID ABNORMALITIES**LIPODYSTROPHY**LACTIC ACIDOSIS**OTHER METABOLIC COMPLICATIONS**KEY POINTS**SUGGESTED RESOURCES**REFERENCES**CASES*

OVERVIEW

What is meant by metabolic complications of antiretroviral therapy (ART)?

Metabolic complications refers to a group of adverse drug reactions that have been associated with long-term use of antiretroviral drugs, which include:

- Lipid abnormalities
- Lipodystrophy
- Lactic acidosis
- Hyperglycemia
- Decreased bone mineral density

See Glossary of Antiretroviral Drugs on page viii and the Pocket Guide

Each adverse reaction is more commonly associated with a specific class of antiretroviral drugs, and the agents within the class that cause the reactions do so with variable frequencies. In most cases, the pathophysiologic mechanism of the changes is unknown. The classes of drugs associated with each major adverse reaction are listed in Table 6-1.

What metabolic toxicities should you monitor for in patients taking ART?

Recommendations for monitoring patients for ART-related metabolic complications, listed in Table 6-2, are discussed in detail in the sections below.

Table 6-1. Adverse Reactions of Classes of Antiretroviral Drugs

Adverse Reaction	Cause		
	NRTIs*	NNRTIs**	PI***
Lactic acidosis	++	-	-
Lipid changes			
Elevated triglycerides	-	(+)	++
Elevated LDL cholesterol	-	+	++
Insulin resistance	-	-	++
Fat redistribution			
Fat atrophy	+	-	-
Fat accumulation	-	-	++
* NRTIs = Nucleoside and nucleotide reverse transcriptase inhibitors ** NNRTIs = Non-nucleoside reverse transcriptase inhibitors *** PIs = Protease inhibitors (+) = possibly causes adverse reaction + = sometimes causes adverse reaction ++ = frequently causes adverse reaction			

LIPID ABNORMALITIES

What antiretroviral medications adversely affect lipid levels?

Available data suggest that drugs in the protease inhibitor (PI) class have the greatest adverse effect on triglycerides, total cholesterol, and low-density lipoprotein (LDL) cholesterol levels. The mechanism remains unclear. Among the PIs, ritonavir (RTV) and ritonavir-boosted regimens appear to have the greatest impact on triglycerides and total cholesterol levels. Because some patients who receive ritonavir had no significant changes whereas others have dramatic increases, genetic predisposition may play a major role. The PI atazanavir (ATV) does not significantly affect lipid levels. The impact of nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) on lipid levels has not been well defined, but the impact appears much less than changes associated with PIs. In 96-week data from a trial that compared stavudine (d4T) plus lamivudine (3TC) plus efavirenz (EFV) with tenofovir (TDF) plus

lamivudine plus efavirenz, those patients in the stavudine arm had significantly higher cholesterol and triglyceride levels. The NNRTI nevirapine (NVP) has no adverse affect on lipids, and the changes with efavirenz are variable. Patients receiving PIs should undergo regular monitoring of lipid levels (see Table 6-2).

Do antiretroviral drugs cause an increase in cardiovascular disease?

Several isolated case reports initially suggested ART could lead to cardiovascular disease, including death from myocardial infarction, in HIV-infected patients. More recent aggregate data from over 20,000 patients in cohort studies indicate the risk related to ART is low and substantially lower than the risk of smoking (Friss-Moller, et al, 2003). In addition, in a large study that involved more than 36,000 veterans, investigators found the benefit of these drugs far outweighed the risks. Because cardiovascular disease may take 10-15 years to manifest, investigators will need long-term followup of individuals who have received ART to determine the long-term impact.

Table 6-2. Recommendations for Assessment and Monitoring of Metabolic Complications of Antiretroviral Therapy for HIV Infection

Glucose and lipid abnormalities	- The following assessments are recommended before initiation of potent ART, at the time of a switch of therapy, 3 to 6 months after starting or switching therapy, and at least annually during stable therapy: - Fasting glucose (if therapy includes a PI) - Fasting lipid panel (total cholesterol, HDL, and LDL cholesterol [calculated or direct], and triglyceride levels) - A blood glucose level after oral administration of 75 g of glucose may be used to identify impaired glucose tolerance in patients with risk factors for type 2 diabetes mellitus or those with severe body fat changes.
Body fat distribution abnormalities	No specific technique can be recommended at the present time for routine assessment and monitoring of body fat distribution changes.
Lactic acidemia	- Routine measurement of lactic acid levels is not recommended. - Lactic acid levels should be monitored in those receiving NRTIs who have clinical signs or symptoms of lactic acidemia, and in pregnant women receiving NRTIs. - If alternative NRTIs are resumed in those who have interrupted antiretroviral therapy for lactic acidemia, lactate levels should be monitored every 4 weeks for at least 3 months.
Osteopenia, osteoporosis, and osteonecrosis	- Routine screening for osteoporosis or osteonecrosis is not recommended. - Radiographic examination of involved bone is recommended for those with symptoms of bone or joint pain; the contralateral joint should also be assessed.
DEXA = dual-energy x-ray absorptiometry HDL = high-density lipoprotein LDL = low-density lipoprotein NCEP = National Cholesterol Education Program NNRTI = non-nucleoside reverse transcriptase inhibitor NRTI = nucleoside reverse transcriptase inhibitor Source: Schambelan M, Benson CA, Andrew Carr A, et al. Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: Recommendations of an International AIDS Society-USA Panel. <i>J Acquir Immune defec Syndr</i>. 2002;31:269. Reprinted with permission of Lippincott Williams and Wilkins. http://www.com.	

Should you treat abnormal lipid levels in HIV-infected persons?

Although prospective studies have not clearly defined the long-term adverse cardiovascular effects associated with hyperlipidemia in HIV-infected persons, abnormal lipid levels appear to pose the same long-term risks as have been well established in persons who do not have HIV infection and thus need to be managed appropriately (see Table 6-3). Accordingly, clinicians should address abnormal lipid levels and the individual patient risks, including prior cardiovascular events, smoking, hypertension, diabetes, family history, obesity, and baseline lipid levels. The potential interventions include 1) switching to a regimen less likely to cause abnormal lipids (if possible without sacrificing antiviral effectiveness), 2) implementing dietary changes, 3) using a lipid-lowering agent according to

recommendations in Table 6-4, and 4) addressing other lifestyle habits that affect cardiovascular risk, such as smoking and exercise.

What statins are recommended for treating patients on PIs?

Significant drug interactions may occur with PIs and lipid-lowering statins; for patients on PI-based ART, most experts consider pravastatin and atorvastatin as preferred statins and avoid using lovastatin or simvastatin. Initial therapy should consist of a low dose of either pravastatin (20 mg po qd) or atorvastatin (10 mg po qd), with monitoring of response to therapy and, if required, gradual and cautious increases in doses of the statin. Triglyceride levels in excess of 1000 mg/dL place the patient at risk for developing pancreatitis. Most experts recommend intervening

Table 6-3. Recommendations for Treatment of Metabolic Complications of Antiretroviral Therapy for HIV Infection

Glucose intolerance and diabetes mellitus	• Weight loss for overweight subjects is recommended. • Follow established guidelines for treating diabetes in the general population, with preference given to insulin sensitizing agents such as metformin (except for those with renal disease or history of lactic acidemia) or thiazolidinediones (except for those with preexisting liver disease). • Avoid use of a PI as initial therapy in patients with preexisting glucose intolerance or diabetes mellitus.
Lipid and lipoprotein abnormalities	• Follow NCEP III guidelines for assessment of risk factors for cardiovascular disease, and dietary and lifestyle alterations for lowering cholesterol and triglyceride levels. • Avoid use of PIs, if possible, in those with preexisting cardiovascular risk factors, family history of hyperlipidemia, or elevated lipid levels. • Follow NCEP guideline thresholds for lipid-lowering therapy. • Fibrates are recommended as initial therapy for those with isolated fasting hypertriglyceridemia. • Pravastatin or atorvastatin are preferred statin agents for those with isolated fasting hypercholesterolemia requiring treatment in the setting of PI or other CYP 3A4 inhibitor therapy. • If combination therapy for hypercholesterolemia and hypertriglyceridemia is indicated, therapy should begin with a statin, followed by the addition of a fibrate if there is insufficient response after 3 to 4 months of treatment.
Body fat distribution abnormalities	• No therapies for fat distribution abnormalities in the absence of other metabolic complications can be routinely recommended.
Lactic acidemia	• ART should be withheld for all patients with confirmed lactate levels >10 mmol/L (90 mg/dL) or those with confirmed lactate levels >5 mmol/L (45 mg/dL) who are symptomatic. • No intervention apart from NRTI cessation is recommended. • Restart combination NNRTI and PI therapy after lactate levels return to normal and symptoms resolve.
Osteopenia, osteoporosis, and osteonecrosis	• Surgical resection of involved bone is the only effective therapy for symptomatic osteonecrosis. • If osteoporosis is demonstrated by radiography or regional DEXA scanning, or if a pathological fracture occurs in the setting of osteoporosis, therapy with a bisphosphonate should be considered.

DEXA = dual-energy x-ray absorptiometry
HDL = high-density lipoprotein
LDL = low-density lipoprotein
NCEP = National Cholesterol Education Program
NNRTI = non-nucleoside reverse transcriptase inhibitor
NRTI = nucleoside reverse transcriptase inhibitor

Source: Schambelan M, Benson CA, Andrew Carr A, et al. Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: Recommendations of an International AIDS Society-USA Panel. *J Acquir Immune Defic Syndr*. 2002;31:269. Reprinted with permission of Lippincott Williams and Wilkins, <http://www.com>.

Table 6-4. Summary of National Cholesterol Education Program Treatment Recommendations Based on LDL Cholesterol*

Risk Category	Initiate therapeutic lifestyle changes†	Consider drug therapy	LDL** cholesterol goal	Non-HDL** cholesterol goal
With CHD or CHD** risk equivalent (10-year risk >20%, noncoronary atherosclerotic vascular disease, or type 2 diabetes mellitus)	≥100 mg/dL (≥2.6 mmol/L)	≥130 mg/dL (≥3.4 mmol/L) 100–129 mg/dL (2.6–3.3 mmol/L): therapy optional	<100 mg/dL (<2.6 mmol/L)	<130 mg/dL (<3.4 mmol/L)
2 or more risk factors (10-year risk <20%)‡	≥130 mg/dL (≥3.4 mmol/L)	10-year risk of 10%–20%: ≥130 mg/dL (≥3.4 mmol/L) 10-year risk of <10%: ≥160 mg/dL (≥4.1 mmol/L)	<130 mg/dL (<3.4 mmol/L)	<160 mg/dL (<4.1 mmol/L)
0 or 1 risk factor‡	≥160 mg/dL (≥4.1 mmol/L)	≥190 mg/dL (≥4.9 mmol/L) 160–189 mg/dL (4.1–4.9 mmol/L): therapy optional	<160 mg/dL (<4.1 mmol/L)	<190 mg/dL (<4.9 mmol/L)

* For patients with high triglyceride levels in whom LDL cholesterol cannot be measured, non-HDL cholesterol level (total cholesterol – HDL cholesterol) may be used as an approximation if 30 mg/dL (0.8 mmol/L) is added to the LDL cholesterol threshold. For those with triglyceride levels >200 mg/dL (2.3 mmol/L), the non-HDL cholesterol level is considered a secondary target of therapy and the goals of therapy are as indicated under the heading of non-HDL cholesterol goal.

‡ Risk factors include cigarette smoking; hypertension (blood pressure ≥140/90 mm Hg or taking antihypertension drugs); HDL cholesterol level below 40 mg/dL (1.0 mmol/L); family history of premature CHD (in first-degree male relatives <55 years and first-degree female relatives <65 years); age (>45 years for men and >55 years for women). Risk factor equivalent: diabetes. If HDL cholesterol is over 60 mg/dL (1.6 mmol/L), subtract 1 risk factor from the total.

† Therapeutic lifestyle changes refer to reducing saturated fat and cholesterol intake; enhancing the reduction in LDL cholesterol level by the use of plant stanols/sterols and increased soluble fiber; weight reduction; and increased physical activity.

** CHD, coronary heart disease; HDL, high-density lipoprotein; LDL, low-density lipoprotein; VLDL, very low-density lipoprotein.

Source: Schambelan M, Benson CA, Carr A, et al. Management of Metabolic Complications Associated with Antiretroviral Therapy for HIV-1 Infection: Recommendations of an International AIDS Society–USA Panel. *J Acquir Immune Defic Syndr*. 31:262. Nov 1, 2002. Adapted from Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 2001;285:2486–2497. Reprinted with permission of Lippincott Williams and Wilkins, <http://www.com>.

when triglyceride levels exceed 500 mg/dL. Although dietary changes can improve triglyceride levels, most patients with PI-associated hypertriglyceridemia will require pharmacologic intervention. Patients with isolated hypertriglyceridemia should receive a fibric acid derivative, either gemfibrozil (600 mg po bid) or fenofibrate (200 mg po qd). For those who have high triglyceride and LDL cholesterol levels, a statin drug should be used first with the plan of adding a fibric acid derivative after 4 months if the response to the statin is suboptimal. Because both the statin drugs and the fibric acid derivatives can cause rhabdomyolysis, caution should be used if these medications are given concurrently. In patients with severe hypertriglyceridemia refractory to a fibric acid derivative, some experts would recommend a trial of adding fish oil supplements to the lipid-lowering regimen.

Does switching ART improve lipid abnormalities?

Although some antiretroviral medications clearly have a greater adverse impact than others on lipids, modifying the regimen in an attempt to improve the lipid profile is sometimes difficult, mainly because of the need to maintain antiretroviral efficacy. Examples of possible changes likely to improve lipid abnormalities include switching a PI to either nevirapine (NVP) or using the alternative PI atazanavir (ATV). Changing from a PI to efavirenz (EFV) has not produced consistent results. Preliminary data from one study has shown that patients who switched from stavudine (d4T) to tenofovir (TDF) had a significant improvement in cholesterol and triglyceride levels. Future work will better determine whether changes from one nucleoside to another will affect lipid levels.

LIPODYSTROPHY

What is lipodystrophy?

Although lipodystrophy was first reported in the mid-1990's, investigators have not agreed on a standardized, objective definition for this disorder. Most researchers and clinicians loosely define lipodystrophy as any significant change in body morphology that does not result from either weight gain or weight loss. The general term lipodystrophy now typically includes 3 subsets of morphologic changes: generalized fat accumulation, focal fat accumulation, and fat atrophy. Fat accumulation most often occurs in the abdominal, breast, or dorsocervical region. Fat atrophy most often occurs as buccal fat pad atrophy (facial wasting) or subcutaneous fat wasting in the buttocks or extremities. Because a standardized definition for lipodystrophy is lacking, the incidence varies depending on the exact criteria investigators use to define lipodystrophy in their specific study. Tests for abnormalities in body fat distribution have included computed tomography (CT) scanning, magnetic resonance imaging (MRI), bioelectrical impedance analysis (BIA), DEXA (dual energy x-ray absorptiometry) scans, and anthropometric measurements. The CT and MRI tests are generally considered the most accurate, but not practical for routine screening purposes, primarily because of their high cost. Anthropometric measurements can estimate visceral adipose tissue and subcutaneous adipose tissue and can easily be performed in the clinic without major costs. Despite the many options available for measuring abnormalities in fat distribution, no technique has shown adequate sensitivity and specificity to recommend performing routinely.

What causes lipodystrophy in HIV-infected persons?

Despite intense investigation, the exact pathogenesis of lipodystrophy remains unclear. Initial reports linked PI use with lipodystrophy, but subsequent reports have identified lipodystrophy in patients who had never received a PI. Several studies have shown that the most important risk factors for development of lipodystrophy are a history of severe immune suppression (nadir CD4 count < 100 cells/mm³), older age, prolonged use of antiretroviral drugs, and highly active antiretroviral therapy. Investigators have found that patients with lipodystrophy often have high insulin levels and evidence of insulin resistance, a finding that suggests insulin resistance is associated with lipodystrophy, but does not prove that insulin resistance causes lipodystrophy. Many clinicians have observed that fat accumulation is more often associated with PI-based therapy, whereas fat wasting has been most closely linked to NRTIs, particularly stavudine (d4T). In 96-week data

from a trial that compared stavudine plus lamivudine (3TC) plus efavirenz (EFV) with tenofovir (TDF) plus lamivudine plus efavirenz, those patients in the stavudine arm had substantially higher rates of lipodystrophy.

Can fat redistribution be reversed?

First, it is important to evaluate the severity of the lipodystrophy, the degree to which the patient is bothered by the body changes, and how strongly the patient wants to try to reverse the lipodystrophy. Although fat redistribution does not appear to directly alter health outcome, many patients experience notable unfavorable changes in their physical appearance that may affect their quality of life. Moreover, these changes in body appearance may broadcast their HIV diagnosis. That lipodystrophy changes thus may even lead some to stop their antiretroviral medications. If lipodystrophy develops, there are 3 treatment options: 1) Switch therapy, meaning a substitution for the implicated drug. This usually involves a substitute for stavudine (d4T) if lipoatrophy has developed or a change to a non-PI-based regimen if fat accumulation has occurred. Initial results with switches showed limited success, and when there was a response it took a long time. More promising results were seen in a recent study in which replacing stavudine (d4T) with abacavir (ABC) or zidovudine (AZT) resulted in significant improvement after 48 weeks in patients with stavudine-induced lipoatrophy (McComsey, et al, 2004). 2) Drug therapy is another option. Metformin, thiazolidinediones, testosterone, other anabolic steroids, and growth hormone have been used with partial success with fat accumulation, but all have drawbacks and do not address the underlying lipoatrophy. 3) The third option is plastic surgery, which may be particularly useful for buccal fat atrophy or dorsothoracic fat accumulations; however, results have been highly variable, and these procedures are usually regarded as cosmetic surgery and not covered by insurance companies.

LACTIC ACIDOSIS

What are ART-related hyperlactatemia and lactic acidosis?

ART-related abnormalities of serum lactate levels (hyperlactatemia) range from asymptomatic hyperlactatemia to symptomatic hyperlactatemia with mild acidosis, to fulminant lactic acidosis, liver failure, and death. In addition, some patients develop hepatic steatosis. The development of fulminant lactic acidosis, although very rare, has clearly emerged as one of the most dreaded adverse effects associated with ART.

What antiretroviral drugs cause hyperlactatemia?

Hyperlactatemia and lactic acidosis result from abnormal mitochondrial toxicity caused by NRTIs that inhibit the critical enzyme mitochondrial DNA polymerase gamma. There is no evidence that NNRTIs or PIs cause mitochondrial toxicity or abnormalities in serum lactate levels. In vitro data and retrospective clinical data show that stavudine (d4T) and didanosine (ddI) are the most likely medications in the NRTI class to cause this complication, especially if used together. Zidovudine poses some risk but significantly less than either stavudine or didanosine. Tenofovir (TDF), abacavir (ABC), emtricitabine (FTC), and lamivudine (3TC) appear to pose the least risk of causing lactic acidosis. Identified risk factors, in addition to the use of NRTIs, include pregnancy, female gender, obesity, or concurrent treatment with ribavirin, hydroxyurea, or metformin.

How do you collect and interpret a serum lactate test?

The normal serum lactate level is < 2 mmol/dL. Proper blood collection and appropriate transport are essential for obtaining an accurate result. The patient should not exercise for 24 hours prior to the test and should be well hydrated, and should rest for at least 5 minutes prior to the blood draw. The blood should be drawn without tourniquet and the patient should be instructed not to clench his or her fist. The sample should be submitted promptly for processing using a pre-chilled fluoride-oxalate tube transported on ice. The specimen should be processed within 4 hours after being drawn.

For interpretation, levels of 2-5 mmol/dL are often associated with no symptoms, levels of 5-10 mmol/dL are usually associated with symptoms that require discontinuation of NRTIs, and levels of > 10 mmol/dL are associated with a fatality of $> 30\%$ and require immediate intervention. Abnormal levels should usually be confirmed.

How do you diagnose lactic acidosis?

Routine monitoring of serum lactate levels in asymptomatic patients is not recommended (see Table 6-2), but obtaining a serum lactate level is critical if hyperlactatemia is suspected (see previous question for correct technique). Patients with mild increases in serum lactate levels generally do not have significant symptoms, and if symptoms are present, they are most likely nonspecific. With more severe increases in serum lactate levels, patients may have marked fatigue,

nausea, anorexia, vomiting, abdominal pain, dyspnea, and hyperventilation. Although a chemistry panel may show a decreased serum bicarbonate level or increased anion gap level, some reports have documented patients with severe lactic acidosis who do not have abnormal serum bicarbonate or increased anion gap measurements. CT scan of the liver may show enlargement and fatty infiltration.

How do you manage severe hyperlactatemia or lactic acidosis?

Patients with severe hyperlactatemia or lactic acidosis should immediately discontinue ART (see Table 6-3). Seriously ill patients may require IV bicarbonate, mechanical ventilation, or dialysis. Most respond to drug withdrawal. Case reports have suggested improvement in lactic acidosis with use of compounds such as riboflavin, thiamine, L-carnitine, or co-enzyme Q, with the benefit hypothetically resulting from improvement in mitochondrial function; however, the use of these agents to prevent hyperlactatemia and lactic acidosis has not been studied. Unfortunately, even after discontinuing ART, recovery from lactic acidosis typically takes about 8 weeks, since regeneration of severely damaged mitochondria is a prolonged process.

Once a lactic acidosis episode is resolved, can a patient resume ART?

For those patients who recover from an episode of lactic acidosis, the optimal management of their subsequent ART remains unclear. For those patients who clearly need ART, the safest option would be to use a regimen that does not contain an NRTI, such as lopinavir plus ritonavir plus efavirenz (LPV/r + EFV), saquinavir plus ritonavir (SQV + RTV), or indinavir plus ritonavir plus efavirenz (IDV + RTV + EFV). Available data suggest tenofovir (TDF), lamivudine (3TC), emtricitabine (FTC), and abacavir (ABC) are the NRTIs least likely to cause severe hyperlactatemia or lactic acidosis. In a report of 17 patients who developed symptomatic hyperlactatemia while receiving stavudine (d4T), the patients were rechallenged with abacavir or zidovudine; none of the 17 had a recurrence of symptomatic hyperlactatemia. Nevertheless, providers should obtain expert consultation and also observe the patient closely when restarting a new regimen that includes one or more NRTIs in any patient with a history of lactic acidosis.

OTHER METABOLIC COMPLICATIONS

Does ART cause hyperglycemia and diabetes?

Although several studies have shown that PIs can have a direct effect on glucose metabolism, predominantly by increasing insulin resistance, it remains unclear whether ART significantly increases the risk for developing diabetes mellitus. Available data would suggest that ART, particularly with PIs, likely causes a slightly increased risk of developing overt diabetes mellitus. Routine monitoring for hyperglycemia is recommended for any patient on a PI-based regimen (see Table 6-3). Studies of patients with hyperglycemia and insulin resistance have consistently shown that switching from a PI to either nevirapine (NVP), efavirenz (EFV), or abacavir (ABC) will significantly improve the hyperglycemia and insulin resistance. Nevertheless, further study is needed to better clarify the risk of a patient's developing diabetes mellitus while taking a PI and the long-term clinical benefit of switching from a PI to a regimen that causes less insulin resistance.

Does ART cause abnormalities in bone density?

Several retrospective reports have suggested that ART may cause decreases in bone mineral density and, rarely, avascular necrosis. Recently, the relationship between ART and decreases in bone mineral density has become very controversial and prospective studies are needed to resolve the issue. From a clinical perspective, avascular necrosis should be suspected when a patient complains of focal bone pain; either CT or MRI can confirm the diagnosis. Avascular necrosis most often involves the femoral or humeral head, can consist of necrosis at a single or multiple sites, does not respond to medical therapy, and typically requires surgical intervention (see Table 6-3). There are no data regarding modifying an ART regimen either to prevent avascular necrosis or to improve the condition once it has already developed.

KEY POINTS

Metabolic complications include the long-term consequences of antiretroviral agents: lactic acidosis (due to NRTIs [nucleosides]), dyslipidemia (usually due to PIs), insulin resistance (usually due to PIs), fat redistribution (usually due to NRTIs and PIs).

All PIs except atazanavir (ATV) are associated with variable increases in the LDL cholesterol and/or triglycerides.

Cardiovascular risks of dyslipidemia associated with PI therapy are assumed to be the same as for persons without HIV infection; they are usually managed with lifestyle changes (smoking cessation, diet modifications, and exercise) and, if necessary, lipid-lowering drugs; if statins are used, pravastatin or atorvastatin are preferred to avoid drug interactions with the PIs.

Patients receiving PIs should have blood lipids and glucose monitored at baseline, at 3-6 months and then at least annually, and more frequently depending on other risks and severity of abnormalities.

ART is associated with fat redistribution, both fat accumulation (abdomen, breasts, dorsocervical) and fat wasting (buccal fat with face thinning, buttocks, and extremities). These changes can result in major unfavorable changes in physical appearance and can have a significant impact on quality of life.

There are no effective treatments for reversing fat redistribution. Discontinuing or switching therapy has moderate effect at best and improvement requires a very long time; with face thinning the best results are with discontinuing stavudine (d4T) early.

Lactic acidosis is a result of mitochondrial toxicity caused by prolonged use of NRTIs, primarily stavudine (d4T), didanosine (ddI) and to a lesser degree zidovudine (AZT).

The usual symptoms of lactic acidosis are fatigue, abdominal pain, nausea, and weight loss; the usual laboratory finding is a serum lactate exceeding 5 mmol/dL. The main treatment is to discontinue the implicated drugs or switch to NRTIs that are less likely to cause this.

Type 2 diabetes is an occasional complication of PI therapy due to insulin resistance. Monitoring should include fasting blood glucose at baseline and at 5-8 months with subsequent measurements depending on risk and prior results.



SUGGESTED RESOURCES

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CASES**1.**

A 36-year-old HIV-infected man has received stavudine (d4T) plus lamivudine (3TC) plus indinavir (IDV) for approximately 4 years. This regimen was his first regimen and before starting therapy his HIV RNA was 59,000 copies/mL and his CD4 count was 34 cells/mm³. His antiviral and immunologic response has been excellent, with HIV RNA levels persistently less than 50 copies/mL and a CD4 count that has increased to 526 cells/mm³. In the past 9 months, however, he has developed hyperlipidemia, hyperglycemia, and body fat changes, most notably enlargement of his abdominal region and facial thinning. He has been very hesitant to change his regimen but now comes into the clinic to discuss this matter again.

Question: If he changes his antiretroviral regimen, will he likely continue to have excellent control of HIV?

Answer:

Since this patient has experienced excellent long-term viral suppression and this was his first regimen, it is highly likely that a switch from a PI to a NNRTI (efavirenz [EFV] or nevirapine [NVP]) would maintain continued viral suppression. Similarly, a change from one NRTI to another would likely have no adverse effect on HIV suppression. In patients who have previously developed resistance and are currently on a salvage regimen, changing a medication because of side effects can pose a much greater risk of not maintaining excellent virologic control.

Question: What improvements would he likely expect if he makes a change?

Answer:

Among the problems this patient has developed as a complication of ART, insulin resistance and hyperlipidemia are the most likely to improve with a regimen change. In particular, several studies have shown switching from a PI to either nevirapine, efavirenz, or abacavir (ABC) typically leads to significant improvement in hyperglycemia and insulin resistance. Improvements in lipids are most likely to occur if the PI is switched to either nevirapine or abacavir. Switching from one PI to the new PI atazanavir (ATV) may provide significant improvement in lipid abnormalities. Unfortunately, changing from a PI to an NNRTI has not produced reliable improvements in lipodystrophy. Changing from stavudine to either abacavir or tenofovir (TDF) may provide some improvement in lipodystrophy for some patients. Although tenofovir causes less lipodystrophy than stavudine, studies that examine the effect of changing stavudine to tenofovir have not been performed.

2.

A 33-year-old woman on stavudine (d4T) plus didanosine (ddI) plus efavirenz (EFV) presents with severe fatigue. No obvious cause for the fatigue is discovered and 1 week later she returns with even worse fatigue. Serum chemistries now are notable for a bicarbonate of 17 mmol/L. A serum lactate level is drawn and a lactate level of 6.3 mmol/L is reported from the laboratory. The patient is not taking any other medications and is not taking any herbal preparations.

Question: Is the serum lactate level of 6.3 mmol/L concerning in this patient?

Answer:

Experts have stratified serum lactate levels based on the risk of developing complications from hyperlactatemia. Those with a serum lactate level of 2.1-5.0 mmol/L are considered to have mild hyperlactatemia, those with a serum lactate level of at least 5 mmol/L have serious hyperlactatemia, and those with a lactate level at least 5 mmol/L plus a bicarbonate level less than 20 mmol/L have lactic acidosis. Accordingly, the patient's serum lactate of 6.3 mmol/L (along with the serum bicarbonate of 17 mmol/L) is extremely concerning and suggests lactic acidosis, a potentially life-threatening problem.

Question: If lactic acidosis is suspected, how should the patient be managed?

Answer:

Because hyperlactatemia and lactic acidosis result from NRTI-induced mitochondrial toxicity, the first step in managing this problem is to immediately discontinue ART. Although several case reports have suggested improvement in lactic acidosis by using compounds such as riboflavin, thiamine, L-carnitine, or co-enzyme Q, supportive care remains the mainstay of therapy. After discontinuing ART, regeneration of severely damaged mitochondrial typically requires prolonged periods, and recovery from lactic acidosis can take several months. Following recovery, the optimal management of subsequent antiretroviral therapy remains unclear. Preliminary reports suggest changing the NRTIs (typically replacing stavudine) can safely be performed, but should be done with expert consultation.

Chapter 7:

Adherence to HIV Therapies

*Laura W. Cheever, MD, ScM**OVERVIEW**ASSESSMENT**INTERVENTIONS**KEY POINTS**SUGGESTED RESOURCES**REFERENCES**CASES*

OVERVIEW

What is meant by medication adherence?

Medication adherence means a patient takes the prescribed dose of prescribed medications on the prescribed schedule, following prescribed dietary instructions. Patient adherence to medical appointments and to behaviors that minimize the risk of transmission of HIV to others correlates strongly with adherence to medications and is an important part of primary care of HIV-infected patients but will not be addressed in this chapter.

Why is medication adherence so important in HIV therapy?

Nonadherence to prescribed therapy is a ubiquitous problem in medicine. In chronic diseases, including asthma, diabetes, and hypertension, only 50 % of patients take their medication as prescribed more than 80 % of the time. The same is true of patients with HIV infection. However, because of the rapid multiplication and mutation rate of HIV and the relatively low potency and short half-life of most antiretrovirals, very high levels of adherence to antiretroviral schedules are necessary to avoid viral resistance. In comparison with patients who are adherent to antiretroviral therapy (ART), nonadherent patients have: 1) Higher mortality (2.5 adjusted relative hazard) (Wood, et al, 2003), 2) Lower increase in CD4 cell count (6 cells/mm³ increase for nonadherent patients versus 83 cells/mm³ increase for adherent patients) (Paterson 2000), and 3) Increased hospital days (12.9 days/1000 days of followup for nonadherent patients versus 2.5 hospital days/1000 days for adherent patients) (Paterson, et al, 2000).

How adherent do patients need to be to avoid viral resistance?

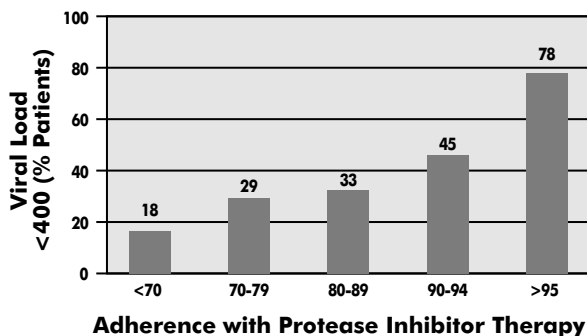
Results of a study of adherence and response to therapy among primarily antiretroviral-experienced patients taking protease inhibitors (PIs) showed that a > 95 % adherence rate was necessary for 78 % of patients to achieve an undetectable viral load (Paterson, 2000); however, some patients with significantly less adherence also had success (see Figure 7-1). Exactly how adherent individual patients need to be is not known and probably depends on several factors, including preexisting antiretroviral resistance, viral load, viral genetic barriers to the development of drug resistance, and drug half-life. Patients should be counseled that the risk of viral resistance increases with nonadherence and that nearly perfect adherence is the goal. Of note, patients with very low levels of adherence may be at decreased risk of developing viral resistance because there is not enough selective pressure (Bangsberg, et al, 2003).

ASSESSMENT

What factors impact adherence?

Many factors contribute to a patient's ability to adhere to medication schedules (Table 7-1). Note that race, education level, and income are generally not predictive of adherence. Providers must remember that factors predicting adherence or nonadherence are only associations and are not absolutely predictive. For example, although patients who use addictive substances are more likely to be nonadherent, some patients with heavy alcohol or drug use are adherent to ART.

Figure 7-1: Adherence Rates Predict Viral Load Response



Source: Adapted from Paterson DL, Swindells S, Mohr J, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Ann Intern Med.* 2000;133:21-30. Copyright American College of Physicians. modified with permission.

7

One of the primary predictors of adherence is “self-efficacy” or patient readiness. Patients who have confidence in their ability to take their medications as instructed (ie, they have good self-efficacy) are much more likely to be compliant than patients who lack this confidence. Among HIV-infected patients, the common comorbidities of substance abuse and untreated mental illness contribute significantly to nonadherence. Because side effects of the medications also are a significant barrier to patient adherence, providers need to vigorously address complaints of side effects.

What is the best way to assess a patient’s adherence?

There is no gold standard for measuring adherence. A provider’s “impression” of a patients’ adherence, without specific assessments, is very unreliable. Mechanisms to measure adherence include assessment of serum drug levels, electronic monitoring of pill bottle openings, pill counts made at clinic visits or at surprise home visits, pharmacy record reviews, and patient responses to questioning. In general these different measures have good correlations to adherence levels, although asking the patient will be more likely to overestimate adherence than objective measures. Computer-assisted questioning of patients will improve self-reporting reliability. Serum drug level assessment provides only information about the most recent dose and is quite costly and not practical in clinical practice..

Table 7-1: Factors that Promote Patients’ Adherence to Medication Regimens

Patient-related factors
Absence of mental illness/depression Absence of substance abuse (alcohol and other drugs of abuse) Perceived ability to take medication as instructed (self-efficacy) Older age Higher literacy Strong social support network Adherence with medical appointments Stable housing Adherence with previous therapies Positive attitude toward efficacy of medication
Medication-related factors
Fewer medications Fewer doses Fewer pills Fewer side effects Lack of dietary restrictions Shorter time on therapy Good “fit” of regimen into patient’s daily routine
Health system-related factors
Trusting relationship with health care provider Patient education: • Patients understand their regimen, including food restrictions • Patients understand the association of adherence and resistance Convenient access to medications and refills

How should providers ask patients about adherence to get the most reliable information?

With appropriate education at the start of ART, a patient should know the importance of adherence. It is important to approach the discussion of adherence at follow-up visits in a nonjudgmental way and “give permission” for missing doses. Also, asking specific questions will yield specific information. An example of an inquiry might be: “Everyone misses doses of their medication some of the time. How many times in the last 3 days/week/month have you missed taking doses of your medicine?” From there, a discussion of the specific events that led to missing doses can lead to problem-solving with the patient to overcome these barriers.

The provider should ask patients to recount exactly when and how they are taking their medications in order to identify any lack of understanding of the regimen itself or of special dietary instructions.

INTERVENTIONS

What can be done to improve adherence?

The most important intervention is making sure patients start medication only when they are “ready.” Providers need to discuss with patients the risks associated with nonadherence that can result from starting medications before they are ready versus waiting while they “prepare.” Preparing can mean entering into substance abuse treatment, finding stable housing, or attending a support group to overcome fears of medication side effects and concerns about confidentiality. Pregnant women and patients with serious complications of HIV infection and very low CD4 counts may not have the luxury of postponing therapy, but for others, being ready to adhere may be critical to the outcome of ART.

Interventions to improve adherence in chronic diseases tend to have, at best, modest effects on adherence. They are most effective if they are multifaceted, ie, they target several aspects of the adherence behavior and are repeated over time. Barriers to adherence differ among patients. Thus, interventions should be tailored to the patient’s specific needs. In addition, barriers to adherence vary over time, so interventions need to vary as well. Interventions can occur at the level of the provider, care team, clinic, and/or pharmacy. Ideally, interventions are occurring throughout the patient’s medical visit and beyond.

The most commonly used interventions address patient readiness using both one-on-one education and support groups. Peer counseling and support are key for many patients to work through concerns related to medication-taking. Making patients partners in the decisionmaking process about when to start and which regimen to use is also important. The regimen should be as simple as possible and should be the one least likely to cause the side effects that the patient fears the most. Substance abuse and mental illness should be treated *before starting* medication whenever possible.

After the patient begins the regimen, close followup and monitoring of adherence is critical, often through frequent clinic visits during the first weeks of therapy even if other medical interventions are not necessary. Providers should ask patients about adherence and

address barriers to adherence at each followup visit. Providers should be open to changing the regimen if a patient has significant problems with it, whether related to side effects or to scheduling. Patients should be encouraged to use pill boxes and incorporate reminder systems as needed. Various kinds of interventions have been used in HIV and other chronic diseases (see Table 7-2).

What is the role of Directly Observed Therapy (DOT) for medication adherence?

Directly observed therapy (DOT) refers to medical staff supervising patients taking each dose of medication. DOT has increased treatment completion and decreased the resistance rates of tuberculosis therapy. Whether it is feasible in HIV therapy is currently under investigation. A majority of ongoing studies are using modified DOT, with only 1 daily dose of medication observed over the first several months of therapy or during the administration of methadone maintenance therapy. The results of these studies will provide valuable information about the long-term patient acceptability, cost, and efficacy of this approach to improve adherence over the long term.

Table 7-2: Interventions That Have Been Used to Support Adherence in HIV and Other Chronic Diseases

Intervention	Comments
The Patient	
Start when patients are ready	For patients with complications of HIV infection, low CD4 cell counts, or pregnancy, the cost-benefit analysis of treatment is different.
Treat substance abuse and depression before initiating ART	If there is no antiretroviral emergency, patients with active substance abuse and depression should have these comorbidities addressed before starting an antiretroviral regimen.
Engage patients in medication tailoring	Discuss with patients in detail how the medications will fit into their daily routine- ie, when (and if) meals are eaten, what patients do on a daily basis that can be linked to dosing times.
Educate (group/individual) regarding: - the regimen - side effects management - consequences of nonadherence	- Patient education is essential -- both group and one-on-one. - Involve caretakers and patient support network in educational efforts. - Patients need to know exactly how to take their medication. A daily calendar with pills on it will help a patient visualize the regimen. - Prior to initiating therapy, patients should know which side effects to expect, what they can do to manage them, and when to call the provider. - Patients need to understand the serious consequences of nonadherence and what to do in the event of a late or missed dose.
Increase support	Patients should enlist the aid of family and friends to promote their adherence. The HIV health care team can provide support through office visits, home visits, and telephone calls, especially in the early days and weeks of ART.
Use skill building exercises	Patients who are concerned about their ability to adhere should use a trial of jellybeans in a pill box to accustom themselves to their pill taking schedule prior to initiating therapy. This may not increase adherence, but it may give patients insight into their adherence and affect their decision to start medications.
Address barriers to adherence	- Have patients consider when medications are likely to be missed and make plans to decrease these events. - Some patients store a few doses in places where they spend a lot of time, such as at the houses of friends and relatives.
Use reminders	- Alarm clocks, in the form of watch alarms, pagers, or pill boxes can decrease missed doses due to simply forgetting. - Patients can place medications in locations where they will notice them at dosing times, such on the breakfast table.
The Regimen	
Simplify as much as possible	- Once or twice-a-day regimens are easiest for patients. - Use as few pills and medications as possible. - Try to use regimens that can be followed without regard to food intake.
Tailor the regimen to the patient's lifestyle (and not the patient's lifestyle to the regimen)	- Ask patients about their daily routine and comfort in taking medications in front of others and at work. - Construct a regimen that works for the patient.
Use pill boxes	- Use of pill boxes allows patients a mechanism for carrying their daily medication. - Pill boxes allow patients to easily recognize when they have missed taking a dose.
Make refills accessible	- Develop policies to allow patients ready access to refills.
The Clinician-Patient Relationship	
Develop a trusting relationship	- Rarely is initiation of antiretroviral regimens required at the first visit. Invest in the doctor-patient relationship prior to initiating therapy.
Ask about adherence	- Providers cannot predict adherence; they must ask patients. - Ask in a nonjudgmental way, with a specific time frame, to get good information. - Give permission for missed doses prior to asking. - Ask repetitively over time.
Use positive reinforcement	Share viral load and CD4 results and reinforce the relationship to adherence.
Listen to the patient	- Individualize therapy based on patient preferences regarding fear of specific side effects or specific medication. - Negotiate the regimen with patients.
System of Care	
Maintain close followup at initiation of regimen	Have telephone, office, or home contact with patients within first few days of therapy to assess for side effects and accurate understanding of regimen.
Develop patient education program	- Consider using nurses, case managers, pharmacists, and peers in patient education. - Have written materials accessible.
Incorporate the adherence message throughout the medical practice	- All staff members need to understand and promote the importance of adherence. - Have pill boxes, alarms, and other adherence aids available to patients.

KEY POINTS

Medication adherence is a significant challenge in all chronic diseases, but is particularly important in ART because of the high levels of adherence that must be maintained to prevent viral resistance.

Patients should not start taking antiretroviral medications until they are ready. Providers should take the time to assess their readiness, conduct interventions to prepare them to begin therapy, and follow them closely once they start.

Interventions to support adherence should be multifaceted and repeated over time. However, interventions have a modest effect on adherence.

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CASES

1.

AR is a 37-year-old woman who uses heroin and cocaine daily and has a CD4 count of 300 cells/mm³ and an HIV viral load of 150,000 copies/mL. Since she was diagnosed with HIV infection 10 years ago she has primarily sought care when acutely ill. She comes to clinic for the first time in 6 months because she has decided to start “the cocktail.”

Question: How do you manage this patient?

Answer:

This patient is not engaged in primary care and is using heroin daily. Although she might be able to adhere to therapy, she probably won't. Beginning ART is reasonable given her CD4 cell count and viral load; however nothing makes it critical to start therapy immediately.

The patient did not agree with her physician's assessment that her substance abuse was a barrier to medical care or medication adherence. She agreed to contract with her physician to start ART after she made 5 consecutive clinic visits. After several attempts at consecutive visits, the patient enrolled in a methadone-based substance abuse treatment program. She began to come regularly to clinic, engaged in in-depth medication education, and eventually started ART. She had good adherence, maintaining an undetectable viral load for 18 months before a drug abuse relapse. When she began to miss doses, she stopped all her medications as instructed and did not develop significant resistance.

2.

DP is a 4-year-old with perinatally-acquired HIV infection. He is taken care of by his maternal great-grandmother, who is also caring for 3 other great-grandchildren. He resists taking ART because of the taste, so that it takes his great-grandmother 30-60 minutes to administer each dose when she can get him to take it. Although she has worked closely with the behavior modification team at the pediatric clinic, the situation has not improved. His viral load and CD4 cell count have not changed significantly on therapy.

Question: What do you do to treat this patient?

Answer:

Given the patient's refusal to take medication, the decision was made to place a g-tube for ease of administration. Within 1 month the viral load was undetectable, and the time to administer medications had decreased to less than 10 minutes per dose. The great-grandmother reported a significant improvement in their relationship and in DP's behavior in a number of domains. Although this may seem extreme, this is an example of individualizing the intervention to the barriers that exist for the patient (Shingadia, et al 2000).

Chapter 8:**Symptom Management**

Tara Evans Nysoe, MD
Douglas S. Paauw, MD, FACP

*WORKUP OF SYMPTOMS**MEDICATION-RELATED ISSUES**NAUSEA**PULMONARY SYMPTOMS**FATIGUE**NEUROPATHIC PAIN**DERMATOLOGIC SYMPTOMS**MOUTH LESIONS**WASTING**MYALGIAS**DIARRHEA**HEADACHE**KEY POINTS**SUGGESTED RESOURCES**CASES***WORKUP OF SYMPTOMS****How should you approach the workup of symptoms in patients infected with HIV?**

Symptom evaluation in HIV-infected patients must include knowledge of the CD4 count and viral load as well as close attention to the medication list. An opportunistic disease (OD) is an unlikely cause of symptoms in patients with CD4 cell counts $> 200/\text{mm}^3$. Antiretroviral medications are a common cause of HIV-related symptoms.

MEDICATION-RELATED ISSUES**What are the most common symptoms related to antiretroviral medications?**

Nausea and diarrhea are the two most common symptoms associated with antiretroviral therapy (ART). Pruritus and skin rashes are also common, especially with nonnucleoside drugs. Lower extremity pain due to neuropathy is seen with didanosine (ddI), stavudine (d4T), and zalcitabine (ddC).

What are the common side effects of each of the antiretroviral drugs?

The different classes of drugs have many similar as well as distinct side effects (see Table 8-1).

What symptoms could be due to life-threatening acute drug reactions?

Symptoms of life-threatening acute drug reactions are not to be missed. A patient with myalgias, nausea, vomiting, diarrhea, abdominal pain, fever, rash, malaise, and extreme fatigue who has started taking abacavir (ABC) within the previous 6 weeks is

probably suffering from an abacavir hypersensitivity reaction. In this case, abacavir should be permanently discontinued. The hypersensitivity reaction occurs in up to 5% of patients starting on abacavir and can lead to hypotension and death if the patient is rechallenged with abacavir. If a patient taking one of the “d-drugs” (didanosine [ddI], zalcitabine [ddC], stavudine [d4T], dapsone [for *Pneumocystis pneumonia* prophylaxis]) has rapid onset of nausea/vomiting and constant, severe abdominal pain in the epigastrium or upper quadrants that radiates to the back, drug-induced pancreatitis is possible. Patients taking a nucleoside (NRTI) who have vague symptoms including nausea, vomiting, abdominal pain, weight loss, malaise, fatigue, dyspnea, or fever must have lactic acidosis with hepatic steatosis ruled out. This occurs 5-13 months after initiating therapy and has a 60% fatality rate. Patients taking nevirapine (NVP) who have fatigue, malaise, nausea, vomiting, jaundice, and right-upper-quadrant abdominal pain could have nevirapine-induced hepatitis. Also, up to half the patients taking nevirapine may have a rash; however, if the rash is moist, involves the mucous membranes, or is extensive with an associated fever, Stevens-Johnson syndrome, which also occurs in patients taking trimethoprim-sulfamethoxazole (TMP/sulfa), must be considered. Severe cases of Stevens-Johnson syndrome, including toxic epidermal necrolysis (TEN), are medical emergencies and must be managed as burn cases. For all drug-induced, life-threatening illnesses, immediate discontinuation of the offending drug is the crucial first step in care.

What are the most important drug interactions that occur with antiretroviral medications?

Drug interactions are frequently the cause of symptoms and must be closely watched for. Not only do antiretroviral drugs react with each other, they react with numerous prescribed drugs and recreational drugs (see Tables 4-8 in the Pocket Guide).

Table 8-1. Side Effects of Antiretroviral Drugs

Drug	Side effects
Nucleosides (NRTIs)	
Class effect	Hepatic steatosis/lactic acidosis
abacavir (ABC)	Hypersensitivity reaction (nausea, anorexia, fever, rash, dyspnea, cough)
didanosine (ddI)	Pancreatitis, peripheral neuropathy, nausea, diarrhea
lamivudine (3TC)	Very few side effects
stavudine (d4T)	Peripheral neuropathy, pancreatitis
tenofovir (TDF) (a nucleotide)	Nausea, vomiting, diarrhea
zalcitabine (ddC)	Peripheral neuropathy, mucosal ulcers, pancreatitis
zidovudine (AZT)	Anemia, myopathy, headache, nausea
emtricitabine (FTC)	Nausea, very few side effects
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
efavirenz (EFV)	Confusion, insomnia, rash, disturbing dreams
nevirapine (NVP)	Rash (15%), hepatitis
Protease inhibitors (PIs)	
Class effect	Hyperglycemia, hyperlipidemia, lipodystrophy, hepatitis
amprenavir (APV)	Nausea, diarrhea, rash, paraesthesias
atazanavir (ATV)	Elevated bilirubin
fosamprenavir (FAPV)	Diarrhea
indinavir (IDV)	Nausea, renal sludging, renal stones, increased indirect bilirubin
lopinavir+ritonavir (LPV/r or Kaletra)	Nausea, vomiting, diarrhea
nelfinavir (NFV)	Diarrhea common (can be limiting)
ritonavir (RTV)	Nausea, vomiting, circumoral paraesthesias, hepatitis, taste abnormalities
saquinavir (SQV)	Nausea, diarrhea

What natural products are potentially useful in treating the symptoms of patients with HIV?

Some commonly used complementary medicine treatments are listed in Table 8-2. Ginger for the treatment of nausea is probably the most effective of the natural products for symptom management.

Table 8-2. Complementary Medicine Treatment Options for Various Symptoms

Problem	Treatment option	Comments
Nausea	Ginger	Studies have shown possible benefit
Hepatitis	Milk thistle	Inconclusive long-term benefit; may inhibit the p450 system
Migraine prophylaxis	Riboflavin	Randomized controlled trial showed benefit
Immune system dysfunction	Co-enzyme Q	Studies have shown possible benefit in CD4 cell counts but no outcome benefit has been shown

NAUSEA

What are the important causes of nausea in patients with HIV?

The most common cause of nausea in patients with HIV is medication side effects. Many of the antiretroviral drugs can result in prominent nausea. Full dose ritonavir (RTV) probably causes the most severe and frequent symptoms, but nausea can be seen with all of the protease inhibitors (PIs). Zidovudine (AZT) frequently causes nausea when first taken. Didanosine (ddI), stavudine (d4T), and zalcitabine (ddC) can all cause nausea, or nausea may be an early sign of the pancreatitis these drugs can lead to. All classes of antiretroviral drugs can cause hepatitis, which may present as intense nausea and fatigue. Nevirapine (NVP) and PIs are the most likely to do this, but nucleosides can cause life-threatening lactic acidosis in association with hepatic steatosis. Nausea can be a component of abacavir (ABC) hypersensitivity reaction, usually associated with fever, rash, vomiting, and anorexia. The commonly used antibiotics trimethoprim-sulfamethoxazole (for *Pneumocystis pneumonia* [PCP] prophylaxis) and azithromycin or clarithromycin (for *Mycobacterium avium* complex [MAC] prophylaxis) can cause nausea.

Nonmedication causes to consider include viral hepatitis (acute hepatitis A, B, or C). Nausea is a common feature of cryptococcal meningitis; other sources of increased intracranial pressure such as CNS lymphoma or toxoplasmosis can also present with severe nausea and vomiting.

What are the best options for managing nausea?

If nausea is due to medications, stopping the medication or removing an interacting drug is the best option. Symptomatic therapy with prochlorperazine or metoclopramide may help. A natural product option is ginger, at a dose of 2 grams daily (no more than 4 grams/day). Switching the time of the dose of the offending drug to be taken with food may be helpful.

PULMONARY SYMPTOMS

What are the possible causes of cough in an HIV-infected patient?

The CD4 cell count is crucial information in determining the cause of cough. In patients with CD4 cell counts $> 200/\text{mm}^3$, viral upper respiratory infections, bacterial pneumonia (caused by *S. pneumoniae* or *H. influenzae* most commonly), tuberculosis (TB), and sinusitis with post-nasal drip are all important causes of cough. Bacterial bronchitis is more common in patients with HIV than in non-HIV-infected patients. In patients with low CD4 cell counts ($< 200/\text{mm}^3$) *Pneumocystis carinii* pneumonia must be considered. The risk of PCP is markedly diminished if the patient is taking trimethoprim-sulfamethoxazole for PCP prophylaxis. The cough that occurs with PCP is usually dry and persistent and will usually have been present for several weeks before a patient seeks evaluation. Fungal disease due to cryptococcus, histoplasmosis, or coccidioidomycosis is more common with lower CD4 cell counts.

What workup is appropriate?

In patients with CD4 cell counts $> 200/\text{mm}^3$ the history and physical exam should determine what testing to do. If the patient has a cough but no fever or productive sputum, no dyspnea, and a normal pulmonary exam, then chest x-ray is not necessary. A patient at high risk for TB should have an x-ray if there is a prolonged cough ($> 2-3$ weeks) regardless of CD4 cell count. In a patient with a low CD4 cell count ($< 200/\text{mm}^3$) the possibility of PCP is much more likely and an aggressive approach is warranted; a chest x-ray can begin the workup. If it is normal, then consider obtaining oxygen saturation measurements with ambulation. An individual who has oxygen desaturations should have further workup. For evaluation of suspected PCP see Chapter 9, Management of Opportunistic Diseases.

Are patients infected with HIV at increased risk of developing bacterial pneumonia?

Available data clearly suggest that HIV-infected patients have an increased risk of developing bacterial pneumonia. In the 1993 CDC classification system, recurrent pneumonia (2 or more episodes in 1 year) is defined as a category C (AIDS-indicator) condition. Pneumococcal pneumonia is the most common bacterial pneumonia in persons infected with HIV, and it occurs approximately 10 times more frequently than in persons not infected with HIV. In addition, the development of pneumococcal pneumonia can occur early in the course of HIV disease, before other manifestations of immune suppression. HIV-infected persons with pneumococcal pneumonia have clinical signs and symptoms similar to those in HIV-negative individuals, but they have an approximately 20-fold higher risk of developing pneumococcal bacteremia. Treatment of pneumococcal pneumonia is generally the same in persons with and without HIV infection. Several studies have shown that HIV-infected persons have a slightly increased risk of developing pneumonia caused by *Pseudomonas aeruginosa*.

How common is sinus disease in patients with HIV?

Sinus disease is very common in patients with HIV. The lower the CD4 cell count, the more severe and more widespread (number of sinuses involved) sinusitis is. In patients with lower CD4 cell counts, chronic sinusitis and lack of response to therapy are more common. The most common organisms involved are *Streptococcus pneumoniae*, *Streptococcus viridans*, and *Pseudomonas aeruginosa*. Pseudomonal sinus infections are more common in patients with CD4 cell counts of $< 50/\text{mm}^3$. Fungal (*Aspergillus*) and viral (Cytomegalovirus) sinusitis can occur in patients with CD4 cell counts $< 100/\text{mm}^3$. Aggressive treatment of sinus disease with saline irrigation, antihistamine/decongestant combinations and full-dose nasal steroids is appropriate. Antibiotics should be given for the normal duration for episodes of acute sinusitis (3-6 week course). If antibiotic therapy and aggressive irrigation do not resolve the problem, referral to an ENT specialist for drainage procedures and for consideration of sinus surgery is appropriate.

FATIGUE

What are the common causes of chronic fatigue in patients with HIV?

Fatigue can have a large impact on the quality of a patient's life. Common descriptors of fatigue include tiredness, weakness, lack of energy, sleepiness, and exhaustion. Of the many possible causes of chronic fatigue in patients with HIV, the most common is depression. Other psychosocial causes include stress, anxiety, use of recreational substances, sleep disturbances, domestic abuse, and lack of exercise. ODs must be considered as a possible cause of fatigue in patients with low CD4 cell counts. Other disease states such as anemia, hypothyroidism, hypogonadism, adrenal insufficiency, influenza and other non-opportunistic infections, diabetes, liver disease, and malnutrition can also present as fatigue. Fatigue can be a side effect of ART and other medications commonly taken by patients with HIV. HIV-associated fatigue is a diagnosis of exclusion.

How do you determine the cause of a patient's fatigue?

Ask if the patient is having other symptoms of depression: change in sleep or appetite patterns, depressed mood, anhedonia, agitation or retardation, difficulties with concentration, decreased self-esteem, and suicidal ideation. Take a thorough social history and determine if multiple life stressors are present. Inquire as to how many hours of sleep the patient is getting per night and the number of middle-of-the-night awakenings; ask if the patient feels rested in the morning. Important history questions that help differentiate a physical from a psychological etiology for fatigue are in Table 8-3. Identify any barriers to effective sleep. Ask about the patient's diet and exercise habits, and determine if the patient drinks alcohol or uses recreational drugs, including caffeine. Thoroughly review the patient's medication list and identify any medications, such as certain antiretroviral drugs, beta-blockers, antihistamines, etc., that can be associated with fatigue. Do a complete review of systems and physical exam to elicit other symptoms or signs that may suggest an OD or other disease state. Simple laboratory tests, such as alanine aminotransferase (ALT), blood glucose, thyroid stimulating hormone (TSH), and hematocrit, can help to rule out common diseases that can cause fatigue. Electrolyte abnormalities can suggest adrenal insufficiency. Order other laboratory or diagnostic tests as symptoms and signs direct.

Table 8-3. History Questions to Differentiate Physical from Psychological Causes of Fatigue

	Psychological cause	Physical cause
Onset	Often follows problem or conflict	Related to onset of physical ailments
Duration	Chronic	Of recent onset
Progression	Fluctuates	Increases as disease advances
Effect of sleep	Unaffected by sleep	Relieved by sleep
Diurnal	Present in morning, may improve	Increases as the day progresses

NEUROPATHIC PAIN

What is the most common cause of neuropathic pain and paresthesias in patients with HIV?

Distal symmetrical polyneuropathy (DSP) is most commonly caused by antiretroviral drugs. The drugs didanosine (ddI), zalcitabine (ddC), stavudine (d4T) can all cause DSP at high doses. Studies have shown zalcitabine to be the most likely to cause neuropathy at standard doses; concurrent alcohol use or vitamin B12 deficiency may increase risk. HIV-related DSP is less common than drug-induced DSP. The two types of neuropathies present similarly, although onset may be more acute in drug-induced DSP. HIV-related DSP does not appear to respond to viral suppression with ART.

How do you diagnose and treat DSP?

Diagnose drug-related DSP by linking the onset of the symptoms with the initiation of drug therapy. Treat by drug removal; symptoms may worsen temporarily but should regress within several weeks. Residual painful symptoms of DSP may be treated with tricyclic antidepressants, narcotic analgesics, or gabapentin. The topical medication capsaicin may be helpful if the neuropathy is limited to a small surface area.

DERMATOLOGIC SYMPTOMS

How do you manage generalized pruritus in a patient with no cutaneous signs on exam?

If a patient with HIV has generalized pruritus with no obvious cutaneous diagnosis, acute drug reactions such as Stevens-Johnson syndrome, which can be life-threatening, and coexisting systemic illness such as hepatic dysfunction must be ruled out (see Table 8-4 and earlier section on medication-related issues). Order a complete blood count, liver function tests, and blood chemistries. Occasionally, scabies can present with minimal to no cutaneous signs. Pruritus due solely to HIV infection is a diagnosis of exclusion; it can respond to ART. (Symptomatic treatments for generalized pruritus are listed in Table 8-5.) In general, if a clear cause is not identified, xerosis, a common condition in patients with HIV disease, will be the most likely diagnosis. In this case, decreasing the amount of bathing, avoiding dry soaps, using emollient creams, and ceasing scratching are the basis of symptomatic treatment. In addition, general agents such as H-1 antagonists can be used. The best studied of these is hydroxyzine, which offers the benefit of sedation for nocturnal itching.

Table 8-4. Common Causes of Pruritus in Patients with HIV	
Very common	Less common
• <i>Staphylococcal folliculitis</i> • <i>Xerosis</i> • <i>Atopic dermatitis</i> • <i>Scabies</i> • <i>Psoriasis</i> • <i>Hypersensitivity to insect bites</i> • <i>Drug reactions</i>	• <i>HIV-associated pruritus</i> • <i>Eosinophilic folliculitis</i> • <i>Granuloma annulare</i> • <i>Lymphoma</i> • <i>Hepatic failure</i> • <i>Renal failure</i>

How does scabies manifest differently in HIV-infected persons?

Among HIV-infected persons with mild-to-moderate immune suppression, scabies causes similar clinical manifestations as seen in persons without HIV infection, namely multiple pruritic papular lesions. Treatment consists of applying 30-60 g of 5% permethrin cream to the entire body from the neck down, leaving it on for 8-12 hours, then washing it off, and repeating the entire process one week later. In HIV-infected persons with severe immune suppression (CD4 count of < 100 cells/mm³), an atypical form of scabies known as crusted or "Norwegian" scabies may develop. Crusted scabies is characterized by an enormous number of scabies

mites and manifests as nonpruritic, thick, grayish-white, plaque-like lesions. In severe cases, the large lesions can develop deep fissures. Treatment of crusted scabies consists of ivermectin 200µg/kg orally with a repeat dose a week later.

Table 8-5. Therapy Strategies and Treatment Options for Generalized Pruritus	
Therapy	Comment
Prevention of scratching	Scratching causes secondary irritation
Lubrication with ointments and creams with a fatty basis	eg, propylene glycol, wax esters
Avoidance of histamine induction by heat	eg, bathing in lukewarm or cold water
Avoidance of irritating substances	eg, alkaline soaps, wool clothing
Antihistamines	The evidence is sparse; watch for side effects
Topical agents • <i>Coolants</i> • <i>Anesthetic agents</i>	eg, menthol, phenol eg, EMLA® Cream (lidocaine 2.5% and prilocaine 2.5%)
Lindane	Empiric treatment for scabies if risk factors
UVB therapy	Three times a week, up to 20 treatments for maximal benefit
Hypnosis	Studies have demonstrated benefit

What are the causes and treatments of blisters and cutaneous ulcers in persons with HIV?

Several studies have suggested that HIV-infected persons, when compared with age-matched HIV-negative persons, have an approximately 10-fold increased risk of developing "shingles," a complication resulting from reactivation of varicella-zoster virus. Herpes zoster can occur at any CD4 cell count and thus does not require advanced HIV-related immune suppression. Indeed, the development of herpes zoster may serve as one of the first clinical events prompting an HIV-infected person to seek medical care. Persons with HIV can have more than one episode of herpes zoster. For unknown reasons, HIV-infected persons who start aggressive ART have an increased risk of developing herpes zoster in the 6-month period after starting ART; in this scenario, the herpes zoster does not reflect worsening immunologic function or waning effectiveness of ART.

Because immune-suppressed persons who develop herpes zoster have an increased risk of disseminated herpes zoster, most experts recommend that all HIV-infected persons with zoster receive therapy. As long as the patient has no evidence of disseminated disease, central nervous system disease, or cranial nerve involvement, oral therapy can be used. Therapy for localized dermatomal zoster consists of 7-10 days of oral therapy with valacyclovir (1000 mg tid), acyclovir (800 mg 5x/day), or famciclovir (500 mg tid). In addition, acute zoster-associated pain often requires therapy. Therapy for zoster in HIV-infected persons should not include corticosteroids. No evidence exists to suggest HIV-infected persons have a higher risk of developing post-herpetic neuralgia as a complication of zoster infection.

Among HIV-infected persons with mild or moderate immune suppression (CD4 count > 350 cells/mm³), herpes simplex virus (HSV) infections cause clinical manifestations similar to those in HIV-negative persons, namely self-limited oral or genital lesions that typically appear with vesicular or ulcerated lesions. Recommended therapy for episodic HSV infection consists of either acyclovir 400 mg po tid x 5-10 days, famciclovir 500 mg po bid x 5-10 days, or valacyclovir 1000 mg po bid x 5-10 days. In persons with more advanced immune suppression, particularly those with severe immune suppression (CD4 count < 100 cells/mm³), HSV infection may present as a non-healing, large, ulcerated lesion anywhere on the body. Therapy for these chronic, ulcerated lesions typically requires longer duration. In addition, those HIV-infected persons with severe immune suppression who receive chronic suppressive therapy for HSV have an increased risk of developing acyclovir-resistant HSV infection.

How does molluscum contagiosum manifest in severely immunosuppressed persons with HIV?

Among HIV-infected patients with severe immune suppression (CD4 count < 100 cells/mm³), molluscum contagiosum typically presents as flesh-colored, papular lesions, most often on the face, neck, chest, or genitalia. In contrast to immune competent patients who typically have a self-resolving illness, HIV-infected persons with severe immune suppression generally have a progressive increase in the number and size of the molluscum lesions, often culminating in very large and disfiguring lesions referred to as “giant molluscum.” These lesions are particularly problematic if located on the face. Extremely large lesions may require surgical removal, moderate-sized lesions typically respond to

liquid nitrogen therapy, and multiple small lesions are best treated with topical tretinoin 0.025% applied once a day. In addition, effective ART with improvement in immune function may help in managing molluscum.

How do you recognize and treat seborrheic dermatitis?

Although seborrheic dermatitis is a well-known dermatologic disorder in persons who do not have HIV infection, this disorder occurs with increased frequency and severity among HIV-infected persons. Patients with HIV infection and seborrheic dermatitis typically have symmetrical erythematous, scaled patches and flaking, most often on the scalp, eyebrows, beard, central chest, and axillae. Typically, seborrheic dermatitis spares the central part of the face. Most patients respond to topical antifungal creams, such as 2% ketoconazole cream. In some instances, adding 1% hydrocortisone cream may be required.

MOUTH LESIONS

Many patients with HIV have mouth pain: what are the most common mouth lesions?

The two most common oral lesions in HIV patients are oral candidiasis and oral hairy leukoplakia; they are clinical markers of symptomatic HIV infection. Oral hairy leukoplakia is a raised, white lesion that is usually seen on the lateral surface of the tongue. Hair-like projections can occasionally be visualized. It is usually asymptomatic, but may cause discomfort and impair taste and eating as it grows in size. The lesion appears more frequently in patients with lower CD4 counts and is thought to be caused by the Epstein-Barr virus.

Mucosal *candida* infections are seen as the CD4 cell count falls below 200-300 cells/mm³. The manifestations vary; they can involve the hard and soft palates, buccal mucosa, tongue, pharynx, and hypopharynx. The most common presentation is pseudomembranous candidiasis, or thrush. “Cottage cheese” plaques are seen on the soft palate, tonsils, and buccal mucosa and can be removed with a tongue blade. Atrophic candidiasis is a less seen and underdiagnosed form of candidiasis, consisting of flat, erythematous plaques in the same distribution as pseudomembranous candidiasis but lacking the white exudates. Mouth pain and loss of acuity of taste are common symptoms with atrophic candidiasis.

Diagnosis of a *candida* infection is commonly based on physical exam findings. Examination of a KOH preparation of a plaque scraping may also be used; culturing is rarely necessary. Response to a trial of topical antifungal agents (clotrimazole troches are easier than liquid nystatin to use) establishes the diagnosis. If the above diagnostics do not suggest *Candida*, a biopsy of the lesion may be performed. Oral hairy leukoplakia needs to be treated only if it causes mouth pain. It can be treated with high-dose acyclovir, valacyclovir, or famciclovir.

What are the causes of painful oral ulcers in patients with HIV?

Oral ulcers are common in patients with HIV. HSV causes primary or recurrent small, smooth, painful ulcers on the lips, gums, hard palate, or buccal mucosa. They can present as solitary lesions or in clusters. Lesions often last weeks, and treatment with acyclovir can shorten the course. Patients with disseminated cytomegalovirus (CMV) infection can occasionally have a large, solitary oral lesion. Aphthous stomatitis can present as single or multiple painful ulcers on the buccal and labial mucosa and the lateral aspect of the tongue. Aphthous ulcers are often exudative or necrotic in patients with HIV, and the course is usually more prolonged than in patients without HIV. Drug therapy with zalcitabine (ddC) can also cause ulcers. In managing oral ulcers, biopsy and viral culture establishes the etiology; some suggest treating empirically for HSV. If the lesion is consistent with aphthous ulcers, treat either with topical or oral steroids or thalidomide. An oral suspension consisting of diphenhydramine, viscous lidocaine, tetracycline, and dexamethasone may offer some pain relief. Removal of the offending drug is the treatment for drug-induced ulcers.

How do you recognize and treat gingivitis and periodontal disease?

These diseases can develop either insidiously or abruptly in patients with HIV and may be severe. Gingivitis is common and can occur at any CD4 cell count. Severe pain, foul breath, bleeding gums, and loosening of teeth are common symptoms, and exam may show a bright red marginal line on the gingiva, gingival erosion, necrosis and ulceration of interdental papillae, exfoliation of enamel, and loose teeth. The cause is unclear, although aerobic and anaerobic gram-negative bacteria, spirochetes, and yeast have been implicated. Severe, ulcerating gingivitis can be caused by *Klebsiella pneumoniae*, *Enterobacter*

cloacae, and other gram-negative bacilli. Treatment includes debridement, irrigation with povidone-iodine/ chlorhexidine oral solutions, and topical antiseptic agents or metronidazole.

WASTING

What are the common causes of weight loss and wasting in patients with HIV?

There can be many different psychological and physical causes of weight loss in HIV disease (see Table 8-6).

Table 8-6. Common Causes of Weight Loss in Patients with HIV

Inadequate dietary intake resulting from
Depression
Painful oral lesions
Esophageal lesions causing dysphagia
Reduced taste sensation (thrush/meds)
Medication side effects (eg, nausea)
Chronic diarrhea (malabsorption) resulting from
Cryptosporidia
Giardia
Hypermetabolic states
Infection
Occult malignancy (eg, B-cell lymphoma)
Endocrine problems
Hypogonadism
Adrenal insufficiency
Diabetes (PI-induced)

How do you work up a patient with weight loss and wasting?

The workup is driven by results of the history, physical exam, and CD4 cell count; a higher CD4 count is more suggestive of causes such as endocrine disorders, malignancies, depression, or medication side effects. Serum testosterone, glucose, and thyroid tests to assess hormone status may be ordered. If malnutrition is suspected, it is important to address this promptly, since malnutrition decreases the function and number of immunity cells and leads to increased morbidity and mortality. Evaluation of GI function, calculation of caloric intake, estimation of protein and energy requirements, measurement of serum prealbumin, albumin, folate, and vitamin B12, and determination of the extent of lean body mass lost make up a comprehensive nutritional assessment. Body cell

mass can be measured using mid-arm circumference. Specific dietary deficiencies should be addressed, vitamin and mineral supplements should be prescribed, and high-calorie protein-containing foods should be recommended. In the patient with a low CD4 count (< 100 cells/mm³), OIs such as *Mycobacterium avium* complex (MAC), tuberculosis, cytomegalovirus infection, cryptosporidiosis, and *Pneumocystis carinii* pneumonia (PCP) should be ruled out, as well as lymphoma. Order a complete blood count, chemistries, blood cultures, chest x-ray, oximetry, and gastrointestinal biopsies or stool cultures as indicated. Referral to a nutritionist or registered dietician is often helpful. Also see *Health Care and HIV: Nutritional Guide for Providers and Clients* under Suggested Resources for practical assessment tools and algorithms for providers as well as patient handouts.

What are the medical treatment options for AIDS wasting?

If an underlying cause of wasting has been identified, treatment of that cause is the first step in restoring weight. One important factor may be switching to ART that does not cause gastrointestinal/anorexia symptoms preventing food intake. Any infectious process should be identified and treated. For nonspecific AIDS wasting, the mainstay of treatment is nutritional supplementation along with appetite stimulants and antiemetics. Institution of ART and prevention of OIs are important in restoring weight. Human growth hormone has been shown to rebuild lean body mass, although it is expensive and survival advantage is controversial; some recommend that it be reserved for patients who have intractable, unexplained weight loss and require short-term treatment to maintain body cell mass during an acute illness (see Table 8-7 for treatment options).

MYALGIAS

What are some common causes of myalgias in patients with HIV?

HIV can cause an inflammatory myopathy at any stage of infection. Symptoms include slowly progressive, proximal muscle weakness of the extremities with or without myalgias. Myopathy due to zidovudine (AZT) toxicity presents similarly to HIV-associated myopathy, and it may be difficult to distinguish between these two disorders. Zidovudine toxicity occurs usually after several months of therapy (most commonly after 6 or more months of continual therapy). Myopathy or rhabdomyolysis due to HMG coenzyme A reductase

inhibitors (statins) or fibrates are another important concern with HIV-infected patients. Many patients are on these drugs for treatment of hyperlipidemia caused by treatment with PIs. PIs decrease the metabolism of statins, which can increase the chance of toxicity. Moreover, many patients are on both gemfibrozil and a statin, which can interact to increase the risk of muscle toxicity. Simple myalgias are more common than rhabdomyolysis or myopathy caused by the statins.

Table 8-7. Treatment Options for Specific Causes of Weight Loss

Cause of weight loss	Treatment options	Comments
Anorexia	Appetite stimulants • <i>dronabinol</i> 2.5-5 mg/d • <i>megestrol acetate</i> 800 mg/d	Some studies show that weight gained is from body fat and not lean body stores. Megestrol can raise blood sugar levels, especially when used with protease inhibitors.
Hypogonadism	testosterone • <i>IM</i> 200-300 mg every 2-3 weeks • <i>Transdermally</i> - Patch 5 mg/day - 1% gel 5-10 g/day oxandrolone nandrolone	Liver function tests must be monitored with use of oral anabolic agents.

How do you evaluate and manage a patient with myalgias or myopathy?

The first step is to check creatinine phosphokinase (CPK) levels. This should be done for any patient on zidovudine (AZT) or a statin who has symptoms of myalgias or muscle weakness. Periodic (every 3-6 months) monitoring of CPK levels is appropriate for patients who are on a statin/PI or statin/gemfibrozil combination. Muscle biopsy should be performed if signs and symptoms of myopathy do not remit within about a month after drug removal or if a patient has muscle enzyme elevations and is not on a drug known to cause muscle damage. Organisms may be seen on muscle biopsy, indicating an infectious myopathy. If no organisms are seen and there are signs of inflammation on biopsy, an inflammatory myopathy secondary to HIV is likely, and a trial of corticosteroids or therapy with intravenous immune globulin (IVIG) should be implemented.

DIARRHEA

What are the common causes of diarrhea in patients with HIV?

The main causes of diarrhea are related to either infections or medications. Infectious diarrhea can be caused by a number of organisms, dependent on the patient's CD4 cell count (see Table 8-8). Nelfinavir (NFV) is the antiretroviral drug most commonly associated with diarrhea. All the PIs can cause diarrhea. Didanosine (ddI) is the nucleoside most associated with diarrhea, but diarrhea is less common when the enteric coated (EC) form is used. Metformin, a drug used for treatment of lipodystrophy syndrome and diabetes, commonly causes diarrhea.

Table 8-8. Infectious Causes of Diarrhea in Patients with HIV

Any CD4 cell count (acute diarrhea)
Viruses (especially Norwalk virus)
<i>Clostridium difficile</i> (previous antibiotic exposure)
<i>Salmonella</i> spp
<i>Shigella</i> spp
<i>Campylobacter</i> spp
Any CD4 cell count (chronic diarrhea)
<i>Clostridium difficile</i>
<i>Giardia lamblia</i>
CD4 count <300 cells/mm³ (chronic diarrhea)
Microsporidia
Cryptosporidia
<i>Mycobacterium avium</i> complex (CD4<100)
<i>Isospora belli</i>
Cytomegalovirus (CD4 count <100/mm ³)
Idiopathic

What is the best approach to the evaluation of chronic diarrhea in the patient with HIV?

For patients who are on medication that can cause intractable diarrhea, one option is a trial of antidiarrheal medications (loperamide or atropine/phenoxylate either alone or in combination) and continuation of the previous antiretroviral regimen. If this does not work, another option is a trial off medication. If a patient is on ART, stop all medications for the 1-week evaluation

period. If there is a response, then a new agent can be substituted for the most likely causative drug, usually nelfinavir (NFV) or lopinavir plus ritonavir (LPV/r, or Kaletra). If there is no response when medications are stopped, then stool studies should be done. If the patient has a high CD4 cell count ($> 300/\text{mm}^3$), start with *C. difficile* toxin and *Giardia* antigen. If the CD4 cell count is low ($< 300/\text{mm}^3$), do a full workup with *C. difficile*, *Giardia* antigen, *Microsporidia*/*Cryptosporidia* assay, and modified AFB stain for cryptosporidia. If no organisms are identified, in patients with very low CD4 cell counts ($< 100/\text{mm}^3$) obtain blood cultures for *Mycobacterium avium*, and if these are negative, pursue lower endoscopy with particular emphasis on detection of cytomegalovirus on biopsy. In patients with higher CD4 cell counts, clinical followup and trials of antimotility drugs are a reasonable approach before pursuing endoscopy.

HEADACHE

What are the important causes of headaches in HIV-infected patients?

The causes of headache vary according to CD4 cell count. Patients with a CD4 count of > 300 cells/mm³ usually have headaches with common causes such as muscle tension, migraine, or drug side effect. Sinusitis is more frequent in patients with than without HIV and may cause headaches. In patients with low CD4 counts (< 200 cells/mm³) opportunistic infections (eg, Cryptococcal meningitis, toxoplasmic encephalitis) and malignancies (eg, CNS lymphoma) are important causes to consider.

How should you work up patients with headache?

Patients with CD4 counts of < 200 cells/mm³ should have a contrast head CT scan or MRI, followed by lumbar puncture if the scan does not reveal a cause. In a study of CT scans for evaluation of headaches in HIV-positive patients *all* cases with mass lesions or white-matter lesions occurred in patients with CD4 counts of < 200 cells/mm³. Serologic tests for cryptococcal antigen and *Toxoplasma* titers are helpful in patients with CD4 counts of < 200 cells/mm³.

KEY POINTS

Antiretroviral medications are a common cause of HIV-related symptoms. Some drugs can cause life-threatening reactions and conditions, including hypersensitivity reaction, pancreatitis, lactic acidosis, and Stevens-Johnson syndrome.

The CD4 cell count and viral load are important in symptom evaluation; symptoms associated with OIs in immunocompromised patients have other causes in patients with intact immune function.

Nausea and diarrhea, very common side effects of PIs, zidovudine, and didanosine, can be managed by switching drugs or with symptomatic therapy.

Pneumococcal pneumonia, the most common bacterial pneumonia in persons with HIV, can occur early in the course of the disease, before other manifestations of immune suppression. Sinus disease is also common in persons with HIV.

Chronic fatigue requires a careful assessment to differentiate psychological from physical etiologies so that the underlying cause can be addressed.

Painful neuropathy, frequently caused by antiretroviral medications, can also result from HIV disease. Treatment may include stopping a drug or treating with tricyclic antidepressants, narcotic analgesics, or gabapentin.

Dermatologic problems common in HIV disease include pruritus, crusted scabies, herpes zoster, molluscum contagiosum, and seborrheic dermatitis.

Common oral lesions include oral candidiasis, oral hairy leukoplakia, ulcers, and gingivitis. Common causes of oral ulcers are zalcitabine, HSV, and aphthous ulcers.

Wasting may have a treatable cause, but even nonspecific AIDS wasting can be treated with nutritional supplementation, appetite stimulants and antiemetics.

Myalgia, an especially common side effect of taking a PI and a statin, may require muscle biopsy and treatment with either an antibiotic or IVIG or steroids if the condition does not improve after stopping the implicated medications.

Headaches, common with HIV disease, may be due to a CNS infection or neoplasm if the CD4 count is less than 200 cells/mm³.



SUGGESTED RESOURCES

Graham CB, Wippold FJ, Pilgram TK, Fisher EJ, Smoker WR. Screening CT of the brain determined by CD4 count in HIV-positive patients presenting with headache. *Am J Neuroradiol.* 2000; 21:451-454.

Health Care and HIV: Nutritional Guide for Providers and Clients. 2002. Rockville, MD: Health Resources and Services Administration. Available at <http://www.aidsetc.org>. Accessed 12/03.

Penzak Sr, Chuck SK, Stajich GV. Safety and efficacy of HMG-CoA reductase inhibitors for treatment of hyperlipidemia in patients with HIV infection. *Pharmacotherapy.* 2000;209:1066-1071.

CASES**1.**

A 45-year-old HIV-positive man, last CD4 count 150 cells/mm³, comes to see you reporting aching in his right arm for 3 weeks. It began with only mild tenderness, but in the last week has become more painful and seems swollen. He is on ART with zidovudine (AZT), efavirenz (EFV), and nelfinavir (NFV). He is taking atorvastatin for hyperlipidemia. On physical exam, he is febrile, and his right arm is edematous and radiating heat without erythema. You obtain a CPK level which is normal.

Question: What is the most likely diagnosis?

Answer:

This patient has symptoms and signs of infectious myositis or pyomyositis, which usually develops insidiously over 2-3 weeks. In the first phase of infection, the involved muscle is tender with mild swelling. After 2-3 weeks a second phase manifests, usually with fever and edema, heat, and painful induration of the involved muscle. Erythema over the muscle is usually not seen. Laboratory values are usually notable for a lower than expected CPK but may include an elevated sedimentation rate and leukocytosis. Zidovudine-induced, statin-induced, and HIV-associated myopathy are less likely, as CPK would be elevated in these disorders, and the symptoms and signs in this patient are localized to one muscle group. Confirm the diagnosis of infectious myopathy with ultrasound or CT or MRI scanning, which will show a purulent abscess in the involved muscle. Blood cultures are not useful. If not treated, septic shock often ensues.

Question: What is the most likely cause?

Answer:

Most cases of infectious myositis are due to infection with *Staphylococcal aureus*. Other organisms reported have included *Streptococcus*, *Toxoplasma gondii*, cytomegalovirus, *Microsporidia*, *Cryptococcus neoformans*, *Mycobacterium avium intracellulare*, *Salmonella*, *Nocardia*, and gram-negative organisms.

2.

A 37-year-old man with Category 3 HIV disease (an AIDS indicator condition plus CD4 count nadir of <200 cells/mm³), last CD4 count 350 cells/mm³, comes to your office complaining of fatigue, nonspecific abdominal pain, nausea, and vomiting for the past 12 days. Review of systems is otherwise negative. He takes stavudine (d4T), zidovudine (AZT), and nelfinavir (NFV) as ART and fluoxetine for depression. On physical exam, his temperature is 37.9 degrees, respiratory rate is 25, abdomen is diffusely mildly tender to palpation, with increased tenderness in the right upper quadrant, no signs of jaundice, guaiac is negative.

Question: What is the differential diagnosis of causes related to ART?

Answer:

The differential diagnosis of ART-related etiologies in this case should include pancreatitis, based on symptoms of abdominal pain, nausea, and vomiting in a patient taking stavudine, although pancreatitis usually presents more acutely with more severe pain. Hepatitis should be considered with these symptoms in patients taking PIs. Lactic acidosis should always be suspected in a patient with these symptoms taking a nucleoside.

Question: What initial lab work should be ordered?

Answer:

Initial lab work may include CBC, basic metabolic panel, liver panel, amylase, lipase, lactate level, and coagulation studies. In the case of this patient, the lactic acid level was elevated. Further support for the diagnosis of lactic acidosis would include an increased anion gap, decreased bicarbonate, and elevated aminotransferases, lipase, amylase, CPK, and LDH.

Chapter 9:**Management of Opportunistic Diseases**

Constance A. Benson, MD

OVERVIEW*PNEUMOCYSTIS JIROVECI (CARINII) PNEUMONIA (PCP)**MYCOBACTERIUM AVIUM COMPLEX (MAC)**CYTOMEGALOVIRUS INFECTION (CMV)**CANDIDA ESOPHAGITIS**CENTRAL NERVOUS SYSTEM DISEASES**MYCOBACTERIUM TUBERCULOSIS**MALIGNANCIES**KEY POINTS**SUGGESTED RESOURCES***OVERVIEW****What are the major opportunistic diseases (ODs) in patients with HIV/AIDS?**

The diseases that occur as a result of HIV-related immunodeficiency include both opportunistic infections (OIs) and malignancies. The risk of developing an OI has declined dramatically with the widespread use of potent combination antiretroviral therapy (ART) (see Figure 9-1). The major OIs that occur in patients with HIV are *Pneumocystis carinii* pneumonia (the organism that causes human disease in PCP is now classified as *Pneumocystis jiroveci*, but PCP remains the conventional abbreviation in clinical use), tuberculosis, disseminated *Mycobacterium avium* complex (MAC) disease, cytomegalovirus (CMV) disease, *Candida* esophagitis, central nervous system (CNS) infections such as cryptococcal meningitis or *Toxoplasma* encephalitis, and cryptosporidiosis. While *Mycobacterium tuberculosis* is an infection that occurs in both immunocompetent and immunosuppressed patients, it remains one of the most common opportunistic co-infections in persons with HIV disease and is responsible for considerable morbidity and mortality worldwide. A host of other OIs may be seen less commonly or in patients in geographic areas where specific infections are endemic, eg, histoplasmosis in the central Midwest part of the U.S. or isosporiasis in South Florida and Puerto Rico.

**See Pocket
Guide Adult OI
Tables 1–6**

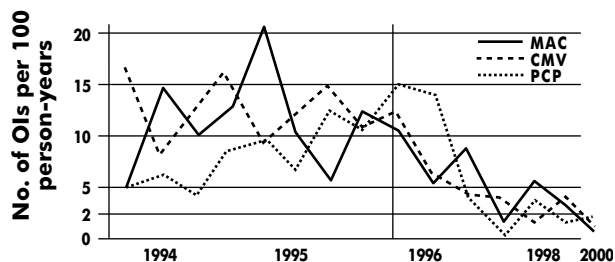
What factors are associated with higher risk of developing an OI?

OIs occur primarily in HIV-infected individuals who are not receiving either OI prophylaxis or ART (or who have not responded to it with an increase in their CD4 cell counts above the threshold that predicts risk of developing an OI). The principal risk of

Table 9-1. Risk Factors Associated with Development of Major Opportunistic Infections in HIV-Infected Individuals

Opportunistic Infection	CD4 Count Risk Threshold (cells/mm ³)	Other Risk Factors
<i>Pneumocystis carinii</i> pneumonia	≤200	Prior PCP Percent CD4 cells <14% Fever of unexplained etiology Presence of oral candidiasis
<i>Mycobacterium tuberculosis</i>	Any	PPD (tuberculin skin test) positive Exposure to an infectious contact
<i>Mycobacterium avium</i> complex	≤50	Prior respiratory or gastrointestinal colonization Prior OD High viral load (>10 ⁵ copies/mL)
Cytomegalovirus disease	≤50	Seropositive (IgG antibody to CMV) CMV viremia Prior OD High viral load (>10 ⁵ copies/mL)
Cryptococcal meningitis	≤50-100	Environmental exposure
Toxoplasmosis	≤100-200	Seropositive (IgG antibody to <i>T. gondii</i>)
<i>Candida</i> esophagitis	≤100	Prior <i>Candida</i> colonization High viral load (>10 ⁵ copies/mL)
Cryptosporidiosis	≤100	Environmental exposure (contaminated water, soil, animal exposure)
Histoplasmosis	≤100	Exposure (endemic areas – Midwest, Southeast U.S.)
Coccidioidomycosis	≤100	Exposure (endemic areas – Southwest U.S., Mexico)

Figure 9-1 Decline in the Incidence of Opportunistic Infections in HIV-1-Infected Individuals Receiving Potent Combination Antiretroviral Therapy



Source: Adapted from Palella FJ Jr, Delaney KM, Moorman AC, et al. Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection. HIV Outpatient Study Investigators. *N Engl J Med*. 1998;338:853-860. Copyright 1998 by the Massachusetts Medical Society. Modified with permission (data extrapolated through 2000).

developing a specific OI is determined by the degree of immunosuppression, as measured by the CD4 cell count. The CD4 threshold of risk differs for each specific OI (see Table 9-1). It is uncommon for an OI to occur in HIV-infected individuals with CD4 cell counts above its threshold. For patients with the same CD4 cell count, those with high viral loads (plasma HIV RNA levels > 100,000 copies/mL) have a greater risk for developing an OD than those with a low viral load. Other factors that contribute to increased risk for ODs include previous exposure to or infection with a specific pathogen, prior occurrence of an OD, environmental exposure in the absence of a host response, and the use of ART.

What malignancies are associated with HIV infection?

The most common are Kaposi sarcoma (KS) and lymphomas. There is also a modest increase in the frequency of cervical cancer. In general, these 3 forms of malignancies correlate with immunosuppression, meaning the frequency increases with low CD4 cell counts, but the association is less strong than it is with the traditional AIDS-defining ODs. The rate of KS is approximately 20,000-fold higher with HIV infection compared with the general population, the frequency of non-Hodgkin lymphoma is 200- to 600-fold more frequent with HIV infection, and the rate of cervical cancer is 5-fold greater. Both lymphomas and KS are less frequent in the era of ART.

PNEUMOCYSTIS JIROVECI (CARINII) PNEUMONIA (PCP)

What are the clinical manifestations of PCP in patients with HIV infection?

PCP usually presents as an acute or subacute respiratory illness associated with fever, dyspnea, nonproductive cough, and fatigue. Physical findings on examination include tachypnea, fever, and inspiratory rales. Rarely, disseminated *Pneumocystis* occurs in HIV-infected patients with profound immunosuppression. Laboratory abnormalities associated with PCP include leukocytosis, hypoxemia, an elevated lactate dehydrogenase (LDH), and chest radiographic findings of localized or diffuse interstitial infiltrates. Occasionally, nodular or cavitory lesions may be observed. Pneumothorax in patients with advanced HIV is almost always associated with underlying *Pneumocystis* infection. The degree of hypoxemia is a measure of disease severity; severe PCP is defined as an arterial blood gas PO_2 of < 70 mm Hg with an arterial-alveolar O_2 gradient (AaO_2) of > 35 mm Hg. The diagnosis is confirmed by demonstrating the presence of *P. jiroveci* organisms in sputum or tissue samples obtained by sputum induction, bronchoscopy with bronchoalveolar lavage, or tissue biopsy. In the rare circumstance in which acute PCP presents very early with a normal chest radiograph, a gallium scan may demonstrate diffuse uptake in the lung compatible with an interstitial inflammatory process; however, this diagnostic test is nonspecific.

How should you manage PCP?

The preferred initial treatment for PCP in HIV-infected individuals is trimethoprim-sulfamethoxazole (TMP-SMX). Route of administration (oral or parenteral) is generally based on the severity of the disease. For those with severe PCP, parenteral therapy with trimethoprim 15-20 mg/kg and sulfamethoxazole 75-100 mg/kg, in 6-8 hour divided doses, is recommended. In addition, adjunctive treatment with corticosteroids, in a dose equivalent to 40 mg twice a day of prednisone for the first 5 days, followed by a tapering schedule of 40 mg/day for days 6-10, and then 20 mg/day to complete 21 days of therapy, should be initiated as soon as possible after starting treatment but preferably within the first 72 hours. For patients with mild to moderate PCP (PO_2 > 70 mmHg and AaO_2 gradient < 35 mmHg), oral treatment with 2 double-strength tablets of TMP-SMX every 8 hours is recommended. Gradual dose escalation may reduce the rate of occurrence of adverse reactions to TMP-SMX. For those unable to tolerate TMP-SMX, a number of alternative regimens are available for treatment (see Table 9-2).

Table 9-2. Alternative Regimens for the Treatment of *Pneumocystis carinii* Pneumonia in Those Unable to Tolerate Trimethoprim and Sulfamethoxazole

Disease Presentation	Alternative Treatment Regimens
Severe ($PO_2 < 70$ mm Hg; A-a O_2 gradient > 35 mm Hg)	Pentamidine 3-4 mg/kg/d IV IV Trimetrexate 45 mg/M ² /d IV + Leucovorin 0.5 mg/kg IV q6h Primaquine 15-30 mg/d (base) po + Clindamycin 600-900 mg IV q8h
Mild-moderate	Trimethoprim 15-20 mg/kg/d po + Dapsone 100 mg/d po q8h Primaquine 15-30 mg/d (base) p.o. + Clindamycin 300-450 mg po q6-8 hours Atovaquone suspension 750 mg po bid

What adverse reactions occur with treatment for PCP?

Patients should be carefully monitored for adverse reactions to treatment and response to therapy. Many patients will demonstrate acute worsening of signs and symptoms and have radiographic abnormalities in the first 3-5 days of treatment. This is the rationale for adjunctive corticosteroids in those with severe PCP. Five to 7 days of treatment may be required before a clinical response is observed, defined as a reduction in fever, and improvement in hypoxemia, respiratory symptoms, and radiographic abnormalities.

Adverse reactions to treatment are common in patients with AIDS. Many patients can be treated through these with supportive care and adjunctive medications to ameliorate symptoms; however, severe adverse reactions may require substituting alternative treatment regimens. Adverse effects most often associated with TMP-SMX include skin rash (rarely, Stevens-Johnson syndrome or toxic epidermal necrolysis), fever, hepatotoxicity, leukopenia, thrombocytopenia, renal dysfunction, and hyperkalemia. Major side effects of pentamidine include pancreatitis, renal dysfunction, dysglycemia, electrolyte abnormalities, and cardiac dysrhythmias. Toxicities commonly observed with trimetrexate include bone marrow suppression (particularly in those who are not treated with leucovorin), fever, rash, and hepatitis. Dapsone may cause fever, skin rash, and methemoglobinemia with hemolysis (particularly in those with G-6-PD deficiency). Primaquine also causes methemoglobinemia and

anemia, and clindamycin toxicities include nausea, rash, hepatitis, *Clostridium difficile* toxin-associated diarrhea, and rarely toxic megacolon. Atovaquone is associated with nausea, vomiting, diarrhea, rash, fever, and hepatitis.

Is secondary prophylaxis or maintenance therapy required after treatment of the acute episode of PCP?

All patients with a CD4 count of < 200 cells/mm³ should receive primary prophylaxis to prevent PCP. All patients who have experienced an episode of PCP should receive secondary prophylaxis to prevent a recurrence of PCP. Prophylaxis should be continued for life unless immune recovery occurs with ART. Prophylaxis for PCP should be discontinued if the CD4 count increases to levels of > 200 cells/mm³ and is sustained for at least 3 months. Prophylaxis should be restarted if the CD4 count declines to < 200 cells/mm³ or if PCP recurs regardless of CD4 cell count. Table 9-3 summarizes recommended and alternative regimens for primary and secondary prevention of PCP. It should be noted that TMP-SMX and dapsone plus pyrimethamine are also adequate for prevention of toxoplasmosis in susceptible individuals; dapsone alone, atovaquone alone, and aerosolized pentamidine are not.

Table 9-3. Recommended and Alternative Regimens for the Prevention of *Pneumocystis carinii* Pneumonia in Persons with HIV-1 Infection

Agents	Doses
Preferred	
Trimethoprim-sulfamethoxazole	One double-strength tablet po qd One single-strength tablet po qd
Alternative	
Trimethoprim-sulfamethoxazole	One double-strength tablet po 3x/week
Dapsone	100 mg po qd or 3x/week
Atovaquone	1500 mg po qd
Dapsone + pyrimethamine + leucovorin	200 mg + 75 mg + 25 mg po once/week
Aerosolized pentamidine (Respigard II)	300 mg once/month

MYCOBACTERIUM AVIUM COMPLEX (MAC)

What are the symptoms of MAC?

Disseminated *M. avium* complex disease is a multiorgan infection, usually occurring in patients with AIDS who have CD4 counts of < 50 cells/mm³ and principally affecting blood and lymphoreticular organs (lymph nodes, spleen, liver, bone marrow). Symptoms are nonspecific, usually consisting of high fevers, night sweats, weight loss, anorexia, and fatigue. Hepatosplenomegaly and less commonly central or peripheral lymphadenopathy are seen. Respiratory tract disease with interstitial or occasionally lobar or cavitary pulmonary infiltrates is a less common manifestation but may be seen in the context of multiorgan infection. Although there are no specific laboratory abnormalities associated with disseminated MAC, isolated elevation of alkaline phosphatase, marked anemia, and leukopenia or thrombocytopenia secondary to bone marrow infiltration may occur. The diagnosis is confirmed by the isolation of the organism from a biopsy or a sample obtained for culture from blood or involved tissue; 80%-85% of those with disseminated multiorgan disease have a positive mycobacterial blood culture. Blood cultures may require 7-10 days of incubation before growth of *M. avium* is detectable.

What is the recommended approach to treatment for disseminated MAC?

Disseminated MAC should be treated with a combination of clarithromycin 500 mg twice a day or azithromycin 500-600 mg/day plus ethambutol 15 mg/kg/day. The addition of rifabutin, 300-450 mg/day, as a third drug decreases the occurrence of relapse due to drug-resistant mycobacteria and is associated with improved survival in profoundly immunosuppressed individuals. This approach should be considered for those with very low CD4 cell counts who are not receiving or responding to ART. Treatment should be continued for life unless immune recovery occurs following ART that results in an increase in CD4 cells to levels > 100 /mm³ sustained for at least 6 months. In this setting, antimycobacterial therapy for those who have completed at least 12 months of effective treatment and have no signs or symptoms of disease may be discontinued. Therapy should be re-started if the CD4 cell count again declines to < 100 /mm³.

Primary prophylaxis to prevent disseminated *M. avium* complex disease is recommended for all HIV-infected adults and adolescents who have a CD4 count of < 50

cells/mm³. The preferred regimens are azithromycin 1200 mg once a week or clarithromycin 500 mg twice a day. Azithromycin is preferred when patients are receiving other drugs metabolized by the cytochrome P450 3A4 isoenzyme system, to avoid drug-drug interactions with clarithromycin. Rifabutin 300 mg/day is a second line alternative for prophylaxis, but is less effective than azithromycin or clarithromycin, and also must be monitored and dose-adjusted when used with other drugs metabolized by the cytochrome 3A4 isoenzyme.

CYTOMEGALOVIRUS (CMV) INFECTION

What are the major clinical syndromes associated with CMV infection in patients with HIV infection and how are they diagnosed?

Cytomegalovirus retinitis is the most common CMV-associated clinical syndrome observed in patients with AIDS. Patients with CMV retinitis involving peripheral portions of the retina may have no symptoms, or only minor visual complaints such as floaters or peripheral visual field defects. Central lesions may result in central scotomata and loss of central vision. The diagnosis is based on ophthalmologic examination demonstrating creamy white retinal exudates with hemorrhage; lesions obscure visualization of underlying vessels and other retinal structures. Retinitis is bilateral in up to 20% of patients. Disease progresses rapidly to blindness unless treated.

The second-most common clinical syndrome associated with CMV disease is gastrointestinal disease, either CMV colitis or CMV esophagitis. CMV colitis presents with fever, diarrhea, weight loss, and colon ulceration often with bleeding. Appropriate diagnosis usually requires colonoscopy and biopsy of ulcerations; tissue histopathology confirms the presence of characteristic intranuclear inclusions in mucosal cells or CMV antigens on immunohistochemical staining. CMV esophagitis presents with fever, odynophagia, and retrosternal pain. Exudative ulcers are demonstrated by esophageal endoscopic exam. Biopsy and histopathologic examination are necessary to confirm the diagnosis. Other less common CMV clinical syndromes in patients with AIDS are CMV encephalitis/encephalopathy, interstitial pneumonitis, hepatitis, and pancreatitis.

What is the recommended treatment for CMV retinitis?

CMV retinitis should be managed in cooperation with an experienced ophthalmologist. For patients with CMV retinitis that is immediately sight-threatening (central lesions approaching or involving the optic nerve or the fovea) systemic therapy with either IV ganciclovir or oral valganciclovir is the preferred initial treatment; many experts would also recommend surgical treatment with a ganciclovir intraocular implant (see Table 9-4). IV ganciclovir or oral valganciclovir is administered in an acute “induction” dose for 14-21 days, followed by a once-a-day chronic maintenance therapy dose. This approach is superior to other alternatives for preventing or delaying disease progression and provides systemic treatment to prevent other organ system involvement. If effective ART is not administered or patients remain immunosuppressed, the ocular implant should be replaced every 7-8 months. For patients with peripheral CMV retinitis that is not immediately sight-threatening, oral valganciclovir is the preferred treatment because of its ease of administration compared with other parenteral alternatives.

Table 9-4. Treatment Options for Cytomegalovirus Disease		
Drug	Induction dose	Maintenance therapy dose
Ganciclovir implant	N/A	Replace every 7-8 months
Oral valganciclovir	900 mg bid x 14-21d	900 mg/d
IV ganciclovir	5 mg/kg bid x 14-21d	5 mg/kg/d
Foscarnet	90 mg/kg bid x 14-21d	90 mg/kg/d
IV cidofovir (+ probenecid)	5 mg/kg once/w x 2 wks	5 mg/kg every 2 weeks

Chronic maintenance treatment for CMV retinitis should be continued for life unless ART results in a sustained increase in CD4 counts to levels of $> 100 \text{ cells/mm}^3$ for at least 6 months. If the CD4 count again declines to $< 100 \text{ cells/mm}^3$, maintenance therapy should be reinitiated. Immune recovery vitritis is a recognized complication of acute rises in CD4 cell counts and decreases in plasma HIV RNA levels following initiation of ART. It may be associated with an acute decrease in visual acuity due to the inflammatory cells clouding the vitreous fluid. Treatment with local corticosteroids while continuing anti-CMV therapy is associated with rapid improvement in most patients.

What is the recommended treatment for CMV gastrointestinal disease?

Treatment with either oral valganciclovir or IV ganciclovir or IV foscarnet is the recommended approach to treatment of CMV esophagitis or CMV colitis. In general, clinical symptoms and signs resolve within 2-3 weeks, and the suggested duration of treatment is 21-28 days, depending on the severity of the clinical presentation. Chronic maintenance treatment is not recommended unless recurrent episodes occur.

Strategies for treatment in those with relapse or progressive disease include either re-induction followed by maintenance therapy with the same agent, or switching to an alternative agent, a combination of 2 agents, or specifically for those with CMV retinitis, systemic therapy coupled with intravitreal injection. Recurrent or progressive disease should be managed by an expert.

CANDIDA ESOPHAGITIS

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What are the presenting signs and symptoms of *Candida* esophagitis and how is it diagnosed?

The most common manifestations of *Candida* esophagitis are fever, anorexia, odynophagia, and retrosternal pain. Occasionally, nausea and rarely UGI bleeding from ulceration may occur. Esophagoscopy reveals adherent whitish plaques with shallow ulcers surrounded by erythematous borders. Invasive esophageal candidiasis can occur in the absence of oral candidiasis and must be distinguished from esophagitis due to CMV, herpes simplex virus, and aphthous esophagitis, all of which may be seen in patients with HIV infection. Isolation of *Candida* species in culture from a specimen obtained from the mucosal surface or the base of an ulcer provides supportive information but is not diagnostic, as colonization of mucosal surfaces with *Candida* is common in immunosuppressed individuals, particularly those who are receiving antibacterial therapies such as TMP-SMX for prophylaxis of PCP. The diagnosis can be confirmed by a biopsy of the ulcer and demonstration of yeast forms in tissue. The finding of oral candidiasis associated with esophageal symptoms has a positive predictive value of close to 100 % for *Candida* esophagitis. In patients with oral candidiasis and esophageal symptoms empiric therapy for *Candida* esophagitis should be given. If there is no clinical response after 5-7 days, upper endoscopy should be performed.

How do you treat *Candida* esophagitis?

Candida esophagitis requires systemic therapy. A number of options are available; however, the preferred treatment is fluconazole 100 mg/d for 14 days. Ketoconazole and itraconazole are effective alternatives, but drug-drug interactions with other anti-HIV therapies are common, and absorption is diminished in those with primary or drug-induced hypo- or achlorhydria. For patients unable to tolerate oral therapy, parenteral amphotericin B is effective. Chronic maintenance therapy or secondary prophylaxis is not recommended, but may be considered for patients who have frequent recurrent episodes. Chronic suppressive therapy with fluconazole has been associated with an increased risk of fluconazole (and other azole) resistant disease.

CENTRAL NERVOUS SYSTEM DISEASES

9

How do you distinguish cryptococcal meningitis from toxoplasmic encephalitis and CNS lymphoma in HIV-infected patients?

Patients with AIDS and a CD4 count of < 200 cells/mm³ may be at risk for developing CNS OIs such as cryptococcal meningitis or toxoplasmosis, as well as CNS lymphoma; most infections occur in those with CD4 counts of < 100 cells/mm³. Toxoplasmic encephalitis is rare in patients who are seronegative for *Toxoplasma gondii* (negative IgG antibody). CNS infection due to *T. gondii* and *Cryptococcus* spp. as well as CNS lymphoma may be relatively insidious in onset and associated with symptoms of fever, headache, and mental status changes. Focal neurological deficits and seizures are more likely to occur with toxoplasmic encephalitis and CNS lymphoma, although they sometimes occur in those with cryptococcal meningitis as well. The best diagnostic tests for a differential diagnosis of CNS disease are radiographic imaging of the CNS (with either a contrast-enhanced computerized tomographic [CT] scan or magnetic resonance imaging [MRI] scan) and lumbar puncture with cerebrospinal fluid (CSF) examination. Multiple localized enhancing lesions are common with toxoplasmic encephalitis; MRI is more sensitive than a CT scan for detecting these. CNS lymphoma is more likely to be associated with single and less commonly multiple space-occupying lesions, while cryptococcal meningitis is only rarely associated with space-occupying lesions. The CSF may demonstrate a normal to mild lymphocytic pleocytosis, normal to slightly elevated protein, and

normal to mildly decreased glucose for each, but a CSF cryptococcal antigen will be positive in 99%-100% of individuals with cryptococcal meningitis. Confirmation of the diagnosis of toxoplasmic encephalitis generally requires either demonstration of the organism in CSF by polymerase chain reaction (PCR) or culture (may not be routinely available) or a brain biopsy and demonstration of the organism in tissue. In practice, a trial of therapy is usually the first diagnostic tool for patients who have suggestive neuroimaging and positive *Toxoplasma* serology. Brain biopsy is reserved for patients who do not respond to empiric therapy. A brain biopsy is necessary to confirm the diagnosis of CNS lymphoma.

How do you treat cryptococcal meningitis?

Amphotericin B (0.7 mg/kg/d or the dose equivalent of liposomal or lipid complex amphotericin B), combined with flucytosine 100 mg/kg/day in divided doses, for the first 2 weeks, is the recommended initial treatment for cryptococcal meningitis. If a treatment response is evident this regimen is followed by fluconazole 400 mg/day for an additional 8 weeks or until CSF cultures are negative. The CSF opening pressure should always be measured when a lumbar puncture is performed, and if elevated above 200 mm H₂O, measures to reduce the pressure should be implemented. These may include serial lumbar puncture with CSF drainage sufficient to reduce the pressure by 50%, or in the case of severe increased intracranial pressure, the use of a lumbar drain or ventriculoperitoneal shunt. Secondary prophylaxis or chronic maintenance therapy with fluconazole, 200 mg/day, should be continued for life unless ART results in immune recovery. In this instance, maintenance therapy may be discontinued for those who have successfully completed a course of therapy for cryptococcal meningitis, have no residual signs or symptoms, and have a sustained increase in CD4 count to levels of > 100 -200 cells/mm³ for at least 6 months. Maintenance therapy should be re-initiated if the CD4 count again decreases to < 100 -200 cells/mm³.

MYCOBACTERIUM TUBERCULOSIS

Does the presentation of tuberculosis differ in HIV-infected and non-HIV-infected individuals?

Patients with HIV infection have an increased risk of infection with *Mycobacterium tuberculosis* following exposure to a person with active disease, and an

increased risk of developing active disease following an exposure. The risk of developing active disease is 30%-40% in the first year following a new exposure, and for HIV-infected patients with a positive tuberculin skin test related to prior TB exposure, the risk of developing active disease may be as high as 7%-8% per year.

For patients with a CD4 count of > 250 cells/mm³, the clinical signs and symptoms of tuberculosis are generally the same as for HIV-noninfected persons. Pulmonary tuberculosis accompanied by fever, cough, sputum production, chest pain, night sweats, weight loss, and anorexia is the principal manifestation. As immunosuppression progresses, the likelihood of extrapulmonary or disseminated (miliary) disease increases, although in most instances, pulmonary involvement is also present. Chest radiograph demonstrates lobar consolidation with cavitation, usually involving upper lobes, when reactivation tuberculosis is present. In those with primary tuberculous pneumonia, lower lobe infiltrates are more common. Hilar or mediastinal lymphadenopathy, pleural effusion, and interstitial infiltrates may be more common in patients with lower CD4 cell counts.

How do you diagnose TB in persons with HIV?

The diagnosis is the same as for non-HIV-infected persons, relying on a combination of compatible clinical signs and symptoms, radiographic findings, a positive tuberculin skin test, and a sputum sample demonstrating acid-fast bacilli (AFB). The diagnosis is confirmed by culture of the organism from sputum, blood, or other tissue. However, patients with advanced immunosuppression may have less extensive consolidation or lung cavitation, and sputum AFB smears may be positive in a lower proportion, because of the lower mycobacterial burden in the lung. Also, tuberculin skin tests are less likely to be positive because of impaired cell-mediated immune function. In immunocompromised patients, more aggressive means for making a diagnosis may be necessary, such as bronchoscopy with bronchoalveolar lavage or transbronchial biopsy to obtain samples for AFB smear and culture. Biopsy or culture of specimens obtained from extrapulmonary sites such as bone marrow and lymph nodes may be useful. All initial isolates of *M. tuberculosis* should be tested for susceptibility to antimycobacterial drugs, and susceptibility testing should guide the choice of initial treatment.

How do you treat tuberculosis in patients with HIV infection?

The recommendations for treatment of tuberculosis in patients with HIV infection depend in part on whether or not patients are on ART, and if they are, the specific antiretroviral regimens employed. All patients should receive directly observed therapy. See Adult OI Tables 2 - 7 for the recommendations for treatment of latent tuberculosis and drug-susceptible tuberculosis disease. Treatment with 4 drugs (isoniazid, rifampin or rifabutin, ethambutol, and pyrazinamide) is recommended either for the first 2 months of therapy or until results of susceptibility testing are available. If patients have drug-susceptible disease, 2 drugs, isoniazid and rifampin or rifabutin, should then be continued for at least 18 additional weeks. The continuation phase of therapy should be extended to 28 weeks (total duration of 9 months) for HIV-infected patients with advanced immunosuppression (CD4 count of < 100 cells/mm³) or who have an inadequate initial response or cavitary disease. Rifabutin should replace rifampin and doses should be appropriately adjusted for those who are receiving ART with agents likely to interact with rifamycins. The timing of initiation of ART and the most appropriate ART regimen for use in conjunction with antimycobacterial therapy remain controversial. Concurrent ART and tuberculosis treatment should be managed by an expert.

MALIGNANCIES

How does Kaposi sarcoma (KS) present?

KS is a poorly understood multicentric tumor of endothelial cells. The cause is human herpesvirus 8 (HHV-8), an infection that is more frequent in men who have sex with men. The mechanism of transmission is unclear, but the best evidence suggests transmission via saliva and semen. Many carry the virus with no consequences; it causes disease primarily in the presence of immunosuppression. The presentation is highly characteristic, with multiple purple to brown-black macules, or nodules that are usually asymptomatic and occur most frequently on the legs, face, oral cavity, or genitalia. The major complications include lymphedema (especially of the legs, face, and genitalia) and visceral involvement. Visceral involvement is common in the lung and GI tract, but is usually asymptomatic.

How do you diagnose KS?

The skin lesions are usually sufficiently characteristic to make this diagnosis clinically based on appearance, but a biopsy should be done when there is a need for confirmation. The differential diagnosis includes bacillary angiomatosis (which can be proven by biopsy with silver stain), hematoma, nevus, hemangioma, B-cell lymphoma, and pyogenic granuloma. When there is visceral involvement, the usual method used to establish the diagnosis is endoscopic examination to show typical mucosal surface lesions. With lung involvement, the x-ray is variable and may show nodules, infiltrates, effusions, and/or mediastinal/hilar nodes. Lung biopsy is often negative, but the bronchoscopic exam often shows a characteristic cherry-red bronchial nodule. With GI tract involvement, the usual screening test is stool for occult blood, and endoscopy is the usual method to make the diagnosis by showing a hemorrhagic nodule; the biopsy is often negative because of the submucosal location of the tumor.

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How do you treat KS?

Many patients require no therapy except possibly makeup to cover the characteristic lesions. Topical treatment for skin involvement includes vinblastine, Panretin gel, liquid nitrogen, radiation, cryosurgery, or laser. Systemic chemotherapy is preferred when there is an extensive burden, defined as > 25 skin lesions, symptomatic visceral involvement, extensive edema, systemic (B) symptoms, or failure to respond to local treatment. The favored forms of chemotherapy are liposomal anthracyclines (Doxil or DaunoXome) or, less frequently, paclitaxel (Taxol). Immune reconstitution with ART is associated with a substantial reduction in the frequency of KS and a therapeutic improvement in those who already have these lesions. It should be noted that there is no cure for KS, and the goal of local therapy or systemic chemotherapy is to reduce tumor burden and relieve symptoms.

What lymphomas are associated with HIV infection?

The subtypes of lymphomas associated with HIV infection include B-cell large cell lymphoma, primary body effusion lymphomas, B-cell CNS lymphoma, Burkitt lymphoma, plasmablastic lymphoma, and Hodgkin disease. The most common is non-Hodgkin lymphoma.

What are the symptoms of non-Hodgkin lymphoma (NHL)?

Compared with the general population, patients with this complication have high rates of stage IV disease with systemic (B) symptoms and sparse node involvement. Common symptoms are fever of unknown origin, liver dysfunction, marrow suppression, lung disease (effusions, multinodular infiltrates, mass lesions, diffuse infiltrates, and/or hilar adenopathy), GI involvement (any level with pain and weight loss), and CNS with mass lesions.

How do you diagnose lymphomas?

Fine needle aspirates of enlarged nodes are helpful if positive, but false negatives are common. Biopsy is usually necessary.

How are lymphomas treated and what should be expected?

The usual treatment is chemotherapy with cyclophosphamide, doxorubicin, adriamycin, vincristine, and prednisone (CHOP); methotrexate, bleomycin, doxorubicin, cyclophosphamide, vincristine, and dexamethasone + G-CSF (M-BACOD); or etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin (EPOCH). Response rates are 50 % -60 %, but the long-term prognosis is poor unless there is immune reconstitution with ART.

How do you diagnose and treat primary CNS lymphomas?

The typical presentation is confusion, headache, memory loss, focal neurologic changes, usually without fever and usually with a CD4 cell count of < 50/mm³. The MRI shows single or multiple lesions that are isodense or hypodense. The differential diagnosis is primarily toxoplasmosis. Factors suggesting CNS lymphoma are the characteristic MRI findings, negative *T. gondii* serology, failure to respond to empiric treatment of toxoplasmosis within 1-2 weeks, thallium single-photon emission computed tomography (thallium SPECT) scan results, and CSF positive by polymerase chain reaction (PCR) for Epstein Barr virus (EBV) DNA. The definitive diagnosis can be made by stereotactic brain biopsy. Treatment is radiation and corticosteroids, often combined with chemotherapy. The prognosis is poor without immune reconstitution.

KEY POINTS

The risk of persons with HIV developing specific ODs is related to the degree of their immunosuppression, as measured by the CD4 cell count.

All patients with a CD4 count of < 200 cells/mm³ should receive primary prophylaxis to prevent PCP. PCP usually presents as an acute or subacute respiratory illness associated with fever, dyspnea, nonproductive cough, and fatigue.

All patients with a CD4 cell count of < 50 /mm³ should receive primary prophylaxis to prevent disseminated MAC. Disseminated MAC is a multiorgan infection that usually occurs at CD4 cell counts of < 50 /mm³. Symptoms are nonspecific, usually consisting of high fever, night sweats, weight loss, anorexia, and fatigue.

CMV retinitis, the most common CMV-associated clinical syndrome, progresses rapidly to blindness unless treated. CMV gastrointestinal disease, either colitis or esophagitis, presents with fever, diarrhea, weight loss, and colon ulceration often with bleeding.

The most common manifestations of *Candida* esophagitis are fever, anorexia, odynophagia, and retrosternal pain. Treatment requires systemic therapy.

Patients with a CD4 count of < 200 cells/mm³ are at risk for developing CNS ODs such as cryptococcal meningitis or toxoplasmosis, as well as CNS lymphoma. After initial treatment, chronic maintenance therapy should be continued for life unless immune recovery occurs as a result of ART.

Patients with HIV are at increased risk of infection with *Mycobacterium tuberculosis* and of developing active tuberculosis. Immunosuppression increases the likelihood of extrapulmonary or disseminated (miliary) disease. Because tuberculin skin tests are less likely to be positive in immunocompromised patients, more aggressive means for making a diagnosis may be necessary.

All HIV-infected patients with active tuberculosis should receive directly observed therapy. Treatment of tuberculosis in persons with HIV co-infection should be managed by an expert because treatment is complex and the infection is potentially life-threatening.

The major complications of KS, a multicentric tumor of endothelial cells, include lymphedema (especially of the legs, face, and genitalia) and visceral involvement. Extent of involvement determines whether treatment is required and whether it is topical or systemic.

The most common lymphoma associated with HIV is non-Hodgkin lymphoma. Common symptoms are fever of unknown origin, liver dysfunction, marrow suppression, lung disease, GI involvement (any level with pain and weight loss), and CNS mass lesions.



SUGGESTED RESOURCES

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Chapter 10:

Abnormal Laboratory Values in HIV Disease

*David H. Spach, MD**John G. Bartlett, MD**COMMON ABNORMALITIES**HEMATOLOGIC COMPLICATIONS**LIVER DISEASE**RENAL DISEASE**KEY POINTS**SUGGESTED RESOURCES**REFERENCES*

COMMON ABNORMALITIES

What are some common abnormalities found when screening asymptomatic patients?

Some disease processes associated with HIV can be first identified in laboratory screening tests while patients are still asymptomatic. The primary care provider plays an essential role in monitoring for laboratory abnormalities, whether these abnormalities result from diseases or from antiretroviral therapy (ART). Table 10-1 lists screening tests that assist in promptly identifying and managing medical problems in asymptomatic patients. Abnormal laboratory tests occur more frequently in HIV-infected persons because 1) HIV is a multi-system disease, 2) HIV causes immune suppression that may result in opportunistic infections and tumors that involve multiple systems, 3) the drugs used routinely in management can cause adverse reactions that affect multiple systems, and 4) patients at high risk for HIV are often at high risk for other medical conditions.

What constitutes a positive PPD in HIV disease?

Induration of 5mm or more at 48-72 hours constitutes a positive PPD test for tuberculosis in a person with HIV. A PPD should be done at baseline and repeated annually if the initial test was negative and the patient is in a high-risk category for tuberculosis. The test has a relatively high rate of false-negative results in patients with a CD4 cell count of $< 200/\text{mm}^3$. Therefore, if the initial test was done when the CD4 cell count was low, it should be repeated when the CD4 cell count increases to $> 200/\text{mm}^3$ following ART. Patients with a positive PPD test need a chest x-ray and evaluation for active disease before isoniazid (INH) prophylaxis is initiated.

What is the role of a baseline chest x-ray?

A chest x-ray is recommended for detection of latent or active tuberculosis and other lung diseases and as a baseline for patients who are at high risk for pulmonary disease, especially bacterial pneumonia, *Pneumocystis* pneumonia, and tuberculosis. The x-ray is particularly important for any patients with a positive PPD skin test.

What do you do when a patient has a positive VDRL or RPR?

The standard screening tests for syphilis in sexually active patients are the nontreponemal tests, the VDRL or RPR. Any positive screening test should be confirmed with a fluorescent treponemal antibody absorbed test (FTA-ABS). Confirmation is particularly important because for biologic false-positive tests are more common with injection drug use, pregnancy and HIV infection. With a positive test, primary, secondary, and early latent syphilis (less than 1 year) should be treated with a single injection of benzathine penicillin (2.4 million units IM) once, late latent syphilis (more than 1 year or of unknown duration) should be treated with 3 doses at 1-week intervals of benzathine penicillin (2.4 million units IM with each dose), and neurosyphilis should be treated with aqueous penicillin G, 18-24 million units/day IV for 10-14 days. Patients who are not pregnant and do not have neurosyphilis who cannot receive penicillin may be treated with doxycycline (100 mg po bid) given for 14 days for primary, secondary, and early latent syphilis and for 28 days for late latent syphilis. Because the efficacy of doxycycline is not well established, patients who received doxycycline need extra followup. With penicillin allergy and neurosyphilis or pregnancy, there should be penicillin skin testing; if negative, penicillin is given, and if positive the patient should undergo penicillin desensitization followed by penicillin treatment. A lumbar puncture is recommended for any patient with neurologic signs or

Table 10-1. Abnormalities Identified in Screening Tests

Test	Implications of abnormal findings
CBC	Anemia – usually due to HIV or zidovudine Neutropenia – usually due to HIV or drugs, especially ganciclovir and zidovudine Thrombocytopenia – usually due to HIV
Alanine aminotransferase (ALT)	Usual causes of elevated levels are chronic hepatitis (HBV, HCV), alcoholic liver disease, or adverse drug reactions.
Creatinine	Usual causes of renal failure are common medical conditions in this population (hypertension, heroin use, diabetes, IgA nephropathy, etc), adverse reactions to drugs (including indinavir), or HIV nephropathy
Toxoplasma titer	Positive results in 10% of adults in US, higher in other countries. This indicates latent disease with possible activation if CD4 count < 100/mm ³
VDRL or RPR	If positive, need confirmatory FTA-ABS
Screen for <i>N. gonorrhoeae</i> and <i>C. trachomatis</i>	Positive results indicate high-risk behavior and need for treatment
PPD	Induration ≥5mm indicates need for evaluation for active TB and, if negative, INH treatment
Chest x-ray	Ghon complex, adenopathy, or evidence of chronic lung disease
CD4 count	Barometer of immune function
Viral load	Indicates rate of progression of untreated HIV and response to HAART
Hepatitis panel	
Anti-HCV	Positive results ± confirmatory HCV RNA usually indicates chronic HCV infection
Anti-HBc or Anti-HBs serology	Positive results indicate prior antigenic experience with HBV
HBsAg	Indicates HBV; if positive >6 months indicates chronic HBV
Anti-HAV	Positive test indicates prior antigenic experience due to HAV infection or vaccination

symptoms, patients with therapeutic failure (persistent clinical evidence of syphilis or a sustained 4-fold increase in titer), and all patients with latent syphilis, which includes latent syphilis of unknown duration. Some experts have recommended performing lumbar puncture for all HIV-infected persons with syphilis, regardless of the stage of syphilis. With respect to followup, the nontreponemal test should be done at 3, 6, 9, 12, and 24 months.

HEMATOLOGIC COMPLICATIONS

What are the common causes of anemia?

Anemia, which is common in HIV disease, is usually caused by 1) late-stage HIV, presumably due to viral infection of progenitor cells, 2) associated complications that infiltrate the marrow, 3) nutritional deficiency, 4) adverse drug reactions, or 5) iron deficiency. The findings and management are summarized in Table 10-2.

What causes thrombocytopenia?

Most cases are attributed to HIV infection of the multi-lineage hematopoietic progenitor cells in the marrow. This HIV-associated thrombocytopenia can occur in relatively early HIV, but is more common with late-stage disease. Although zidovudine (AZT) may cause anemia or neutropenia, early studies showed that it reverses thrombocytopenia. For patients not receiving ART, the preferred treatment for HIV-associated thrombocytopenia is to promptly initiate ART. The decision to intervene with intravenous immune globulin (IVIG) or corticosteroids is driven by signs or symptoms of active bleeding, the need to do an invasive procedure, or a lack of response to ART.

What causes neutropenia?

Neutropenia is most commonly related to drug therapy, especially with zidovudine (AZT), ganciclovir, or valganciclovir, but it can also be caused by late-stage HIV or marrow-infiltrate disease. With absolute neutrophil counts of < 500/mm³ it is important to monitor for infection and intervene with empiric antibiotics rapidly when appropriate. Address neutropenia by discontinuing the implicated agent or by providing cytokine therapy using G-CSF or GM-CSF.

Table 10-2. Causes of Anemia in HIV				
Cause	Cells	Reticulocyte count	Other tests	Treatment
HIV disease	Normal	Low	Low erythropoietin level	ART Recombinant human erythropoietin (rHU EPO)
Tumors and infectious diseases	Normal	Low	Positive identification of underlying disease (eg, lymphoma, KS, MAC, TB, CMV, histoplasmosis)	Treatment of underlying disease
Parvovirus	Normal	0	Positive serology & PCR for parvovirus	IVIG
Nutritional deficiency	MCV > 100 (but not with AZT or d4T)	Low	Low B12/folate level	Folic acid or cobalamin
Iron deficiency	MCV low	Low	Blood loss, low Fe, transferrin	Treatment of cause Iron therapy
Drug (toxicity)	Normal	Normal	Identify offending drug (zidovudine, ganciclovir, TMP-SMX, etc.)	Stop implicated agent
Drug (hemolysis)	Normal	Increased	Identify offending drug (dapsone, ribavirin); increased LDH, indirect bilirubin/low haptoglobin	RBC therapy Stop drug

LIVER DISEASE

What are the common causes of abnormal liver function tests?

Abnormal screening liver function tests reflect associated conditions (hepatitis B or C viral infection as discussed below), adverse drug reactions, alcoholic hepatitis, and HIV-related complications, including Kaposi sarcoma, lymphoma, *Mycobacterium avium* complex (MAC), tuberculosis, cytomegalovirus (CMV), or histoplasmosis. Start by defining the process as cholangiopathic or hepatocellular based on results of liver function tests (LFTs).

- AIDS cholangiopathy typically presents with right upper quadrant pain, high alkaline phosphatase, characteristic duct dilatation on ultrasound, and a CD4 cell count of < 100/mm³. The usual causes are infection (microsporidia, cytomegalovirus, or cryptosporidia) or idiopathic. Most cases respond temporarily to endoscopic biliary sphincterotomy.
- Hepatocellular injury is much more common and is caused by diverse conditions, including 1) hepatitis viruses, 2) alcoholic hepatitis, 3) cirrhosis, and 4) adverse drug reactions. All antiretroviral drugs are potentially hepatotoxic, but the indications for intervention vary depending on the mechanism and severity (see Table 10-3).

When should you stop antiretroviral drugs because of hepatotoxicity?

There are 3 situations in which antiretroviral drugs should be stopped because of hepatotoxicity (see Table 10-3):

- **Hypersensitivity syndrome (drug rash with eosinophilia and systemic symptoms [DRESS])**
The hypersensitivity reaction seen with abacavir (ABC) and nevirapine (NVP) is characterized by fever, eosinophilia, rash, and GI complaints, and usually occurs during the first 6 weeks of therapy. This situation should be urgently managed, and deaths have been reported.
- **Symptomatic lactic acidosis** This is ascribed to drugs in the NRTI class, which should be stopped.
- **Increased transaminase levels** This is ascribed to the PIs and the NNRTIs nevirapine (NVP) and efavirenz (EFV). The most serious reactions have occurred with nevirapine-associated hepatotoxicity. The mechanism is unclear, and treatment interruption is often considered necessary only when clinical hepatitis occurs.

Do patients infected with HIV have increased rates of hepatitis B virus (HBV) and hepatitis C virus (HCV) infection, and does coinfection affect the natural progression of HIV?

HIV-infected patients have higher rates of chronic HBV infection after exposure to HBV. With HBV coinfection, there is a higher frequency of evidence for HBV replication (higher frequency of HBeAg and higher levels of HBV DNA) and higher rates of HBV-associated liver disease. It is not known if HBV alters the natural history of HIV, but coinfection is associated with increased frequency of hepatotoxicity with ART. The relationship with HCV is similar. HIV coinfection is relatively common, a frequency of about 30% in all HIV-infected patients and as many as 85% in those with injection drug use as the risk factor. HIV has an

Table 10-3. Antiretroviral Drugs That Cause Abnormal Liver Function

Drugs	Frequency of abnormal liver function	Comment
NRTIs		
stavudine (d4T) didanosine (ddI) zidovudine (AZT)	8%-16%	Mitochondrial toxicity; risk highest with stavudine and didanosine together; risk with zidovudine lower than stavudine
lamivudine (3TC) emtricitabine (FTC) abacavir (ABC) tenofovir (TDF)		Rare cause of mitochondrial toxicity
abacavir (ABC)	4%-6%	Hypersensitivity-DRESS syndrome
lamivudine (3TC) emtricitabine (FTC) tenofovir (TDF)		Withdrawal of these drugs may cause HBV exacerbation
NNRTIs		
nevirapine (NVP) efavirenz (EFV)	8%-16%	Mechanism not known
nevirapine (NVP)	Rare	Hypersensitivity – DRESS syndrome
PIs		
All PIs	4%-6%	Mechanism unknown
indinavir (IDV) atazanavir (ATV)	10%-20% 30%-50%	Elevated indirect bilirubin; usually asymptomatic

important effect on promoting more rapid progression of HCV, but it is not clear whether HCV adversely affects the rate of HIV progression. Many studies have shown that HCV coinfection is a poor prognostic factor in the ART era, but this may well reflect the influence of injection drug use rather than HCV-associated liver disease.

Who should you test for HBV and HCV, and what tests should you perform?

At entry into health care, all patients with HIV should be screened for antibodies to HBV and HCV, as well as HBV antigen (see Table 3-1 in Chapter 3). Knowledge of the HBV and HCV status can provide valuable information for those persons with abnormal LFTs. In addition, testing can identify patients who are seronegative for HBV who can receive HBV vaccination. Some patients with HIV have negative HBV surface antibody titers, negative HBV antigen, but positive core HBV antibody. If they have not recently acquired HBV, this serologic pattern suggests a low-level persistent immune response to HBV; these individuals probably have adequate protection to prevent reinfection, but no studies have been done to accurately evaluate their risk. Moreover, no formal recommendation exists to provide a booster HBV vaccine to those persons with negative HBV surface antibody titers but positive HBV

core antibody. Serologic testing using an enzyme immunoassay for HCV is the preferred screening test for HCV, and those with positive tests should have a confirmatory test with either the RIBA assay or a test that detects HCV RNA. Several studies have shown that some persons coinfecting with HIV and HCV, particularly those with severe advanced HIV disease, can have a negative HCV antibody test on the enzyme immunoassay, but a repeatable positive HCV RNA test. Thus, some experts would recommend doing an HCV RNA assay on a person with a negative HCV enzyme immunoassay if HCV infection is suspected (usually because of abnormal LFTs).

How should you treat HBV in persons coinfecting with HIV?

All coinfecting patients should be considered for HBV therapy. Recommendations are somewhat arbitrary, but most recommend therapy with an alanine aminotransferase (ALT) at least 2 times the upper limit of normal (ULN), evidence of active HBV replication (e antigen or HBV DNA level of $> 10^5$ c/mL), and preferably with histologic evidence of moderate disease activity or fibrosis. There are 2 major forms of treatment and neither is “preferred.” One form is interferon- α -2a or α -2b given subcutaneously 3 times a week or once a day for 24-48 weeks. Many authorities now

recommend pegylated interferon with subcutaneous injections once a week, although there are few published studies with this formulation for treatment of HBV. The second form of therapy is nucleosides and nucleotides with activity against HBV. This gets tricky because many of these agents are active against HIV as well, and there are variable rates of HBV resistance. Lamivudine (3TC) is highly active against HBV but is associated with high rates of HBV resistance, up to 90% at 4 years. The same applies to emtricitabine (FTC). Alternatives are adefovir dipivoxil (trade name Hepsera), which is used in a dose that is probably not active against HIV but is highly active against HBV, has good activity against lamivudine-resistant strains, and has low rates of resistance by HBV during treatment. Tenofovir (TDF) has the same attributes as adefovir but is also highly active against HIV. It should be emphasized that the rationale for treating HBV is to reduce viral replication and hepatic disease progression but that cure is rarely achieved. Other standard components of therapy in patients coinfecting with HBV are 1) advising them to avoid or limit alcohol consumption, 2) teaching them appropriate precautions to prevent transmission of both viruses, and 3) administering hepatitis A vaccine if they are susceptible.

Who should receive HBV vaccine?

All HIV-infected persons with no evidence of HBV infection should receive this vaccine, although the response rates are related to age (decreased with increasing age) and with CD4 cell counts (responses decrease with lower counts). The standard is 3 doses followed by a measurement of HBs antibody levels about 1 month after the third dose. If the level is < 10 IU/mL the 3-dose series should be repeated. If the patient does not respond to the second series, no further vaccinations are currently recommended and the patient is considered a “non-responder.”

How do you treat patients with HCV coinfection?

Patients coinfecting with HIV and HCV should be 1) advised to avoid or limit alcohol consumption, 2) counseled to use appropriate precautions to prevent transmission of both viruses, and 3) given hepatitis A and B vaccine if they are susceptible. The prevention message should emphasize that the major route of transmission is by shared needles; the risk of transmission of HCV perinatally or with sexual contact is substantially less than that for HIV or HBV.

With regard to treatment of HCV, the goal is for cure, something that cannot be achieved with HIV or, to a large extent, with HBV. All patients with HCV should be evaluated for HCV therapy. Standard indications in the absence of HIV infection are chronic HCV, detectable HCV-RNA, and a liver biopsy showing bridging or portal fibrosis. The ALT levels may be elevated, but this finding is variable and does not indicate the severity of HCV-associated liver disease and is considered nonspecific. The liver biopsy is important for HCV therapeutic decisionmaking, but it is indicated only if the patient is considered a candidate for treatment based on multiple variables including the severity and stability of HIV, other comorbidities, probability of adherence, and contraindications for interferon. The standard treatment is pegylated interferon plus ribavirin for 48 weeks, regardless of the genotype. There is limited long-term experience with this treatment in patients with HIV coinfection, but it appears that the rate of a sustained virologic response as indicated by negative HCV DNA levels at 6 months post-therapy are significantly lower compared to those who are seronegative for HIV. This particularly applies to genotype 1, which accounts for the majority of cases. It also appears that the optimal response occurs when patients have relatively high CD4 cell counts, so this treatment is often preferred for those in early stage disease and for those who have responded to ART.

What HCV therapy should you use for persons coinfecting with HIV and HCV?

Currently, there are limited published data regarding various HCV treatment regimens for persons coinfecting with HIV. Trials have generally shown relatively poor responses to interferon monotherapy. Based on rapidly accumulating data from trials that have not included HIV-infected persons, pegylated interferon (pegylated interferon-alpha-2a or pegylated interferon-alpha-2b) plus ribavirin is now the standard of care. (For treatment guidelines, refer to Suggested Resources.) In addition, several series involving persons coinfecting with HIV and HCV have suggested better sustained viral response rates with pegylated interferon plus ribavirin than with older regimens. For persons not infected with HIV, recent guidelines have recommended that those with genotypes 2 or 3 receive 24 weeks of therapy and those with genotypes 1 and 4 receive 48 weeks of therapy. The optimal duration of therapy for persons coinfecting with HIV and HCV remains unknown, but most trials have used 48 weeks, regardless of genotype.

Are there special considerations regarding adverse effects of HCV therapy in persons coinfecting with HIV?

Treatment with interferon (or pegylated interferon) and ribavirin has significant possible adverse effects, including reactions at injection sites, bone marrow suppression, thyroid dysfunction, neuropsychiatric symptoms, and birth defects. Because interferon may cause significant leukopenia, CD4 cell counts should be monitored, and patients should be warned that CD4 counts might transiently decline while they are receiving interferon. Persons coinfecting with HCV and HIV may suffer drug interactions and toxicities. Ribavirin causes anemia; because this complication occurs more frequently when ribavirin is combined with AZT, either this combination should be avoided or more frequent use of erythropoietin should be anticipated. Ribavirin may enhance intracellular didanosine (ddI) levels and augment toxicity of the drug resulting with higher rates of pancreatitis and lactic acidosis; didanosine should not be given with ribavirin.

Is liver transplantation an option for HIV-infected persons?

Liver transplantation is an option in some transplant centers that combine expertise in HIV management with the transplant service. In a study at 5 institutions of 24 HIV-infected patients survival rates were similar to rates in patients without HIV infection (Ragni et al, 2003). Nevertheless, management is complicated by problems of drug interactions between ART and the standard immunosuppressive agents, poor tolerance of ART after liver transplantation, and relatively high frequency of acute graft rejection. As in patients without HIV infection, the prognosis with liver transplantation is poorer when liver disease is caused by HCV. The recommendation at present is to give the highest priority in patients with HIV infection to those without HCV and to those receiving and tolerating ART who have achieved HIV virologic control and immune reconstitution.

RENAL DISEASE

What are the possible causes of abnormal renal function tests?

Renal function is important to monitor because abnormal renal function may require altering drug dosage regimens, and it is important to know the cause of the abnormality. In general, renal dysfunction in patients with HIV infection can be caused by adverse drug reactions, HIV-associated nephropathy, and non-HIV-related conditions. The multitude of conditions that are not necessarily complications of HIV infection or its treatment include hypertension, glomerulonephritis, and heroin use.

For the patient on ART, what drugs are most likely to cause renal disease?

Adverse drug reactions that cause renal disease are most commonly associated with aminoglycosides, amphotericin, foscarnet, and cidofovir. The antiretroviral agent that is most frequently implicated is indinavir (IDV), which may cause indinavir crystals in the collection system, resulting in nephrolithiasis. The presentation may be renal colic, or it may be asymptomatic with evidence of crystals on urinalysis. In addition, indinavir can cause a crystal-induced nephropathy. On rare occasions, tenofovir (TDF) may cause renal insufficiency.

What are the cause and implications of HIV-associated nephropathy?

HIV-associated nephropathy, which is apparently the result of HIV infection of the kidney, presents as large, echogenic kidneys on ultrasound, nephrotic-range proteinuria, and rapidly progressing renal failure. This may occur at any stage of HIV but is most common as a late complication. Pre-ART studies show benefit from treatment with ACE inhibitors and possibly with corticosteroids; more recent studies show anecdotal evidence of a sometimes dramatic response to ART, but data from controlled trials are not available. Renal biopsy is necessary to establish the diagnosis. For patients with end-stage renal disease, there is increasing interest in and experience with renal transplantation. The usual criteria are irreversible renal failure combined with HIV response to ART resulting in virologic control and a CD4 cell count of $> 200/\text{mm}^3$.

KEY POINTS

Laboratory tests are frequently abnormal in HIV disease because 1) HIV is a multi-system disease, 2) HIV causes immune suppression that may result in opportunistic infections and tumors, 3) treatment has many potential adverse reactions affecting multiple systems, and 4) patients with HIV are often at high risk for other medical conditions.

Hematologic complications include anemia, neutropenia, and thrombocytopenia. The most common causes of anemia and neutropenia are either drug toxicity or the direct effect of HIV on progenitor cells; the cause of thrombocytopenia is most commonly a direct effect of HIV.

Liver disease is common because of high rates of concurrent viral hepatitis, especially HCV, and because all antiretrovirals are potentially hepatotoxic.

Abnormal renal function is usually a direct effect of HIV infection of the kidneys resulting in a rapid progression with nephrosis and end-stage renal disease; abnormal renal function from any cause is important to know about because it requires altering dose regimens for nucleosides.



SUGGESTED RESOURCES

(CONTINUED)

Management of Hepatitis C: 2002. NIH Consensus and State-of-the-Science Statements. 2002 Jun 10-12;19:1-46. Available at: <http://www.consensus.nih.gov>. Accessed 12/03.

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Sulkowski MS, Thomas DL. Hepatitis C in the HIV-infected person. *Ann Intern Med* 2003;138:197-207.

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SUGGESTED RESOURCES

Kimmel PL, Barisoni L, Kopp JB. Pathogenesis and treatment of HIV-associated renal diseases. *Ann Intern Med.* 2003;139:214-226.

Lok ASF, McMahon BJ. AASLD Practice Guidelines *Hepatology* 2001;34:1225-1241. Available at http://www.cdc.gov/ncidod/diseases/hepatitis/b/hepatitis_b_guidelines.pdf Accessed 1/04.



WEBSITES

CDC National Center for Infectious Diseases: <http://www.cdc.gov/ncidod/diseases/hepatitis/> Accessed 2/04.

Hepatitis B Foundation: <http://www.hepb.org> Accessed 2/04.

HIV and Hepatitis: <http://www.hivandhepatitis.com> Accessed 2/04.

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Ragni MV, Belle SH, Im K, et al. Survival of human immunodeficiency virus-infected liver transplant recipients. *J Infect Dis.* 2003;188:1412-20.

Chapter 11:**Postexposure Prophylaxis**

*Renslow Sherer, MD
Bruce D. Agins, MD, MPH
Caroline J. Teter, PA-C, MPH*

*OVERVIEW**INTERVENTIONS FOR PEP IN HEALTH CARE SETTINGS**INTERVENTIONS FOR NONOCCUPATIONAL PEP (NPEP)**HIV PEP TREATMENT RECOMMENDATIONS**HEPATITIS PEP TREATMENT RECOMMENDATIONS**KEY POINTS**SUGGESTED RESOURCES**REFERENCES**CASES***OVERVIEW****What is postexposure prophylaxis (PEP)?**

Postexposure prophylaxis (PEP) prevents or aborts transmission of HIV with rapid initiation of short-term antiretroviral therapy (ART) following occupational or nonoccupational exposure. PEP should be considered in all health care personnel (HCP) and non-HCP exposed to blood or potentially infectious body fluids via percutaneous, mucous membrane, and nonintact skin exposures, injection drug use, intentional or unintentional sexual exposures, and human bites. Hepatitis B infection may be prevented following administration of immune globulin and vaccination when indicated.

PEP policies should be instituted in all health care settings. The essential elements include:

- Written protocols for documenting and managing exposures
- Assessment, counseling, and intervention immediately after any exposure
- Rapid access to medications and/or immunization, if indicated

What do we know about the effectiveness of PEP for HIV?

Retrospective case-control studies support the efficacy of PEP for occupational exposure to HIV, and 4 factors are associated with increased transmission rates: 1) deep injury, 2) visible blood on device, 3) needle placement in artery or vein, and 4) late stage HIV disease in source (this risk factor was identified prior to viral load testing, thus high viral load is likely an independent risk factor). Evidence of the effectiveness of nonoccupational PEP comes from small observational human studies,

extrapolation of data showing the interruption of maternal-infant transmission, and animal studies showing some degree of protection from genitally and intravenously acquired HIV. Even with optimal implementation, the degree of protection afforded by PEP is incomplete. Studies of PEP have demonstrated the greatest reduction in HIV transmission when antiretroviral medications are administered immediately after exposure to HIV-infected blood and body fluids. The efficacy of PEP is diminished after 36 hours and is minimal after 72 hours.

What do we know about the effectiveness of PEP for hepatitis B and C?

Hepatitis B transmission can be prevented through administration of immune globulin and hepatitis B vaccine. PEP for hepatitis C virus (HCV) has thus far proven to be ineffective.

What body fluids are infectious for HIV, HBV, HCV?

Blood is the most infectious body fluid. In the health care setting, cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids are all considered potentially infectious, although the only documented cases of occupational HIV infection have been with blood, body fluids with visible blood, or HIV viral cultures. Unless there is visible blood with the exposure, saliva, nasal discharge, tears, sweat, vomit, urine, and feces are not infectious. Semen and vaginal secretions are infectious for HIV, HBV, and HCV in the setting of nonoccupational exposure.

INTERVENTIONS FOR PEP IN HEALTH CARE SETTINGS

What types of exposures merit consideration of PEP in health care personnel (HCP)?

HCP are at increased risk from percutaneous, mucous membrane, and nonintact skin exposures to bloodborne pathogens, including hepatitis B, hepatitis C, and HIV. The risk of transmission is dependent on many factors, including the type, amount, route, and severity of exposure, the infection status of the source, and the HBV, HCV, and HIV immunity of the exposed worker (see Tables 11-1 and 11-2).

Table 11-1. High-risk Occupational Exposures

Exposures with higher risk of transmission of bloodborne pathogens
Deep percutaneous injury
Injury with a hollow-bore blood-filled needle
Exposure to blood of a patient in an advanced disease stage (high viral load)
Exposure to a large quantity of blood or body fluids

Table 11-2. Exposures with Low Risk of Transmission of Bloodborne Pathogens

Exposures with low risk of transmission (PEP not recommended)
Blood or fluid splashes on intact skin
Minor scratches or abrasions without evidence of percutaneous penetration
Penetration by small-bore needles without visible blood

An accurate history of the exposure is essential in determining the real risk of transmission. In studies, transmission of HIV by occupational exposure has an estimated 0.3 % risk with percutaneous exposure and 0.09 % with mucous membrane splash (Bell, 1997). The risk of infection for HBV (in individuals who have not been vaccinated to hepatitis B, or who were vaccine unresponsive) after percutaneous exposure is 37 %-62 % when the source is hepatitis B surface antigen (HbsAg) positive and hepatitis B e antigen (HBeAg) positive, and the risk of developing clinical hepatitis is 22 %-31 %. When the source is HbsAg positive and hepatitis B e antigen negative, the risk of HBV seroconversion is 1 %-6 %, and the risk of developing clinical hepatitis is 23 %-37 %. The risk of transmission is higher, ie 22 %-31 %, when the source has clinically evident hepatitis B hepatitis (Werner and Grady, 1982; CDC, 2001). Transmission of HCV through occupational exposure carries an average risk of 1.8 %.

What are immediate actions and initial considerations in PEP following a possible occupational exposure?

First aid for the HCP is the first immediate action, followed by collection of information in order to assess the situation and make rapid decisions regarding appropriate treatment (see Tables 11-3, 11-4, and 11-5). Quick, expert action by the care provider is essential because the effectiveness of PEP is variable and depends on the inoculum, type of injury, potency of the PEP regimen, and speed with which treatment is started. The decision to prescribe medications, as well as medication administration, should be made within 4 hours of the exposure, and must be made within 72 hours, and preferably sooner because of studies suggesting that the efficacy of PEP is diminished after 36 hours. Even with optimal implementation, ie within the first 4 hours, the protection afforded by PEP is not 100 %.

What counseling and education should you give the HCP?

The exposed HCP needs immediate counseling to assist in coping with the emotional stress of the exposure, and may require follow up care by a mental health professional. Psychological services should be available 24 hours a day, 7 days a week. A local crisis management team or an employee assistance program (EAP) may be effective ways to address this need.

The HCP should be told the relative risk of infection with HIV, HBV, and HCV following exposure, the effectiveness of PEP, and the risks and benefits of PEP. Exposed persons should be advised to return immediately if symptoms of acute HIV seroconversion occur, including fever, malaise, rash, swollen lymph nodes, fatigue or myalgias (most likely to occur 2-6 weeks after exposure).

Providers should advise exposed HCPs to prevent transmitting HIV to others, by means of the following measures, until the HCP has a negative HIV test 6 months after exposure:

- Refrain from donating blood, plasma, organs, tissue, or semen.
- Use barrier protection during sexual activity.
- If HCP is female, avoid pregnancy.
- If breast feeding, consider discontinuing, to avoid the risk of HIV transmission through breast milk.

If exposed to HBV, the HCP should follow infection control procedures that are in place at the institution.

Table 11-3: Algorithm for Actions after Occupational Exposure to Blood or other Body Fluids Potentially Contaminated with Bloodborne Pathogens	
1. Treat exposure site	- Wash the exposure site immediately (not using soap). - Flush mucous membranes with water. - Flush eyes with water or saline solution. - Do NOT apply caustic agents or antiseptics or inject disinfectants into the wound, because they may injure viable tissue and facilitate transmission.
2. Gather information about the exposure	- Date and time of exposure - Details of incident - Where and how exposure occurred - If related to a sharp device, type and brand - Details of exposure - Type and amount of fluid or material
3. Obtain information about the exposure source	- Determine if possible whether source materials contained HIV, HBV, or HCV (see Table 11-4). - If the source patient is HIV-positive, obtain a history of the stage of disease, viral load, history of ART, and information on ART resistance.
4. Obtain information about the health care provider	- Determine HIV status (rapid test, if possible) and, HBV vaccination and vaccine-response status (see Table 11-5). - Obtain medical history, including pregnancy and breastfeeding.
5. Assess the indication for PEP	- Using this information, assess the risk of exposure to HIV and decide whether PEP is warranted in this situation. - Assess the risk of exposure to HBV.
6. Manage the exposure	- Ensure appropriate and immediate access to informed counseling for all exposed HCPs, even when PEP is not recommended. - If treatment for exposure to HIV is indicated, initiate medication regimen as soon as possible, and definitely within 36 hours. Do not initiate treatment after 72 hours. - If treatment for exposure to hepatitis B is indicated, initiate treatment as soon as possible within 24 hours of exposure; the efficacy of HIVIG after 7 days is unknown. - Document counseling, postexposure management, and followup.

Table 11-4. Evaluation of Occupational Exposure Sources
Known sources
Test known sources for HbsAg, anti-HCV, and HIV antibody ^{a,b} : - Direct virus assays for routine screening of source patients are not recommended. - Use a rapid HIV-antibody test if available. - If the source person is not infected with a bloodborne pathogen, baseline testing or further followup of the exposed person is not necessary.
For sources whose infection status remains unknown (eg, the source person refuses testing), consider medical diagnoses, clinical symptoms, and history of risk behaviors.
Do not test discarded needles for bloodborne pathogens.
Unknown sources
For unknown sources, evaluate the likelihood of exposure to a source at high risk for infection.
Consider likelihood of bloodborne pathogen infection among patients in the exposure setting.

^a With attention to State regulations regarding confidentiality and informed consent.

^b If positive, confirmatory tests should be performed as appropriate including HBeAg, HIV Western blot, and HCV RNA.

Source: Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR*. 2001;50(RR11):20.

Table 11-5. Laboratory Evaluation and Followup of Exposed Health Care Personnel

Lab tests	Comment	Frequency
HIV antibody test	Test HCP if source patient is HIV positive regardless of whether PEP is given	Baseline, 6 weeks, 12 weeks, 6 months (rapid test at baseline, if possible)
HBV	Test if source patient is HBsAg or HBeAg positive	Baseline and 4-6 months (or 1-2 months after last HBV vaccine)
Anti HCV	Test if source patient is HCV positive	Baseline and 4-6 months; HCV RNA at 4-6 weeks is optional
Liver enzymes	Test if source patient is HCV positive	Baseline and 4-6 months
CBC, renal function, and hepatic function	If PEP is warranted	Prior to initiating PEP and repeated in 2 weeks

Are there special considerations for PEP in dental settings?

Although the number of exposures is relatively high in dental settings, the risk of transmission is low and no different from other HCP settings. Factors that are associated with increased risk of transmission are failure to follow PEP protocols, failure to use puncture-proof containers, treating > 20 patients per day, failure to use eye protection or masks, and male gender. For more information, see Suggested Resources.

INTERVENTIONS FOR NONOCCUPATIONAL PEP (NPEP)

What is the role of nPEP for nonoccupational exposure?

PEP for nonoccupational exposure to HIV (nPEP) is routinely being administered in cases of sexual assault in hospital emergency departments and is increasingly being made available during other cases of sexual exposure or injection drug use exposure and in non-hospital settings. This issue is particularly relevant in the care of HIV discordant couples. Research on risk of HIV transmission from a single nonoccupational exposure is relatively lacking compared with

occupational exposures (see Table 11-6). A national registry has been developed to gather the data with which to develop a CDC recommendation for HIV PEP in the nonoccupational setting. Information about this registry can be found at <http://www.hivpepregistry.org>. In general, PEP for non-HCP is modeled after PEP interventions and procedures for HCP.

Table 11-6. Estimated Risk of HIV Transmission Following Different Types of Exposures

Type of exposure	Estimated risk
Needle-sharing exposure with an infected source	0.67%
Receptive anal intercourse with an infected source	0.5%-3.0%
Receptive vaginal intercourse with an infected source	0.1%
Insertive anal intercourse with an infected source	0.065%
Insertive vaginal intercourse with an infected source	0.05%
Oral sex with ejaculation with an infected source	Conflicting data; however, risk is considered to be extremely low (<0.05%)

Source: Mayer KH, Anderson DJ. Heterosexual HIV transmission. *Infect Agents Dis.* 1995;4:273-284.

What needs to be evaluated for the possible administration of PEP in the nonoccupational setting?

Factors to be considered when considering PEP for nonoccupational exposure are similar to those for occupational exposure, including 1) HIV status of potentially exposed person (a rapid test can be done in 20 minutes), 2) timing (within 72 hours, with rare exception) and frequency of exposure (recurrent exposure would require ongoing PEP and suggests need for prevention counseling as the primary intervention), 3) HIV status of source (if unknown, PEP can be initiated while this is being assessed and discontinued if HIV infection of the source cannot be confirmed), 4) transmission risk of behavior (see Table 11-6), 5) presence of other sexually transmitted diseases, particularly genital ulcer disease (which can facilitate HIV transmission). Exposures to persons who have recently seroconverted may carry a higher risk of transmission because of high HIV viremia.

What is the role of PEP for discordant couples?

Discordant couples (couples in which one person is infected and the other is not) should be routinely educated about how to protect the noninfected person. Both partners should be made aware of the possible effectiveness of PEP in cases of intended or unintended exposures and the importance of early initiation of PEP if it is to be used. Repeated, frequent exposures should signal providers to exercise caution about administration of PEP, since PEP should not be a substitute for avoidance of high-risk behavior. Any request for PEP should prompt additional counseling and psychosocial support to enhance behaviors to prevent HIV infection.

What is the role of PEP following sexual assault?

Persons who have been sexually assaulted should be considered at risk for HIV and HBV, as well as other STDs. The decision to begin PEP should not be based on the perpetrator's likelihood of infectivity or delayed pending the test results of the source (unless immediately available). Pregnancy is an important consideration when considering PEP, and emergency contraception should be considered for women who have been sexually assaulted.

A survivor of sexual assault may have had multiple exposures. When considering PEP, the most recent exposure should be considered, and PEP should be initiated if the exposure took place within 72 hours before the patient arrived at the health care facility. As with any consideration for PEP, weighing the benefits of PEP versus the possibility of medication side effects, the importance of completing the 28-day regimen and adherence issues should all be considered.

The provider should be sensitive to the psychosocial needs of the person who was sexually assaulted; the patient may not be physically or emotionally able to weigh the pros and cons about beginning PEP. Therefore, it is important to follow up within 24 hours to either emphasize the importance of adherence or to continue the discussion about initiating PEP if it is to occur within the 72-hour window.

See Suggested Resources for more information and resources in addressing issues of sexual assault.

What if the person who is exposed is a minor?

In cases involving minors, parental or guardian participation is extremely important, but parental or guardian consent for PEP may not be required. Nonetheless, in all cases, parental or guardian

participation should continue to be sought in the emergency situation and during followup. State laws and hospital policy must be considered.

HIV PEP TREATMENT RECOMMENDATIONS**If PEP is found to be appropriate, what information does the exposed person need regarding treatment?**

The exposed person must understand the risks and benefits of HIV PEP, potential medication toxicities and side effects, instructions on how and when to take the medication, and the importance of adherence to the regimen, including completing the course of 28 days. Women should understand pregnancy-associated risks, including perinatal transmission and teratogenicity. Breast-feeding should be discontinued until the woman receives an HIV-negative result 6 months after exposure.

What are HIV treatment recommendations and options for PEP?

Currently recommended regimens are shown in Tables 11-7, 11-8, and 11-9; however, these recommendations may be altered if the source patient has a history of ART or known viral resistance, is pregnant, breast-feeding, has hepatic or renal disease, or is taking certain medications. If viral resistance in the source patient is known or suspected, an HIV expert should be consulted prior to initiating HIV PEP medications.

Basic HIV PEP regimens include 2 NRTIs. These regimens are relatively simple, ie 1 or 2 pills twice a day, well tolerated, and of sufficient potency to meet the needs of PEP. However, they are substantially less potent than 3-drug regimens. As noted below, some experts, including the authors, believe that only 3-drug regimens should be used for PEP, particularly in the current era of greatly simplified and somewhat better tolerated 3-drug regimens.

Three-drug regimens, comparable to highly active antiretroviral therapy (HAART) regimens used to treat HIV infection, are recommended for more severe exposures, which carry a higher risk of HIV transmission, or with exposures to sources with known HIV resistance mutations. The 3-drug regimens increase the risk of medication toxicity and may worsen adherence, all of which should be weighed when choosing an HIV PEP regimen. The majority of exposures in the past have resulted in the administration of 2 medications; 3-drug regimens

Table 11-7. Recommended HIV Postexposure Prophylaxis for Mucous Membrane Exposures and Nonintact Skin[⊗] Exposures

Exposure Type	Infection Status of Sources				
	HIV-Positive Class 1 [*]	HIV-Positive Class 2 [*]	Source of unknown HIV status ⁺	Unknown source [⊗]	HIV-Negative
Small Volume [†]	Consider basic 2-drug PEP	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} for source with HIV risk factors [§]	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large Volume [†]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} for source with HIV risk factors [§]	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} in settings where exposure to HIV-infected persons is likely	No PEP warranted

[⊗] For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

^{*} HIV-Positive, Class 1 asymptomatic HIV infection or known low viral load (e.g., < 1,500 RNA copies/mL). HIV-Positive, Class 2 – symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

⁺ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

[⊗] Unknown source (e.g. splash from inappropriately disposed blood).

[†] Small volume (i.e., a few drops).

^{**} The designation, “consider PEP,” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

[§] If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

[†] Large volume (i.e., major blood splash).

Source: Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(RR11):25.

Table 11-8: Recommended HIV Postexposure Prophylaxis for Percutaneous Injuries

Exposure Type	Infection Status of Sources				
	HIV-Positive Class 1 [*]	HIV-Positive Class 2 [*]	Source of unknown HIV status ⁺	Unknown source [⊗]	HIV-Negative
Less Severe [†]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} for source with HIV risk factors [§]	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} in settings where exposure to HIV-infected persons is likely	No PEP warranted
More Severe [†]	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} for source with HIV risk factors [§]	Generally, no PEP warranted; however, consider basic 2-drug PEP ^{**} in settings where exposure to HIV-infected persons is likely	No PEP warranted

^{*} HIV-Positive, Class 1 asymptomatic HIV infection or known low viral load (e.g., < 1,500 RNA copies/mL). HIV-Positive, Class 2 – symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

⁺ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

[⊗] Unknown source (e.g. a needle from a sharps disposal container).

[†] Less severe (e.g., solid needle and superficial injury).

^{**} The designation, “consider PEP,” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

[§] If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

[†] More severe (e.g. large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient’s artery or vein).

Source: Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(RR11):24.

Table 11-9. Treatment Options for 2- and 3-drug PEP

	Treatment Options
Basic 2-drug PEP	zidovudine (AZT) 300 mg bid + lamivudine (3TC) 150 mg bid (may be taken as Combivir bid)
	stavudine (d4T) 40 mg bid + 3TC 150 mg bid
	stavudine (d4T) 40 mg bid + didanosine (ddI) 400 mg qd on an empty stomach (No longer recommended because of increased toxicity unless a suitable alternative is not available.)
3-drug PEP	One of the above NRTI* combinations plus a third drug, usually a PI**, an NTRTI#, or an NNRTI*** to be determined in consultation with an HIV expert.
	nevirapine (NVP) (No longer recommended for PEP due to the potential for severe liver toxicity.)

* NRTI: nucleoside or nucleoside reverse transcriptase inhibitor

** PI: protease inhibitor

NTRTI: nucleotide reverse transcriptase inhibitor, i.e., tenofovir (TDF)

*** NNRTI: non-nucleoside reverse transcriptase inhibitors, i.e., efavirenz (EFV)

should be chosen with the advice of an HIV expert. In accordance with the same principles that are used in treating HIV-positive persons; some experts believe that 3-drug PEP regimens should be the mainstay of PEP and that 2-drug regimens should be used only during extenuating circumstances such as an inability to tolerate a protease inhibitor (PI). For example, the New York State PEP Guidelines now recommend zidovudine and lamivudine (Combivir) plus tenofovir (two pills in the morning and one pill in the evening) as the standard PEP intervention. (<http://www.hivguidelines.org>)

Although the current data on PEP for nonoccupational HIV exposures are scant, treatment recommendations for occupational PEP can be generalized to nonoccupationally exposed persons. As in the case of PEP in HCP, nonjudgmental counseling directed towards the reduction of future exposures is an important part of PEP in nonHCP.

What are the side effects of HIV PEP?

Side effects of HIV PEP regimens are common and occur in 30%-50% of patients. Severe side effects occur in 5%-30% of patients and often require discontinuation. Common side effects include gastrointestinal symptoms such as nausea, vomiting, diarrhea, and abdominal pain; rash; fatigue; headache and dizziness; cytopenia; neuropathy; hepatitis; and many others. In reported series to date, over half of HCP in PEP programs fail to complete their 28-day regimens because of side effects. Regularly scheduled

followup either in person or by phone has been shown to greatly improve adherence. Refer to other chapters for more detail on symptom management and metabolic complications with ART.

What medication toxicities should be monitored?

Regular laboratory evaluation for medication toxicity and seroconversion should be performed (see Table 11-5). A complete blood count and renal and hepatic function tests should be done before initiating PEP and repeated in 2 weeks. Continued monitoring is recommended for abnormal lab test results, and medication changes should be considered if abnormalities are severe. Specific monitoring parameters vary with the regimen; for example, glucose levels should be monitored if a PI is used. If the PI is indinavir (IDV) a urinalysis should also be checked to monitor for crystalluria and hematuria. Tenofovir (TDF) is well tolerated, but should be used with caution and careful monitoring in patients with compromised renal function (Refer to Drug Information Tables in the Pocket Guide for medication side effects.)

Two regimens deserve special consideration. Hepatotoxicity, Stevens-Johnson syndrome, and fatal hepatic necrosis have occurred in HCP treated with nevirapine (NVP) as part of their PEP regimen, and therefore its use is not recommended, given the variety of other options. Pregnant women treated with stavudine (d4T) and didanosine (ddI) were found to be at increased risk for fatal and non-fatal lactic acidosis, and therefore this combination is not recommended in the treatment of pregnant women. In addition, recent clinical trial data showed a higher rate of adverse effects with the combination of stavudine and didanosine in adults, and their use in combination is not recommended unless other alternatives are not available.

What are the treatment recommendations when the source patient is known to have specific HIV resistance mutations?

Resistance to HIV medications is an important consideration in the treatment of HIV-positive persons, and known resistance in the source patient should be a consideration when choosing an appropriate HIV PEP regimen. In addition, because of reported increases in resistance mutations in recently acquired HIV infection in several cities in the United States, resistance is increasingly a concern in untreated patients, and thus for PEP in exposures to unknown sources. HIV PEP failures attributed to exposure to resistant virus have been reported in the literature.

Unfortunately, resistance test results are often unavailable at the time of the consideration of PEP, and PEP should not be unduly delayed while this information is sought. A thorough drug, adherence, and HIV history from the source patient and consultation with an HIV expert is needed to make the optimal treatment recommendation.

When should expert consultation be sought?

Expert consultation is potentially valuable in many circumstances with PEP. As above, expert consultation is indicated in the setting of known or suspected drug resistance in the source in order to select drugs to which the patient's virus is likely to be susceptible. Other situations include:

- Delayed report of exposure, since the interval after which there is no benefit from PEP is undefined, in order to determine if PEP is still indicated
- Unknown status of the source, since the decision regarding the use of PEP should be individualized, based on the estimated likelihood of risk to the HCP, considering the severity of the exposure and the epidemiologic likelihood of HIV exposure
- Known or suspected pregnancy in the exposed person, in which case specific treatment recommendations may require modification
- Possible toxicity of the initial PEP regimen, in which case modification of the regimen and/or treatment of the adverse side effect may be considered

HEPATITIS PEP TREATMENT RECOMMENDATIONS

What are the treatment recommendations and options for possible hepatitis B exposure?

HBIG and immunization against HBV following exposure are the most effective methods to prevent HBV transmission (see Table 11-10). PEP for HBV with multiple doses of HBIG has been shown to be 75%-95% effective. Pregnant women can safely receive both the HBV vaccination and HBIG. When considering PEP for HBV exposures, both the source patient's HbsAg status and the exposed person's vaccination status and antibody response should be considered. Both HBIG and the hepatitis B vaccine should be administered within 24 hours of exposure. Anti-HBs should be drawn 1-2 months after completion of the third vaccine, but it is unreliable if the exposed person has received HBIG within the past 3-4 months.

Table 11-10. Recommended Postexposure Prophylaxis for Exposure to Hepatitis B Virus			
Vaccination and antibody response status of exposed workers*	Treatment		
	Source HBsAg positive⁺	Source HBsAg⁺ negative	Source of unknown or not available for testing
Unvaccinated	HBIG [§] x 1 and initiate HR vaccine series [†]		
Previously vaccinated			
Known responder**	No treatment	No treatment	No Treatment
Known nonresponder ^Ø	HBIG x 1 and initiate revaccination or HVIG x 2 [†]	No treatment	If know high risk source, treat as if sources were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs ^{††} 1. If adequate,** no treatment is necessary 2. If inadequate ^Ø , administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate [†] , no treatment is necessary 2. If inadequate [†] , administer vaccine booster and recheck titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.

⁺ Hepatitis B surface antigen.

[§] Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.

[†] Hepatitis B vaccine.

** A responder is a person with adequate levels of serum antibody to HBsAg (ie, anti-HBs $\geq$ 10mIU/mL).

Ø A nonresponder is a person with inadequate response to vaccination (ie, serum anti-HBs < 10mIU/mL).

[†] The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who have previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

^{††} Antibody to HBsAg.

Source: Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR* 2001;50(RR11):22.

What are the treatment recommendations and options for possible hepatitis C exposure?

There are no recommended prophylactic treatments after exposure to HCV blood or body fluids. Current data do not support treatment during acute HCV infection at this time; referral of an individual with recently acquired HCV to a specialist in HCV care is appropriate.

Following exposure, testing should be performed on the source for anti-HCV. If positive, the exposed person should be tested for anti-HCV and alanine

aminotransferase (ALT) initially and in 4-6 months. HCV-RNA and ALT at 4-6 weeks are optional. All anti-HCV results should be confirmed by recombinant immunoblot assay; if positive an HCV RNA should be drawn. Drawing an HCV RNA at 4-6 weeks may be done for earlier diagnosis, but the person should be counseled that false-positives do occur. Current research supports early diagnosis of HCV as basis for the most effective management after exposure are known. Exposed persons should be counseled to refrain from donating blood, plasma, organs, tissue, or semen. Although the transmission risk by sexual activity is low, it is reasonable to recommend a barrier method until the results of testing 6 months after exposure are known. There are currently no recommendations to make any changes in breast-feeding, pregnancy, or professional activities. Mental health counseling should be offered as needed.

KEY POINTS

The goals of PEP are to prevent or abort the transmission of HIV and hepatitis B virus (HBV) and to enable early diagnosis of hepatitis C virus (HCV).

All exposed persons need followup within 24-48 hours depending on the pathogen.

HIV PEP, if determined to be appropriate, should be provided preferably immediately, and definitely within 36 hours of exposure. PEP is NOT recommended for minor exposures. If the provider is inexperienced in using HIV medications or managing PEP patients, an HIV specialist should be consulted before initiating treatment.

The risk of transmission of HBV is far greater than of HIV or HCV. All HCPs should be vaccinated against HBV. HBIG is highly effective in preventing transmission of HBV.

There is currently no recommended PEP medication for HCV. If possible, the source should be tested for antiHCV, and if positive, the exposed person should be monitored.

PEP should be available in all health care settings. PEP protocols should be developed, regularly updated, and included in regular employee training programs.

PEP for nonoccupational exposure (nPEP) is modeled after PEP for occupational exposures. nPEP is routinely administered in cases of sexual assault in emergency departments, and is increasingly being made available for other cases of sexual exposure or injection drug use exposure in non-hospital settings.



SUGGESTED RESOURCES

Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. Available at <http://aidsinfo.nih.gov/guidelines/>.

PEP Steps—a pocket summary of the 2001 PEP Guidelines. Mountain Plains AIDS Education and Training Center. Available at <http://www.uchsc.edu/mpaetc/hivresources.htm> or by telephone at 303-315-2516.

Practice recommendations for health-care facilities implementing the U.S. Public Health Service guidelines for management of occupational exposures to bloodborne pathogens. *MMWR* 2001;50(RR-11):43-44. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a2.htm>.

Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States. Available at <http://www.hivatis.org>.



WEBSITES

Food and Drug Administration: <http://www.fda.gov>. Accessed 1/04.

Hepatitis information: <http://www.cdc.gov/hepatitis>. Accessed 1/04.

HIV PEP registry, for nonoccupational exposures: <http://www.hivpepregistry.org>. Accessed 1/04.

National Rape, Abuse, & Incest National Network: <http://www.rainn.org/>. Accessed 1/04.

Needlestick website, a web-based expert system to help providers manage and document occupational exposures to blood and bodily fluids: <http://www.needlestick.mednet.ucla.edu>. Accessed 1/04.

New York State Department of Health AIDS Institute, PEP guidelines: <http://www.hivguidelines.org>. Accessed 1/04.

STD/HIV Prevention Training Centers (PTCs): <http://depts.washington.edu/nnptc>. Accessed 10/03.

Contact State and local health departments for additional information.



TELEPHONE

National Rape Crisis Hotline: 1-800-658-HOPE.

National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline), expert consultation for providers on occupational exposures to bloodborne pathogens: 1-888-HIV-4911 (1-888-448-4911) or <http://www.ucsf.edu/hivcntr/resources/pep>. Accessed 1/04.

Warmline: National HIV telephone consultation service: 1-800-933-3413

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Mayer KH, Anderson DJ. Heterosexual HIV transmission. *Infect Agents Dis.* 1995;4:273-284.

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CASES**1.**

An employee states that she has just punctured herself with a needle after drawing a patient's blood. The patient has already left the clinic and no one knows anything about his medical history. The employee completed the HBV vaccination series and is hepatitis B surface antibody (HBsAb) positive. During the investigation the HIV prevalence in this setting was found to be low.

Question: What is the risk of HIV transmission?

Answer:

The risk of HIV transmission after a puncture wound with a hollow-bore needle is 0.3%. It is important to remember that the risk of infection is higher when there is a large-volume exposure, a deep percutaneous injury, or an injury with a hollow-bore, blood-filled needle, or if the source has advanced HIV disease or has a high level of HIV viremia. The current CDC recommendations advise against HIV PEP when the source is unknown and in settings where the HIV prevalence is low.

Question: What counseling and followup should be recommended?

Answer:

Because of the low prevalence of HIV in this setting, the employee should be advised against taking HIV medications. Also, because she is HBsAb positive she is not a candidate for HBV PEP. The HCP should be advised to refrain from donating blood, plasma, organs, or tissue, to use barrier methods during sexual activities, and to refrain from sharing any injection or other drug use equipment. She should also be counseled about universal precautions and administration should take steps to reduce the risk of future accidental needle sticks. She should be educated about the symptoms of acute HIV and advised to return immediately if those symptoms occur. Mental health counseling should also be offered.

A baseline HIV antibody and anti-HCV should be drawn. HIV antibody should be repeated at 6 weeks, 3 months and 6 months after exposure. A 12-month followup is recommended if the source is found to be coinfecting with HIV and HCV, or if the exposed becomes infected with HCV following exposure. Anti-HCV and ALT should be repeated within 4-6 months and if positive should be confirmed with supplemental tests.

2.

A patient known to be HIV negative 6 months ago comes to the clinic stating that last night he was the receptive partner of unprotected sexual intercourse with his HIV-positive partner when the condom broke. His partner has been HIV-positive for 5 years, currently has an undetectable viral load, and is taking Combivir (zidovudine + lamivudine) and efavirenz (EFV). He has never had a resistance test.

Question: Should the patient take HIV PEP medications?

Answer:

Although the current recommendations for nonoccupational exposures were released in 1998 and at that time found that PEP for nonoccupational HIV exposure was still unproven, current data support treating. Receptive anal intercourse with an HIV-positive partner carries with it a risk of transmission of 0.5%-3.0%. Your patient's risk is likely lower because of his partner's low level of viremia. PEP in nonoccupational settings is modeled after PEP for HCPs. In this case, the patient had a large exposure from a known HIV-positive source with an undetectable viral load.

Following the model for PEP for HCPs, the patient should be treated ASAP, ie within 4 to 72 hours but not more than 72 hours after exposure and receive 2 medications, although some experts would recommend using 3 medications. It would be reasonable to place the patient on the same combination as his partner because his partner has exhibited good adherence and good virologic control. Treatment should continue for 28 days.

The patient should be counseled about medication side effects and the importance of adherence and followup. Common side effects should be anticipated and pre-empted with counseling and, in some cases, treatment. Changing medications and/or modifying the dosage regimen may increase the likelihood of completion of the HIV PEP regimen. And finally, the patient should be educated about the symptoms of acute HIV infection and advised to return immediately if those symptoms occur.

Question: What lab specimens should be drawn?

Answer:

A baseline HIV Ab should be drawn and repeated at 6 weeks, 3 months, 6 months and 12 months after exposure, as well as an HBsAg, HBsAb, and HCV Ab. If he were unvaccinated against HAV or HBV then vaccination should be initiated immediately. Laboratory monitoring for drug toxicity should be performed at baseline and then 2 weeks after initiating therapy. The medical record of the patient's partner should immediately be reviewed, and treatment for HBV, HCV, or other sexually transmitted diseases should occur, if any of these are found. Expert consultation should be sought if needed.

Chapter 12:

Family Planning and Pregnancy

*María del Carmen Ríos, MD, MPH**José Rafael Morales, MD, FACOG**CARE OF HIV-POSITIVE WOMEN OF CHILDBEARING AGE**PREVENTING MOTHER-TO-CHILD TRANSMISSION (MTCT)**PERINATAL CARE FOR PREGNANT WOMEN WITH HIV**KEY POINTS**SUGGESTED RESOURCES**REFERENCES*

CARE OF HIV-POSITIVE WOMEN OF CHILDBEARING AGE

When should you provide pregnancy counseling to women living with HIV who are of childbearing age?

More than half the pregnancies in the United States are unplanned. For women living with HIV, education and counseling about pregnancy and HIV should be done early in the course of HIV care, not delayed until the woman is pregnant, so that she can make informed decisions about contraception and pregnancy. Many women with HIV mistakenly assume they cannot get pregnant and need to be educated before it is too late.

What counseling interventions should be included in primary care?

All women of childbearing age should receive the benefit of preconceptional counseling as part of routine primary medical care (ACOG, 1995). Women who have HIV should also be counseled about:

- The impact of HIV on the course and outcome of pregnancy
- The impact of pregnancy on HIV progression
- Appropriate contraception to prevent unintended pregnancies
- Perinatal transmission risks, including strategies to reduce the risk of perinatal transmission
- Permanency planning (guardian issues for children)

What primary care interventions are appropriate for women with HIV who want to become pregnant?

Certain measures can help facilitate a successful pregnancy if a woman with HIV wants to become pregnant:

- Institute routine preconceptional care such as genetic screening, screening for STDs, PAP smear, and initiation of folic acid supplementation.
- For women already on antiretroviral therapy (ART) or who have indications for therapy, ensure that medications are not contraindicated in pregnancy (efavirenz [EFV] is contraindicated) and optimize therapy to reduce viral load and reduce side effects.
- Vaccinate as indicated.
- Optimize maternal nutritional status.
- Screen for psychological and substance abuse disorders and treat.
- Refer for perinatal consultation as needed.

Are there options for HIV-positive individuals who are considering reproduction?

There are centers in the United States and in Europe that provide “sperm washing” to decrease the possibility of HIV transmission to the woman during planned conception. However, this method has not been well studied and, as a practical matter, is not available to most HIV discordant couples (Kim et al, 1999). Discordant couples who choose to become pregnant need to be educated about the risk of HIV transmission. To reduce the risk if the man is HIV-positive, his viral load should be as low as possible,

intercurrent STDs should be treated, and attempts to conceive should be well timed around ovulation to avoid unnecessary exposures during periods of decreased fertility. The American College of Obstetricians and Gynecologists has recently endorsed the use of reproductive technology in HIV-infected patients (ACOG, 2004). Which patients should be offered assisted reproduction and what the optimal methods are of decreasing heterosexual and perinatal HIV transmission must be determined.

When should pregnancy testing be done?

Since most pregnancies are unplanned, the diagnosis of pregnancy frequently occurs late in the first trimester, when organogenesis is nearly complete. In order to make the diagnosis earlier, pregnancy tests should be done when sexually active women have:

- Late or missed menses (unless she is using Norplant or Depo-Provera)
- Irregular bleeding (unless she is using Norplant or Depo-Provera)
- New onset of irregular bleeding after prolonged amenorrhea with Norplant/Depo-Provera
- New onset of pelvic pain
- Enlarged uterus or adnexal mass on exam

In addition, women with the potential of becoming pregnant should be tested before starting potentially teratogenic therapies such as efavirenz (EFV), which is the only antiretroviral drug that is contraindicated in pregnancy. Patients should be alerted to potential teratogenic effects on the fetus, and suitable contraception should be prescribed.

What contraceptive methods are recommended for women with HIV who do not want to become pregnant?

Condoms are the most common contraceptive method used by women living with HIV. Condoms, consistently used, have the added advantage of providing protection against STDs, including potential reinfection with HIV. This benefit should be emphasized when contraceptive advice is given to an HIV-positive or at-risk woman even if she is not seeking or does not need contraception but is sexually active.

Hormonal methods of contraception are also frequently used (delivered orally, by injection, or by skin patch). However, there are many important drug interactions between hormonal contraceptives and drugs used to treat HIV infection and HIV-related complications (see next question).

What are the most common drug interactions between oral contraceptives and drugs used in HIV disease?

Oral contraceptives significantly interact with amprenavir/fosamprenavir (APV/FAPV), efavirenz (EFV), lopinavir (LPV), nelfinavir (NFV), nevirapine (NVP), and ritonavir (RTV); an additional method of contraception, such as condoms, is recommended. Similarly, other drugs commonly used by HIV-infected patients, including tetracycline, rifampin, oral anticoagulants, beta-blockers, and antidepressants interact with oral contraceptives, and an additional means of contraception is advisable. Indinavir and atazanavir do not appear to have an interaction.

What contraceptive methods are not highly recommended for women with HIV who do not want to become pregnant?

Spermicides: Generally, a spermicide should be used along with a barrier method to increase its effectiveness. However, in some studies nonoxynol-9 (the active ingredient in spermicidal contraceptives) has been found to cause vaginal irritation and epithelial inflammation when used as the sole contraceptive method and on a regular and frequent basis. This may increase the risk of HIV transmission.

Intrauterine Device: The intrauterine device (IUD) is not recommended for HIV-infected women. The IUD is associated with pelvic inflammatory disease and is also associated with increased menstrual flow. Some studies even suggest that this device is linked to increased susceptibility to HIV transmission.

PREVENTING MOTHER-TO-CHILD TRANSMISSION (MTCT)

Which are the current recommendations for HIV testing of pregnant women?

Since prevention of vertical transmission (from mother to child) of HIV is so effective, identification of HIV infection in all women who are pregnant is imperative. Therefore:

- HIV testing should be a routine part of prenatal care for all women. The “opt out” method, in which HIV testing is included in the routine bloodwork and pregnant women have to refuse the test, results in higher test rates and should be used.

- Testing should be performed as early as possible in pregnancy to allow for timely interventions and decisions.
- HIV-negative women who are at high risk of acquiring HIV should be retested in the third trimester of pregnancy (ideally before 36 weeks). Women are at high risk if they have a history of STDs, exchange sex for money or drugs, have multiple sex partners during pregnancy, use illicit drugs, have HIV-positive or high-risk sex partners, and/or show signs and symptoms of seroconversion.
- Women whose HIV status is unknown and/or who present late in pregnancy or already in labor should be assessed promptly for HIV infection, using rapid HIV testing, to allow for timely prophylactic treatment. Standard confirmatory tests should be done after delivery for women with positive rapid test results.
- CDC recommends timely, routine screening of an infant if the mother has not been tested during pregnancy or delivery (CDC, 2003).

How should HIV testing be done?

HIV testing should be voluntary, and providers should carefully document informed consent. Providers should offer pre- and post-test counseling that includes information on modes of transmission of the virus, risk factors that might be present even if a woman has only one sex partner, and effective interventions to reduce the risk of perinatal transmission of HIV. There should be a discussion of services available for the provision of medical care, and the woman should be reassured that care for her and her infant will not be denied if she declines the test. Laws and regulations on HIV screening of pregnant women and their infants vary by State. Therefore, providers should be familiar with the State regulations and policies that apply to them (CDC, 2001).

When does transmission from mother to infant occur and what are risk factors for transmission?

Vertical transmission can occur during the perinatal period and infancy, that is, before or close to the time of birth or during breastfeeding. Risk factors associated with vertical transmission include (CDC, 2001):

- Advanced disease in the mother
- High plasma viral load
- Maternal injection drug use during pregnancy
- Preterm delivery
- HCV coinfection
- Failure to follow the recommended regimen of zidovudine prophylaxis
- Breast-feeding

- Delivery more than 4 hours after rupture of membranes
- Concurrent STDs
- Chorioamnionitis
- Certain obstetrical procedures

How common is vertical transmission of HIV with and without ART?

In the absence of antiretrovirals, the perinatal transmission rate of HIV infection is approximately 25%. There is a direct correlation between maternal viral load as measured by plasma HIV-1 RNA and probability of perinatal transmission. A large study showed that the rate of perinatal transmission among women with viral load > 100,000 c/mL was 40.6%, with 50,001 to 100,000 c/mL it was 30.9%, with 10,001 to 50,000 c/mL it was 21.3%, with 1,000 to 10,000 c/mL it was 16.6%; and with < 1,000 c/mL it was 0% (Garcia et al, 1999).

Treatment with zidovudine (AZT) alone can reduce transmission to close to 8%. Multi-agent antiretroviral therapy can reduce the transmission rate even further (see Table 12-1).

Table 12-1. Antiretroviral Treatment and Perinatal Transmission

Treatment category	Number treated	HIV transmission rate (95% confidence interval)
Untreated	396	20.0% (16.1, 23.9)
AZT monotherapy	710	10.4% (8.2, 12.6)
Dual therapy, non-HAART	186	3.8% (1.1, 6.5)
HAART	250	1.2% (0, 2.5)

Source: Cooper ER, Charurat M, Mofenson L, et al. Combination antiretroviral strategies for the treatment of pregnant HIV-1-infected women and prevention of perinatal HIV-1 transmission. *J Acquir Immune Defic Syndr*. 2002;29:484-494.

Do pregnant women with very low or undetectable viral loads need ART?

Yes. All pregnant women should receive ART. Analysis of the first study of the effectiveness of ART in reducing perinatal transmission (ACTG 076 study) showed that zidovudine (AZT) significantly reduced perinatal transmission even when the baseline viral load was < 1,000 c/mL (Ioannidis et al, 2001). This study provides the rationale for zidovudine monotherapy in untreated pregnant women with a baseline viral load of < 1,000 c/mL.

What pharmacologic interventions are recommended to reduce the risk of MTCT?

ART should be offered to **all** HIV-infected pregnant women, and zidovudine chemoprophylaxis should be incorporated into the antiretroviral regimen to prevent perinatal transmission because safety and efficacy data are greatest for zidovudine (PHS, 2002) (see Pocket Guide Pregnancy Table 1). Zidovudine prophylaxis is associated with significant reduction in perinatal transmission that is independent of viral load (Sperling, 1996; Shapiro et al, 1999) and of zidovudine resistance (Eastman et al, 1998).

Are there additional interventions to reduce the risk of MTCT and improve maternal/fetal health?

When the woman is HIV positive there are interventions that can reduce the risk of MTCT.

- Pregnant women with HIV should be counseled to refrain from cigarette smoking, injection and illicit drug use, and unprotected sexual intercourse with multiple sex partners.
- STDs in pregnancy should be treated since they are associated with a higher risk of vertical transmission.

Can cesarean section reduce the risk of MTCT?

Elective cesarean section reduces the risk of perinatal transmission and should be offered at 38 weeks to pregnant women when the viral load is likely to be > 1,000 c/mL at delivery (Dominguez, 2003). ACOG in a joint statement with the American Academy of Pediatrics (AAP) recommended offering HIV-positive pregnant women scheduled cesarean section at 38 weeks gestation (AAP, ACOG, 1999; CDC, 2001), rather than waiting until 39 weeks. *There is no evidence of benefit of C-section after onset of labor, after rupture of membranes, or in women with viral loads of < 1000 c/mL.*

What interventions should occur during a scheduled cesarean section?

When a scheduled cesarean section is planned, intravenous zidovudine should start 3 hours before surgery according to standard dosing (see Pocket Guide Pregnancy Table 5). Since infectious morbidity is potentially increased, the obstetrician should consider antibiotic prophylaxis. Other antiretrovirals should not be interrupted at the time of delivery regardless of route of delivery.

What should you advise mothers about breastfeeding?

The risk of HIV transmission with breastfeeding is approximately 16%. Avoidance of breastfeeding is recommended in the United States and other industrialized countries since replacement feeding is safe and accessible. In resource-poor countries where risks of replacement feeding include malnutrition and infections other than HIV, the World Health Organization recommends exclusive breastfeeding during the first 3 months of life since **exclusive** breastfeeding carries a lower risk of HIV transmission than mixed feeding. To minimize the risk of HIV transmission in these settings, breastfeeding by HIV-positive women should be discontinued as soon as feasible, taking into consideration local circumstances and the risks of replacement feeding (WHO, 2001).

What testing should neonates of HIV-positive mothers receive?

When neonates are born to HIV-positive mothers, serial testing for HIV should be done within the first few days of life, at age 1 month, and again at 4-6 months or later (AAP, ACOG, 2002). Early identification of HIV in neonates is crucial for adequate management. Since maternal antibody may be present, HIV antibody testing is not useful until the baby is 18 months old. Using either HIV-DNA PCR or HIV culture, however, pediatricians can usually determine the HIV status of infants by the age of 4 months.

PERINATAL CARE FOR PREGNANT WOMEN WITH HIV

What medical and counseling interventions are appropriate for pregnant women with HIV?

Initial evaluation of an HIV-positive pregnant woman should include an assessment of her HIV disease status. Besides the standard components of prenatal care indicated for all pregnant women, the provider should obtain CD4 cell counts and viral loads, and resistance tests should be performed. Viral loads and CD4 counts should be repeated every 3 months.

The goals of ART during pregnancy are to:

- optimize the health of the woman
- protect the fetus from HIV
- provide regimens that are neither toxic for the woman nor teratogenic for the fetus.

Clinicians should discuss short- and long-term benefits and risks for both the woman and the fetus before initiating or modifying ART. Options should be presented in a non-coercive way, and the final decision always lies with the patient. A long-term plan should be developed, and the importance of adherence to ART should be stressed.

What antiretroviral regimens are recommended for pregnant women with HIV?

The use of the 3-part zidovudine (AZT) chemoprophylaxis regimen, alone or in combination with other antiretroviral agents, should **always** be offered and discussed with all infected pregnant women to reduce the risk of perinatal HIV transmission (see Pocket Guide Pregnancy Table 3). Any pregnant woman with HIV should be offered a treatment regimen that adheres to the currently recommended treatment for HIV-infected adults, which generally consists of 2 reverse transcriptase inhibitors into which zidovudine is incorporated, plus a protease inhibitor (see Pocket Guide Pregnancy Table 4). Efavirenz (EFV) is contraindicated in the first trimester because it has been associated with birth defects in a monkey model. Referral to providers who are experienced in the care of pregnant HIV-infected women is recommended.

Are there special considerations when a woman already on ART becomes pregnant?

When an HIV-infected woman receiving ART is found to be pregnant after the first trimester she should be counseled to continue therapy. Zidovudine should be a component of the antenatal ART regimen after the first trimester whenever possible, although this may not always be feasible. A woman receiving ART whose pregnancy is recognized during the first trimester should be counseled regarding the benefits and potential risks of continuing ART during this period of organogenesis. As discussed above, efavirenz (EFV) is contraindicated in the first trimester. Also, dapsone, a folic acid antagonist, has been reported to increase the risk for neural tube defects. Maternal absorption and metabolism of protease inhibitors (PIs) change during pregnancy, and there are specific recommendations for dose adjustments of nelfinavir (NFV) (<http://www.aidsinfo.nih.gov>).

What are some of the problems that may occur when antiretroviral agents are prescribed during pregnancy?

Hyperglycemia and diabetic ketoacidosis have been reported with PI use during pregnancy. Therefore, pregnant women using PIs should be carefully instructed to watch for symptoms of hyperglycemia, and blood glucose levels should be closely monitored.

Lactic acidosis is more common in the last trimester of pregnancy, and hepatic enzymes and serum electrolytes should be monitored frequently during the last trimester in pregnant women receiving nucleoside analogues. The combination of stavudine (d4T) and didanosine (ddI) in HIV-positive pregnant women is not recommended as it has been associated with maternal mortality from severe lactic acidosis.

Hyperemesis gravidarum is a common complication of pregnancy. If a woman needs to discontinue ART because of pregnancy-related hyperemesis, she should not restart medications until sufficient time has elapsed to ensure that the drugs will be tolerated; all drugs should be stopped at once and reintroduced simultaneously to reduce the potential for emergence of resistance.

What medical and counseling interventions are appropriate for postpartum followup of women with HIV?

Comprehensive care and support services, including primary, obstetric, pediatric, and HIV specialty care, family planning services, mental health and substance abuse treatment, and coordination of care through case management for the woman, her children, and other family members are important for women with HIV and their families. Maternal medical services during the postpartum period must be coordinated between the obstetric care provider and the HIV specialist. When treatment is required for the woman's HIV infection, continuity of ART must be assured.

What followup should be done for the infants of mothers with HIV?

Infants of HIV-positive women on ART should be followed for potential side effects of antiretroviral medications even if the infants are HIV-negative; followup should continue into adulthood because of the theoretical concerns regarding potential carcinogenicity of the nucleoside analogue antiretroviral drugs. Infected children should be followed to determine their need for prophylactic treatment or ART, as well as to assess possible delays in growth and development.

Where should prenatal exposure cases be reported?

Cases of prenatal exposure should be reported to the Antiretroviral Pregnancy Registry. This registry collects anonymous observational data. The Registry can be contacted at:

Antiretroviral Pregnancy Registry
115 N. Third St., Suite 28401
Wilmington, NC 28401
Tel: 800-258-4263
FAX: 800-800-1052

KEY POINTS

All HIV-positive women of childbearing age should receive information about the impact of HIV on the course and outcome of pregnancy, the impact of pregnancy on HIV progression, and appropriate contraception to prevent unintended pregnancy.

To assure early identification of pregnancy in women with HIV who are sexually active, pregnancy tests should be done whenever they have late or missed menses or other signs of possible pregnancy. Women with the potential of becoming pregnant should be tested before starting potentially teratogenic therapies such as efavirenz (EFV). Patients should be alerted on potential teratogenic effects on the fetus, and suitable contraception should be prescribed.

Contraceptive methods recommended for women with HIV include condoms, which also protect against STDs and prevent HIV transmission to their partners, and hormonal methods. The drug interactions between oral contraceptives and many drugs used in HIV disease make an additional means of contraception advisable in many cases. Spermicides and intrauterine devices are not recommended for use by HIV-infected women.

HIV testing should be a routine part of prenatal care for all women. HIV testing should be voluntary using the “opt out” method (the HIV test is part of routine bloodwork and the woman may opt to refuse the test). Pre- and post-test HIV counseling should be provided.

All pregnant women infected with HIV should receive antiretroviral therapy. Zidovudine monotherapy can be provided to untreated pregnant women with a baseline viral load of < 1,000 c/mL, but a 3-part ART regimen including zidovudine should always be offered and discussed. Pregnant women should be offered the currently recommended treatment regimens for HIV-infected adults, except that efavirenz (EFV) is contraindicated in the first trimester.

Medical problems associated with ART during pregnancy include hyperglycemia and diabetic ketoacidosis, lactic acidosis, and hyperemesis gravidarum.



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Chapter 13:

Management of Substance Abuse

Henry Francis, MD

ASSESSMENT OF SUBSTANCE ABUSE PROBLEMS

TREATMENT OF SUBSTANCE ABUSE PROBLEMS

MEDICAL AND PAIN MANAGEMENT ISSUES

HIV/AIDS ISSUES

KEY POINTS

SUGGESTED RESOURCES

REFERENCES

ASSESSMENT OF SUBSTANCE ABUSE PROBLEMS

What is the definition of a substance abuser?

A substance abuser is an individual who repeatedly uses an addictive substance or performs a certain behavior even with the knowledge of its negative health consequences. A person is drug dependent or addicted if he or she uses drugs repeatedly despite the social, interpersonal, or other problems associated with their use and has a physical or psychological tolerance to the drug and experiences withdrawal symptoms after the effects of the drug wear off. Long-term drug abuse can interfere with normal brain activity and metabolism and can become a chronic, relapsing condition characterized by compulsive drug craving and drug seeking. There are other kinds of addiction that may not involve the use of substances, such as gambling, sex, and eating-related disorders, all of which involve a range of dysfunctional behaviors with undesirable social, medical, and economic consequences (see Table 13-1).

Table 13-1: Range of Substances and Behaviors That Can Be Abused

Addictive substances	Behaviors
- Marijuana - Cocaine - Heroin - Amphetamines, other stimulants - Tranquilizers - Hallucinogens - Steroids and recreational drugs	- Eating disorders: anorexia, bulimia, bingeing - Sex disorders: compulsive sexual activity - Gambling - Internet addictions: compulsive use of the internet

How should primary care providers address substance use problems in their patients?

The first task is to consciously look for behavioral and physical signs of maladaptive drug use and to use a simple screening tool such as the CAGE examination (described below) to detect it. Common indicators of drug abuse are frequent absence from work or school, recurrent injuries, motor vehicle accidents, depression, anxiety, labile hypertension, sleep problems, sexual dysfunction, or abdominal symptoms. Physical signs of drug abuse such as tremor, liver disorders, and physical changes such as nasal irritation caused by cocaine are well known to health care providers.

The second task is to tell the patient his or her diagnosis of drug abuse or dependence. Providers are often concerned about upsetting a patient with a stigmatizing diagnosis. Giving a concise, objective description of clinical findings without making judgments is important. Common pitfalls for providers to avoid during this discussion are listed as the DEATH Glossary (Table 13-2).

The third task before sending a patient to treatment is to try a brief intervention in the office. It has clearly been shown that brief interventions given in community centers, hospitals, and ambulatory clinics decrease the morbidity and mortality associated with drug abuse (see Suggested Resources). For physicians who have received training on buprenorphine treatment for opiate addicts, there is the added opportunity to treat opiate drug users in the private practice setting without referring the individuals to drug use centers (see section on Treatment of Substance Abuse below).

Table 13-2: The DEATH Glossary

Common Pitfalls for Providers to Avoid when Diagnosing Drug Abuse Problems

D Drinking or Drug-use	Details are not relevant; talking with a person on drugs is not useful. The simple issue here is talking to the patient when he or she is sober, ie, has not taken a drug before the visit.
E Etiology	Do not spend much time on how drug use started but focus on getting the person to treatment.
A Argument	Avoid arguing at all costs. No meaningful conversation will occur in an argument.
T Threats	Guilt and shame do not promote recovery from chemical dependency. Threats or evoking guilt will not promote successful therapy.
H Hedging	Hedging hurts your credibility. Being ambivalent about giving the diagnosis will not help the patient. If the patient disagrees with you, unequivocally agreeing to disagree is a valid starting point for getting to successful recovery.

Diagnosing drug or alcohol dependence or addiction is not an easy task. Many people who are addicted to alcohol or drugs attempt to conceal or deny that they have an addiction. In addition, diagnostic tests for drug dependence and addiction lack specificity and sensitivity. Although blood and urine tests are usually quite reliable at detecting recent drug use, individuals can be adept at avoiding being tested or at manipulating test results. See Table 13-3 for the duration of time substances are detectable in urine.

Table 13-3: Duration of Time Drugs Are Detectable in Urine

Substance	Duration
Alcohol	48 hours
Amphetamines	12 hours
Barbiturates	10-30 days
Valium	4-5 days
Cocaine	24-72 hours
Heroin	24 hours
Marijuana	3-30 days (in heavy users)
Methaqualone	4-24 days
Phencyclidine (PCP)	3-10 days
Methadone	3 days
Sex, food, gambling	Not applicable

Why is substance abuse such a big issue in HIV care?

Injection drug use is estimated to be responsible for 25% of HIV transmission in the United States and is directly or indirectly responsible for 57% of HIV transmission to women. Less well appreciated is the fact that drug-using behaviors may be a significant HIV transmission risk factor for many men who do not inject drugs. In a recent study of men who have sex with men (MSM), up to 16% may have drug use as a risk factor for acquiring HIV (Chesney, 2003). The high degree of association between injection and noninjection drug use underscores the importance of primary care providers' being able to diagnose drug using behaviors.

Are there tools to help providers assess patients for drug and alcohol use?

Experts in addiction medicine use a combination of behavioral and clinical testing to diagnose drug abuse. There are 9 commonly used drug-use screening tests: Addiction Severity Index (ASI), Alcohol Dependence Scale, Alcohol Use Disorders Identification Test (AUDIT), CAGE (see below), Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA-Ar), Drinker Inventory of Consequences (DrInC), Michigan Alcohol Screening Test (MAST and SMAST), Problem Oriented Screening Instrument for Teenagers (POSIT), and Self-Administered Alcoholism Screening Test (SAAST) (American Society of Addiction Medicine, 1998). Six of them are specifically designed to detect alcohol use.

Which screening tests are most useful in primary care practice?

The CAGE test is a non-threatening quick screening test for detecting drug use in adults (see Table 13-4) and the POSIT test useful for screening adolescents aged 12-19. The questions below are designed to assess key substance-using behaviors. The letters in CAGE correspond to important emotions or behaviors indicative of drug use.

Table 13-4: The CAGE Screening Test	
C	1. Have you felt that you ought to C ut down on your drinking or drug use?
A	2. Have people A nnoyed you by criticizing your drinking or drug use?
G	3. Have you ever felt bad or G uilty about your drinking or drug use?
E	4. Have you ever had a drink or used drugs first thing in the morning (E ye opener) to steady your nerves, to get rid of a hangover, or to get the day started?

The Problem Oriented Screening Instrument for Teenagers (POSIT) examination is a 139 item yes/no questionnaire for assessing adolescent risk factors in substance abuse, physical health, mental health, family and peer relationships, educational and vocational status, social skills, leisure and recreation, aggressive behavior, and delinquency. A nonexperienced provider can conduct the test in 20 to 25 minutes. The questionnaire is available free in English and Spanish from the National Clearinghouse for Alcohol and Drug Information by mail at P.O. Box 2345, Rockville, MD 20847-2345 or by telephone at 1-800-729-6686.

What would provide a more in-depth assessment of drug and alcohol use?

Two detailed evaluations of drug and alcohol use are the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) and Addiction Severity Index (ASI) for alcohol or drug use. The DSM-IV defines the diagnostic criteria for substance dependence as a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by 3 or more of the following, occurring at any time in the same 12-month period:

1. Presence of drug withdrawal symptoms
2. Escalation of drug doses

3. Persistent inability to reduce or control drug use
4. Increased time spent obtaining drugs
5. Personal and business activities reduced by drug use
6. Development of drug tolerance
7. Knowing drug use's negative health and personal effects, yet continuing to use drugs

TREATMENT OF SUBSTANCE ABUSE PROBLEMS

What should you do before referring a person for treatment?

The decision to refer a person for drug abuse treatment should come after the provider has detected a substance use problem, conducted initial evaluations to determine the degree of drug use and physical harm done by the drug use, and provided brief interventions to stop drug abuse. After the diagnosis and brief interventions (if appropriate), the provider should refer the patient to a drug treatment system or an addiction physician.

What role does the primary care provider's attitude play in successful drug abuse treatment?

Drug abuse treatment is successful if the provider addresses his or her own biases about addiction, understands the factors contributing to addiction, provides appropriate pharmacologic and behavioral care, and recognizes that drug addiction is a chronic disease problem. Many drug abuse treatment failures are associated with hostile or unsupportive providers whose behaviors are based on the assumption that drug use is voluntary. Since successful drug abuse therapy depends on adherence to treatment regimens, any factors that facilitate adherence will foster successful treatment outcomes. The patient's perception that the primary care provider is nonjudgmental and supportive is an essential factor in successful therapy.

How can the primary care provider enhance the success of drug abuse treatment?

The primary care provider must prevent or treat exogenous factors that negatively affect successful drug abuse therapy. We now recognize significant environmental (social), genetic, biologic, and behavioral factors that facilitate drug addiction:

Environmental factors Common factors are family or sibling drug use, poverty, poor education, and homelessness. Patient referral to social services and family referral into drug treatment will facilitate the patient's therapy.

Genetic factors Ten percent of drug users have multifactorial genetic predispositions to drug use. Many patients have significant severe drug use problems requiring care from addiction specialists as soon as possible.

Biologic factors Many patients have preexisting mental health problems such as depression and attention deficit and hyperactivity disorder (ADHD) which, if recognized and treated, may prevent or modulate drug use.

Behavioral risk factors For adolescents, peer pressure is a common cause of drug use. Early education by parents and the primary care physician about drug use are very important for preventing drug use by adolescents.

What is the role of drug detoxification in drug abuse treatment?

Drug detoxification is the transitional therapy between identifying drug abuse and beginning a comprehensive program to treat it. The objective of drug detoxification is to facilitate a safe drug withdrawal process in supportive surroundings. Detoxification is not a treatment or cure for drug addiction; it is an intervention to get a person to the stage of comprehensive drug abuse therapy. Two common medical interventions to modulate symptoms are benzodiazepines in alcohol withdrawal and clonidine in opiate withdrawal.

What are the components of a comprehensive drug abuse treatment plan?

Effective drug abuse treatment encompasses a combination of behavioral and pharmacologic therapies to treat the individual's particular substance abuse problems and needs. Drug use medication is only one element of successful, comprehensive drug treatment, which includes addressing the individual's medical, psychological, social, vocational, and legal problems (see Table 13-5). Behavioral drug abuse prevention and treatment programs are provided in residential settings and in prisons. These programs may provide

medications to treat drug abuse, medical treatment for coexisting illnesses, and /or behavioral interventions using a number of personal, family, and community interventions. The most important community interventions are the 12-step or self help programs such as Narcotics Anonymous, Cocaine Anonymous, and Alcoholics Anonymous.

What should you do after the patient has completed a drug treatment program?

The primary care provider's task in assuring successful drug addiction treatment is to treat drug abuse as a chronic disease. Drug abuse treatment is effective if provided correctly and consistently. Approximately 50 % of alcoholics, 60 % of opiate addicts, 55 % of cocaine addicts, and 30 % of nicotine (cigarette) addicts are successfully treated. Note the success rate is generally lower for the legal addictive drugs, which may be because of ready access to those substances. For the illicit drug addictions, success occurs only if the drug abuse therapy is given on a continual basis for the lifetime of the patient. Drug use studies have clearly shown that drug abusers will relapse as any patient would who has a chronic disease. In direct comparisons, drug-addicted patients are actually less likely to relapse into addiction and are more adherent to their medication than persons with diabetes mellitus or hypertension.

Table 13-5: Components of Drug Abuse Treatment

Personal needs	Treatment needs
• Family services • Housing and transport • Financial services • Legal services • AIDS/HIV services • Educational service • Medical service • Vocational service • Child care service	• Behavioral therapy • Clinical and case management • Intake and processing • Treatment plans • Pharmacotherapy • Continuing care • Substance use monitoring • Self help/peer support groups

How do you use maintenance medications in treating drug abuse?

Maintenance treatment medications, important adjuncts to comprehensive drug abuse and dependence treatment, are used in the same way the nicotine patch is used for cigarette smokers. The medications help stabilize the drug user by reducing drug craving and thereby reducing high-risk behaviors associated with acquiring illicit drugs to attain the drug-induced high. Medication is used most effectively by patients who have good social support and higher education levels and are highly motivated to get off illicit drugs.

What are the common medications used in drug abuse treatment?

Use of medications to treat illicit drug use is limited because most of the approved medications are for opiate addiction and alcohol abuse. Effective opiate addiction medications are divided into 2 classes: opiate agonists and opiate antagonists. Opiate agonists are used to substitute for the opiate without causing the euphoria associated with drug abuse. The opiate agonists include methadone, L-alpha-acetyl-methadol (LAAM), and buprenorphine, which has recently been approved for medical use in the United States (Johnson, 2000). The other class is the opiate antagonists, the most important of which is naltrexone. Buprenorphine, actually a partial agonist-antagonist, may be used by physicians who undergo an 8-hour training course on how to use the medication. This medication has the highest potential for providing care in the private practice setting. Details for obtaining buprenorphine training and certification are available at the Office of Substance Abuse and Mental Health Administrations website, www.samhsa.gov, in the addiction treatment section under office-based therapies.

How do you detect, manage, and prevent relapse?

After the patient has been treated and is off drugs, the responsibility of the primary care physician does not end. The most common complication after patients have stopped using drugs is relapse. Four points to remember: 1) relapse should be expected to occur in most users; 2) on average 3-4 episodes may occur before complete abstinence; 3) relapse is not a treatment failure; it is a time to intensify treatment; and 4) the primary care provider is critical in preventing episodes of relapse. The most critical issues for the primary care provider to keep track of in the detection and prevention of relapses are to:

- Provide close followup.
- Do not make medical care dependent on drug abstinence.

- Recognize missed appointments as a sign of relapse and need for followup.
- Encourage and monitor the drug treatment/sobriety program of the patient.
- Treat comorbid psychiatric conditions aggressively.
- Identify drug use trigger points with the patient and discuss how to avoid them.
- Develop a plan to identify and manage relapse early.
- Make every effort to keep communication open and nonjudgmental.

MEDICAL AND PAIN MANAGEMENT ISSUES**What exactly do drugs do to the brain?**

Researchers continue to explore the variety of functional and structural changes that occur in the brain during drug use. Drug dependencies have been linked to disturbances in the dopaminergic pathways of the mesolimbic reward system, which lies deep in the brain. This system interconnects the ventral tegmentum to the nucleus accumbens with other connections to the limbic system and orbitofrontal cortex (Leshner, 1997). Disturbances in these areas are responsible for the behavioral changes and drug craving that characterize the drug-addicted person. Brain imaging studies have suggested that the changes in the brain are chronic, even after the person stops consuming drugs and may cause the relapses of most drug users.

What are the common medical problems of patients who inject drugs?

Patients who inject drugs often have comorbid clinical conditions, which are listed below with specific recommendations.

Mental health problems Treat early. Depression is the most common problem.

Hepatitis C Screen all drug users for hepatitis C and B and treat when indicated. Consult a specialist in HIV/AIDS and hepatitis C for coinfecting patients. Screen for depression before initiating therapy for hepatitis C. Treating hepatitis is important for preventing hepatotoxicity associated with ART.

Sexually transmitted diseases Screen regularly and provide safe sex education. Like other people, drug users often do not stop having sex even if they are infected with multiple diseases.

Tuberculosis Past tuberculosis exposure is common in injection drug users (as many as 30 % are PPD positive); they should be screened for TB.

Skin and soft tissue infections Cellulitis and skin abscesses are very common in injection drug users. The practice of “skin popping” markedly increases the risk of abscess formation.

Noninfectious health problems Treat accordingly. Drug users and alcoholics have multiple health problems that should be treated aggressively. The fewer medical problems patients have, the more likely they are to adhere to the treatment plan. Common problems to be aware of:

- Drug interactions (between medications and between medications and illicit drugs)
- Diabetes mellitus and hypertension
- Social environment (housing, child care)
- Pain management

How do you manage pain in opiate-addicted patients?

It is incorrect to assume that individuals addicted to opiates or any other kind of drug should receive less pain medication because they are addicted. They should receive pain therapy based on the diagnosed cause of the pain just like nonaddicted patients. The therapeutic approach differs according to whether the pain is acute or chronic.

How should you treat acute pain in a person diagnosed as a drug abuser?

Appropriate actions to take for drug-abusing patients in acute pain related to a recent diagnosable injury involve managing the pain:

1. Determine the source of the pain.
2. Provide pain medication that relieves the symptoms. Opiates may be used if they are what will stop the pain.
3. Give the medication in regularly scheduled doses. This prevents undesirable drug-seeking behaviors resulting from treatment on an as-needed (PRN) basis.
4. If pain is persistent or the cause is unclear, check for underlying psychiatric problems or an undetected source of pain.
5. If opiates are used, taper the doses slowly to avoid drug withdrawal.

How should you treat chronic pain in a person diagnosed as a drug abuser?

If the pain is chronic, the treatment strategies shift to not only finding the source of the pain, but also to using the entire spectrum of pain-relieving strategies with or without nonopiate pain medication (see Table 13-6). One exception is a patient with cancer-associated pain, for whom any effective medication (potentially addictive or not) is appropriate.

Table 13-6: Treatments for Chronic Pain in Known Drug Abusers

Medications used for pain control

Nonsteroidal anti-inflammatory drugs (eg, 30 mg ketorolactromethamine, which is equivalent to 6-10 mg morphine)
Tricyclics
Anticonvulsants
Muscle relaxants
Topical agents
Opiates

Physical interventions for pain control

Thermal: heat and cold are both effective and underutilized
Peripheral counterstimulation: transcutaneous electrical nerve stimulation (TENS) and vibration
Manual therapies: massage and chiropractic and osteopathic manipulation
Active movement: stretching and active exercise
Orthotics: splints and other supportive devices

HIV/AIDS ISSUES

Can HIV transmission be prevented in active substance abusers?

A comprehensive HIV prevention strategy in a primary care practice includes interventions to provide drug treatment, to take care of mental health problems, and to prevent HIV transmission during drug use and sexual activity. The primary care provider should routinely screen for drug abuse and treat or refer for treatment as quickly as possible. This is particularly important for adolescents who are at high risk for HIV, hepatitis B and C, and other infections. One study has shown that once adolescents start injecting drugs, over 90 % will become infected with hepatitis C within 18 months. The provider should also counsel patients who are actively using drugs not to share needles with others and to take advantage of programs that distribute clean needles. Programs use the needle distribution strategy as a first step to engage individuals who can then be encouraged to accept medical and drug abuse treatment services.

When is an active substance abuser ready for HIV treatment?

The most important clinical decision for successful treatment of drug-abusing patients with HIV is deciding when they are ready -- both substance abuse treatment and antiretroviral therapy (ART). Patients fall into 3 categories: those who do not want treatment, those who are ambivalent, and those who want treatment. For patients who do not want treatment, the provider should continue to be available with information on HIV and drug abuse treatment until they are ready to consider treatment. For those who are ambivalent about treatment, time is well spent during several clinical visits discussing the health issues of AIDS and drug abuse until they are ready for treatment. For patients who are ready for treatment the next step is to assess what factors will affect their adherence (see Chapter 7: Adherence to HIV Therapies). History of injection drug use, race, gender, age, socioeconomic status, level of education, and occupation are poor predictors of medication adherence. Accurate predictors of adherence are:

- The patient's health beliefs
- Ease of access to health care providers
- Familiarity with the treatment setting
- Existence of a social support system

- Perceived support from clinical staff members
- Simplicity of medication regimens

Interaction with providers and ambiance of the treatment setting account for almost half of the support factors needed to encourage drug users to adhere to treatment regimens. This pattern is true for active drug users, with the possible exception of persons addicted to crack cocaine.

Difficult economic and social situations, including unemployment and unstable housing, may make adherence to clinical treatment plans for both drug addiction and HIV even more difficult to follow. For these reasons some drug abuse treatment centers provide residential treatment to minimize outside influences on drug use. Also, methadone clinics provide an ideal opportunity for rehabilitated substance users to receive adherence support for ART through directly observed therapy (DOT) at the clinic.

What immunizations should drug abusers with HIV receive?

Because of the higher risk of tetanus in injection drug users, tetanus boosters should be given when due. Pneumococcal and influenza vaccines are recommended for all patients with HIV. Drug abusers with no antibodies to hepatitis A and hepatitis B should be immunized. Hepatitis A can be fatal in individuals with hepatitis C.

Are there important drug interactions between antiretrovirals and medications for drug treatment?

A common problem in treating patients with HIV who are drug users is the drug interactions between medications. Studies have shown that interactions of methadone and antiretroviral medications are linked to CYP450 3A4 sites in the liver. The most significant interactions are between methadone and nevirapine (NVP) or efavirenz (EFV), which precipitate rapid drug withdrawal symptoms (see Table 13-7). Methadone programs should be alerted when methadone patients are started on efavirenz or nevirapine, as dose escalation of methadone will probably be required. When methadone and didanosine (ddI) are coadministered the uptake of didanosine may be lowered requiring a higher dose of didanosine (See Drug Tables 7 and 8 in the Pocket Guide). Other interactions caused by drugs such as abacavir

(ABC) and all the PIs except indinavir (IDV), though pharmacologically measurable, are not clinically apparent and standard doses are appropriate. Potential interactions between illicit drugs and HIV medications are less well understood. Methamphetamine products have been associated with sudden death in individuals on protease inhibitors. Anecdotal reports describe how selective serotonin reuptake inhibitor (SSRI) antidepressant medications may produce side effects that mimic drug withdrawal and may decrease AIDS medication adherence.

Table 13-7: Antiretroviral Drugs that Affect Methadone Levels

NRTI	NNRTI	PI
zidovudine (ZDV) ↔	nevirapine (NVP) ↓	indinavir (IDV) ↔
didanosine (ddI) ↔	delavirdine (DLV) ↑	ritonavir (RTV) ↓
zalcitabine (ddC) ↔	efavirenz (EFV) ↓	nelfinavir (NFV) ↓
stavudine (d4T) ↔		saquinavir (SQV) ?
abacavir (ABC) ↓		amprenavir (APV) ↓
		lopinavir (LPV) ↓
		atazanavir (ATV) ↓

↓ = decreases methadone blood levels

↔ = indeterminate effect

↑ = increases methadone blood levels

Source: Adapted from Gourevitch MN, Friedland GH. Interactions between methadone and medications used to treat HIV infection: a review. *Mt Sinai J Med* 2000 67:429-436.

Why are HIV and drug abuse both such noticeable issues now?

HIV and substance abuse are both significant public health problems that merit the attention of public health officials and policymakers. Today, an estimated 40 million people worldwide are living with HIV. Of these, 2 to 3 million people are injection drug users. In the United States, approximately a third of HIV/AIDS cases are related to injection drug use. Research shows that use of drugs, injected or not, can affect decisionmaking – particularly about engaging in unsafe sex – that can endanger the health of the drug user and of others. Substance abuse is a double-edged sword because it increases an individual's risks for continuing drug use while also increasing the likelihood of exposure to HIV and other bloodborne infections. Infectious diseases that are more prevalent among injection drug users than in the general population are HIV, other STDs, including hepatitis B and C, and tuberculosis. Prevention and early treatment of drug abuse and drug-related diseases are critical public health measures to reduce the spread of new infections.

KEY POINTS

Substance abuse and addiction involve compulsive drug-seeking behavior that interferes with an individual's ability to function normally in many aspects of daily life. Substance abuse and mental health problems often occur together and, unless treated, can lead to chronic social and medical consequences.

Accurate and reliable diagnosis of substance abuse or dependence is not a perfect science. Screening techniques, in concert with a thorough medical history and evaluation, are important in detecting and correctly diagnosing a substance abuse-related disorder.

HIV transmission is preventable in people who use drugs. For drug users and the community at large, drug addiction treatment is disease prevention.

Hepatitis C is extremely common in patients with a past or current history of injection drug use. All patients with hepatitis C should be vaccinated against hepatitis A and B if serologic studies show no prior exposure.

The clinical issues to be addressed are to treat comorbid conditions as soon as possible, treat drug use and HIV aggressively, and be aware of common drug interactions seen in patients treated for drug use and HIV simultaneously.



SUGGESTED RESOURCES

Brief Interventions and Brief Therapies for Substance Abuse. Treatment Improvement Protocol (TIP) Series 34. Rockville, MD: Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment; 1999. DHHS Publication No. (SMA) 99-3353. Available at <http://www.health.org/govpubs/BKD341/> Accessed 1/04.

Klein MB, Lalonde RG, Suissa S. The impact of hepatitis C virus coinfection on HIV progression before and after highly active antiretroviral therapy. *J Acquir Immune Defic Syndr.* 2003;33:365-372.



WEBSITES

American Society of Addiction Medicine: <http://www.asam.org/> Accessed 11/03.

National Institute on Drug Abuse: <http://www.nida.nih.gov> Accessed 11/03.

Erowid (detailed biochemical and other information on drugs): <http://www.erowid.org> Accessed 11/03.

Office on National Drug Control Policy: <http://www.whitehousedrugpolicy.gov/> Accessed 11/03.

Substance Abuse and Mental Health Services Administration (drug abuse statistics, clinical treatment information): <http://www.samhsa.gov> Accessed 11/03.

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Principles of Drug Addiction Treatment: A Research-Based Guide. Bethesda, MD: National Institute on Drug Abuse; 1999. NIH Publication 99-4180. Available at <http://www.drugabuse.gov/PubCat/PubsIndex.html> Accessed 1/04.

Principles of HIV Prevention in Drug-Using Populations: A Research-Based Guide. Bethesda, MD: National Institute on Drug Abuse; 2002. NIH publication 02-4733. Available at <http://www.drugabuse.gov/PubCat/PubsIndex.html> Accessed 1/04.

Samet JH, Rollnick S, Barnes H. Beyond CAGE. A brief clinical approach after detection of substance abuse. *Arch Intern Med*. 1996;156:2287-93.

Chapter 14:**Mental Health Disorders***Linda Frank, PhD, MSN, ACRN**Glenn J. Treisman, MD, PhD**Niccolo D. Della Penna, MD**OVERVIEW**DISORDERS OF ATTENTION OR COGNITION**PERSONALITY DISORDERS**MOOD DISORDERS**ANXIETY DISORDERS**SUGGESTED RESOURCES**REFERENCES***OVERVIEW****Why is it important to address mental health disorders in persons living with HIV?**

HIV infection increases the risk of developing psychiatric disorders, including depression, mania, psychosis, and substance abuse (Treisman, 1999). For patients with preexisting mental illness, a diagnosis of HIV can significantly impact their ability to cope with HIV disease, adhere to treatment regimens, and take advantage of support networks and care systems, and can result in deterioration in their quality of life. Individuals with previous histories of mood, cognitive, or anxiety disorders may exhibit a reemergence or exacerbation of symptoms. As persons with HIV/AIDS live longer and the focus of care shifts from acute to chronic, the long-term psychological impact of HIV disease becomes more apparent.

What common HIV-related medical conditions have psychiatric symptoms?

It is essential for primary care providers to be aware of the need for a comprehensive evaluation of psychiatric symptoms in persons with HIV disease. Many psychiatric symptoms can indicate an underlying opportunistic disease or other condition (see Table 14-1).

What are the most common mistakes made in mental health management of HIV-infected patients?

Primary care providers commonly 1) under-diagnose depression, 2) under-dose antidepressant medications, 3) neglect substance use management and treatment, 4) stigmatize patients with psychiatric disorders, and 5) assume that psychotherapy implies a lengthy and detailed conversation.

Table 14-1. HIV-Related Conditions That Can Present With Psychiatric Symptoms

Type of problem	Condition
Opportunistic brain infections	Toxoplasmosis, cryptococcal meningitis, cytomegalovirus infection, tuberculosis, progressive multifocal leukoencephalopathy, neurosyphilis
Opportunistic malignancies	Lymphoma, Kaposi sarcoma
Metabolic complications	Fever, anemia, blood infections, hypoxia, hypotestosteronism
Drug toxicity	Corticosteroids, alpha-interferon, efavirenz (EFV)
Substance abuse complications	Recreational drugs (cocaine, alcohol, methamphetamine, hallucinogens, nitrate inhalant, opiates) Prescribed drugs (benzodiazepines, opiates, psychostimulants)

What conditions warrant psychiatric consultation?

Providers should obtain psychiatric consultation in 1) major depression refractory to medication trials, 2) bipolar disorder, 3) schizophrenia, and 4) suicidal or homicidal thoughts.

DISORDERS OF ATTENTION OR COGNITION**What are the characteristics of delirium in patients with HIV infection?**

Delirium, which is a state of global derangement of cerebral function, occurs more frequently in medically

ill, brain injured, or metabolically unstable patients. The clinical presentation and the differential diagnosis in HIV patients are the same as in HIV noninfected individuals, with the additional possibility that delirium is HIV-related. Presentation may vary in the presence of psychomotor agitation or retardation. Emotional changes are common and often unpredictable, and hallucinations and delusions are frequently seen. Electroencephalography may show diffuse slowing of the background alpha rhythm, which resolves as confusion clears. The syndrome has an acute or sub-acute onset and remits fairly rapidly once the underlying cause is treated.

How do you manage delirium in patients with HIV infection?

Non-pharmacologic treatments include identification and removal of the underlying cause, reorientation of the patient (calendars, clocks, view of outside world, and active engagement with staff members), and pharmacologic management of behavior or psychosis. Low doses of high-potency antipsychotic agents such as haloperidol are often useful. Newer, atypical antipsychotics are currently being used with some success, but those with more anticholinergic activity may worsen the condition. Benzodiazepines should be used cautiously, as they may contribute to delirium in some patients, except in cases of alcohol or benzodiazepine withdrawal deliria. Physical restraint should be used as little as possible as it often worsens delirium.

How do you diagnose and treat minor cognitive-motor disorder (MCMD)?

MCMD is a less severe neurocognitive disorder of earlier HIV infection, and the symptoms are often overlooked because they may be very subtle. Cognitive and motor slowing are most prominent and are often discovered as a result of a minor complaint, such as taking longer to read a novel, dysfunction when performing fine motor tasks, or an increased tendency to stumble. Diagnosis is made by the finding of 2 or more of the following symptoms for more than a month: impaired attention and concentration, mental slowing, impaired memory, slowed movements, lack of coordination, and changes in personality (irritability or emotional lability). Some patients continue to have minor problems, while others progress to frank dementia. Antiretroviral therapy (ART) may be of some benefit in slowing progression, but this conclusion is confounded by a lack of understanding of factors that lead some patients to progress while others remain static.

How do you diagnose and treat HIV-associated dementia?

HIV-associated dementia presents with the typical triad of symptoms seen in other subcortical dementias—memory and psychomotor speed impairments, depressive symptoms, and movement disorders. Initially, patients may notice slight problems with reading, comprehension, memory, and mathematical skills. Patients later develop global dementia, with marked impairments in naming, language, and praxis. Clouding of consciousness is absent, and there is no evidence of another cause. Motor symptoms are often subtle in early stages, including occasional stumbling while walking or running, slowing of fine repetitive movements, and slight tremor. There may be impaired saccadic eye movements, dysdiadochokinesia, and hyperreflexia. Apathy is also a common early symptom, often causing noticeable withdrawal from social activity. A frank depressive syndrome also commonly develops, typically with irritable mood and anhedonia instead of sadness and crying spells. Sleep disturbances are quite common, as is weight loss. Psychosis may develop in a significant number of patients and generally presents with paranoid beliefs, although hallucinations may exist. In 5%-8% of patients, a syndrome known as AIDS mania develops in addition to the HIV-associated dementia. In later stages, there may be frontal release signs and rather severe motor symptoms, including marked difficulty in smooth limb movements, especially in the lower extremities.

HIV dementia is typically seen in late stages of illness, usually in patients who have had a CD4 count nadir of < 200 cells/mm³. Certain risk factors have been associated with eventual development of HIV dementia, namely, higher HIV RNA viral load, lower education level, older age, anemia, illicit drug use, and female sex. Prognosis is rather poor, with a rapidly progressive nature, usually ending in death within 2 years.

Standard of care is to ensure an optimal ART regimen and treat associated symptoms aggressively. Depression can be treated with standard antidepressants, and in some cases methylphenidate or other stimulants may be useful in the treatment of apathy. Safety assessments should be performed as with any other case of dementing illness.

What is the relationship between psychosis and HIV?

Psychosis, including schizophrenia, contributes to behaviors that may lead to HIV infection, including higher rates of injection drug use, unprotected sex,

multiple sex partners, trading sex for money or other goods, and sex while intoxicated (Cournos et al, 1994). Providers who see patients with psychosis should be sensitive to the risk of acquiring HIV and should screen patients carefully for risk behaviors.

Accumulating evidence suggests that HIV infection may be directly linked to the onset of psychosis. Psychosis can be a manifestation of delirium, affective disorders, or schizophrenia, but can it occur in the absence of these conditions. Estimates of the prevalence of new-onset psychosis in patients with HIV range from 0.5%-15%, which is higher than in the general population (Kendler et al, 1996; Sewell et al, 1994). New-onset psychosis may also be a manifestation of HIV-associated encephalopathy. History of substance abuse also is more common among patients with psychosis.

How do you treat HIV-infected patients with schizophrenia?

The principles of treatment for HIV-infected patients with schizophrenia follow the same basic principles as for any other patient with schizophrenia, namely, control of symptoms with medications and psychosocial support and rehabilitation. Quite often, patients require long-term treatment and require various antipsychotic medications to control the delusions, hallucinations, and overall level of disorganization.

PERSONALITY DISORDERS

What is the relationship between personality disorders and HIV infection?

Personality disorders represent extremes of normal personality characteristics and are disabling conditions. Clinical observation suggests that patients with personality disorders who are highly extroverted and highly neurotic are most prone to engage in HIV risk behavior. These individuals are preoccupied by and act upon their feelings, and their actions tend to be unpredictable and inconsistent. Past experience and future consequences have little salience in decisionmaking for individuals who are ruled by feeling; the present is paramount. Their overarching goal is to achieve immediate pleasure or removal of pain, regardless of circumstances. Patients are more fixed upon the reward of sex and remarkably inattentive to the STDs they may acquire. In addition, substance abuse is more likely a comorbidity with these patients. Injection drug use is markedly more common because

the experience is much more intense and pleasurable. Thus, patients with personality disorders are at risk for HIV infection, and if they are already HIV-positive they are at risk for transmitting HIV to others. Management of patients with personality disorders includes encouraging a focus on thoughts rather than feelings, use of a behavioral contract, emphasis on constructive rewards, use of relapse prevention strategies, and coordination with additional health and psychosocial care providers.

MOOD DISORDERS

What are characteristics of adjustment disorders in patients with HIV?

Adjustment disorders are common emotional responses to HIV and often account for the “hopeful highs” and “helpless lows” experienced by some patients. These reactions are typically situational and transient, but reflect significant distress in the patient. Adjustment issues vary according to a variety of factors in addition to stage of illness, risk factors, socioeconomic status, level of education, characteristics of support networks, and comorbid psychiatric disorders. Adjustment reactions are most likely to occur at the time of significant medical events, especially during transition points in the illness. These conditions typically are accompanied by less severe depression and/or anxiety than are classic mood disorders. Treatment is usually non-pharmacologic and includes promotion of a structured environment, reassurance, engagement of the patient in the treatment process, close monitoring for progression of symptoms, and supportive counseling and psychotherapy.

How do you diagnose bipolar disorder in patients with HIV?

Bipolar disorder, also known as manic-depressive illness, is a condition in which patients classically alternate between extended episodes of depression and briefer periods of hypomania or mania with increased mood, increased energy, increased confidence, and grandiose ideas. Manic episodes are associated with increased rates of substance abuse and impulsive behavior, and there has been speculation that bipolar disorder may be a risk factor for HIV infection. AIDS-related mania appears to be specifically associated with late-stage HIV infection and is associated with cognitive impairment and a lack of previous episodes or family

history. The history will usually reveal progressive cognitive decline prior to the onset of mania. Irritable mood is more typical than euphoria, and prominent psychomotor slowing may replace the expected hyperactivity of mania, complicating the diagnosis. The presentation is usually quite severe in its course. AIDS mania appears to be more characteristically chronic, has few spontaneous remissions, and readily relapses with cessation of treatment (Lyketsos et al, 1997).

How do you treat bipolar disorder in patients with HIV?

The treatment of mania in early-stage HIV infection is responsive to mood stabilizing medications, particularly lithium, valproic acid, and carbamazepine. Antipsychotic agents, particularly atypical agents, are often utilized in the acute phase as well. These medications decrease manic symptoms and may prevent recurrence. Treatment strategies may be somewhat different in advanced HIV disease. AIDS mania may respond to treatment with antipsychotics alone. In general, patients are often exquisitely sensitive to dosage changes that might otherwise seem trivial. Few data exist for the newer anticonvulsants such as gabapentin and lamotrigine, and these medications should be used sparingly. The major problem with lithium in AIDS patients has been rapid fluctuations in blood level, even when on previously stable doses. Lithium intoxication is not uncommon in this setting. Valproic acid has been successfully used when titrating to usual therapeutic serum levels of 50-100 ng/dL. Hepatotoxicity may significantly limit treatment, particularly in the setting of chronic viral hepatitis or severe hepatic *Mycobacterium avium* complex infiltration. Hematopoietic abnormalities may also occur, requiring close monitoring of white blood cell and platelet levels. Carbamazepine may be effective but is poorly tolerated because of sedation and potential for bone marrow suppression in combination with antiviral medications and viral burden. Patients with late-stage HIV are also significantly affected by toxic side effects of antipsychotic medications, and a much lower dosage may be required than in other settings.

How do you diagnose major depressive disorder in patients with HIV?

Several lines of evidence suggest that HIV is a causal factor in depression, and that depression is a causal factor in HIV-related morbidity (Ciesla and Roberts, 2001). Differentiating appropriate sadness from pathologic depression may be difficult in the person infected with HIV. Psychomotor retardation and apathy of AIDS dementia complex may be confused with

depression, but will often improve in patients who are on combination antiretroviral treatment. Organic mood disorders may also have symptoms similar to major depression and are responsive to antidepressant medication.

Depression is underrecognized, underdiagnosed, and undertreated (see Table 14-2). At the same time, it is important for providers to consider alternative diagnostic possibilities for depressive symptomatology (see Table 14-3).

Table 14-2. Risk Factors for Depression

History of prior mood disorder
History of substance abuse or active substance use
Prior suicide attempt
History of anxiety disorder
Family history of depression or suicide
Inadequate social support
Nondisclosure of HIV status
Multiple losses
Advancing illness
Treatment failure

Table 14-3. Differential Diagnosis of Major Depression

Nonpathologic states of grief and mourning
Dysthymia
Delirium
Dementia
Demoralization
Substance intoxication
Substance withdrawal
CNS injury or infection
Acute medical illness

What are the pharmacologic treatment options for major depression?

Pharmacotherapy is the mainstay of treatment for major depression (see Table 14-4). No single antidepressant has been found to be superior in treating HIV-infected patients as a group. Patient adherence to regimens is critical, and those who take adequate doses of antidepressants have the best chance of improving. A general rule is to start with low doses of any medication, titrating up to a full dose slowly, in order to minimize early side effects that may act as obstacles to adherence.

Table 14-4. Medications to Treat Depression in HIV Disease

Medication	Starting dose	Usual therapeutic dose	Serum level	Advantages	Interactions with HIV medications
nortriptyline (Pamelor)	10-25 mg qhs	50-150 mg qhs	70-125 ng/dL	Promotes sleep, weight gain, decreases diarrhea	Fluconazole, lopinavir/ritonavir, and ritonavir increase nortriptyline levels.
desipramine (Norpramin)	10-25 mg qhs	50-200 mg qhs	>125 ng/dL	Promotes sleep, weight gain, decreases diarrhea	Lopinavir/ritonavir and ritonavir increase desipramine levels.
imipramine (Tofranil)	10-25 mg qhs	100-300 mg qhs	>225 ng/dL	Promotes sleep, weight gain, decreases diarrhea	Lopinavir/ritonavir and ritonavir increase imipramine levels.
amitriptyline (Elavil)	10-25 mg qhs	100-300 mg qhs	200-250 ng/dL	Promotes sleep, weight gain, decreases diarrhea	Lopinavir/ritonavir and ritonavir increase amitriptyline levels.
clomipramine (Anafranil)	25 mg qhs	100-200 mg qhs	150-400 ng/dL	Promotes sleep, weight gain, decreases diarrhea	Lopinavir/ritonavir and ritonavir increase clomipramine levels.
doxepin (Sinequan)	10-25 mg qhs	150-250 mg qhs	100-250 ng/dL	Promotes sleep, weight gain, decreases diarrhea	lopinavir/ritonavir and ritonavir increase doxepin levels.
fluoxetine (Prozac)	10 mg qam	20 mg qam	unclear	Activating, energizing	Amprenavir, delavirdine, efavirenz, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir, and saquinavir increase HIV medication levels. Nevirapine decreases fluoxetine levels.
sertraline (Zoloft)	25-50 mg qam	50-150 mg qam	unclear		Lopinavir/ritonavir and ritonavir increase sertraline levels.
citalopram (Celexa)	20 mg qam	20-60 mg qam	unclear		Lopinavir/ritonavir and ritonavir increase citalopram levels.
paroxetine (Paxil)	10 mg qhs	20-40 mg qhs	unclear	Mildly sedating	Lopinavir/ritonavir and ritonavir increase paroxetine levels.
fluvoxamine (Luvox)	50 mg qhs	150-250 mg qhs	unclear	Mildly sedating	Amprenavir, delavirdine, efavirenz, indinavir, lopinavir/ritonavir, nelfinavir, ritonavir and saquinavir increase HIV medication levels. Nevirapine decreases fluvoxamine levels.
venlafaxine (Effexor)	37.5 mg qam	75-300 mg qam	unclear		Lopinavir/ritonavir and ritonavir increase venlafaxine levels.
mirtazepine (Remeron)	7.5-15 mg qhs	15-45 mg qhs	unclear	Promotes sleep, weight gain	
nefazodone (Serzone)	50 mg bid	300-400 mg/d in divided doses	unclear	Mildly sedating	Efavirenz and indinavir increase HIV medication levels.
trazodone (Desyrel)	50-100 mg qhs	50-150 mg qhs for sleep 200-600 mg qhs for depression	unclear	Promotes sleep	Lopinavir/ritonavir and ritonavir increase trazodone levels.
bupropion (Wellbutrin)	100 mg qam	150-400 mg/d in divided doses	unclear	Activating, no sexual side effects	

The first week of treatment usually determines whether a patient will be able to tolerate the medication at all. Following this period, the dosage should be increased slowly to either a typical therapeutic dose or serum level, when appropriate. Patients should be encouraged to wait as long as possible for the therapeutic effect, which may take at least 6 weeks to achieve. Close monitoring for side effects should be done at every visit, and the side effects treated whenever possible. For example, insomnia because of selective serotonin reuptake inhibitor (SSRI) use may respond well to low doses of trazodone. Constipation from tricyclic antidepressants is often relieved by increasing water and fiber intake. Sexual side effects from SSRIs are common and may be treated with sildenafil in some, or by drug holidays, switching to bupropion, and addition of buspirone, cyproheptadine, or ginkgo biloba.

For patients showing only partial response to antidepressant medications after an adequate trial period, several other agents are often useful for augmentation strategies. The best studied is lithium, yet its side-effect profile often prevents use in the HIV setting. Olanzapine, risperidone, and pindolol have also been reported to be effective augmenting agents, as well as addition of a second antidepressant, other mood stabilizers, trazodone, methylphenidate, benzodiazepines, sleep deprivation, and phototherapy.

If no benefit is gained from the primary antidepressant, even after augmentation, a new primary agent should be chosen and similarly titrated slowly, and augmented if necessary. There is evidence to suggest that a response may be seen from 1 drug where none was seen from another in the same class.

What are the nonpharmacologic treatments for major depression?

Psychotherapy is an integral part of the treatment of major depression. Treatment with medication plus psychotherapy has been shown to be more effective for patients than either modality alone. Patients often require education about the disease nature of their depression, encouragement, and therapeutic optimism that the treatments will work. Medical providers who keep the concept of psychotherapy in mind will structure their interactions with patients to slowly empower and enable the patients to take control of their lives, thus relying on their providers less and less.

ANXIETY DISORDERS

How do you diagnose anxiety disorder in patients with HIV infection?

Anxiety disorder, which can include generalized anxiety disorder, panic disorder, obsessive-compulsive disorder, and post-traumatic stress disorder, is a common response to the stressors of HIV infection at any stage. True anxiety disorders tend to be less prevalent than depressive disorders, particularly at later stages of HIV infection. Anxiety is often a component of major depression, and further history should be ascertained for patients presenting with symptoms of panic or anxiety. Anxiety may also be due to substance use, and neurologic and physical impairment.

What are pharmacologic treatments for HIV-infected patients with anxiety?

Physicians must aggressively screen for major depression in patients presenting with anxiety symptoms, because both conditions often coexist. In particular, anxiety is a frequent symptom of major depression. Antidepressant medications are very effective in most cases.

In particularly debilitating cases, however, anxiolytic medications can be used for time-limited intervention and in low doses. Exclusion of patients with comorbid substance abuse is essential prior to initiation of anxiolytic medication, because of the abuse liability. Medications with a short half-life should be very cautiously used, as dependence may easily develop over a short period of usage. Particular attention should be given to the issues of hepatic function and choice of anxiolytic. Lorazepam, oxazepam, and temazepam avoid hepatic glucuronide conjugation by means of an alternate metabolic pathway and should be chosen as first-line medications for patients with HIV-associated liver dysfunction, as in patients with viral hepatitis.

What are nonpharmacologic treatments for HIV-infected patients with anxiety?

Specific advantages to utilizing nonpharmacologic intervention for anxiety include a decrease in pill burden, decrease in CNS sedation and cognitive impairment, lack of drug-drug interaction, and avoiding polypharmacy. Some interventions are 1) muscle relaxation, 2) meditation techniques, 3) psychotherapy, 4) exercise, 5) biofeedback, 6) behavioral techniques, 7) guided imagery, and 8) cognitive therapy.



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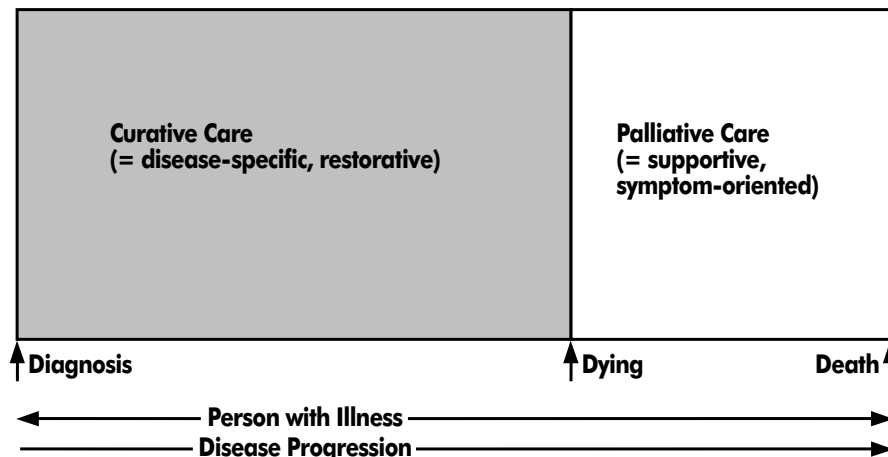
Chapter 15:**Palliative and End-of-Life Care***Carla S. Alexander, MD**Kennita R. Carter, MD**INCORPORATING PALLIATIVE CARE INTO HIV CARE**CARE AT THE END OF LIFE**KEY POINTS**SUGGESTED RESOURCES**REFERENCES***INCORPORATING PALLIATIVE CARE INTO HIV CARE****What is palliative care?**

Palliative medicine is the discipline devoted to the relief of suffering and the promotion of quality of life. Palliative, meaning non curative, has often been misunderstood to be limited to end-of-life or hospice care; it is rather a more general term for the type of supportive care needed throughout the trajectory of any chronic illness or major injury.

In traditional medical care, efforts are primarily curative or restorative until a poorly defined point when provider and patient acknowledge disease progression and decide to shift toward less aggressive management (See Figure 15-1a). In chronic progressive illnesses supportive care might be provided simultaneously assuring maximum quality of life throughout the course of illness for patients, family and caregivers (Figure 15-1b).

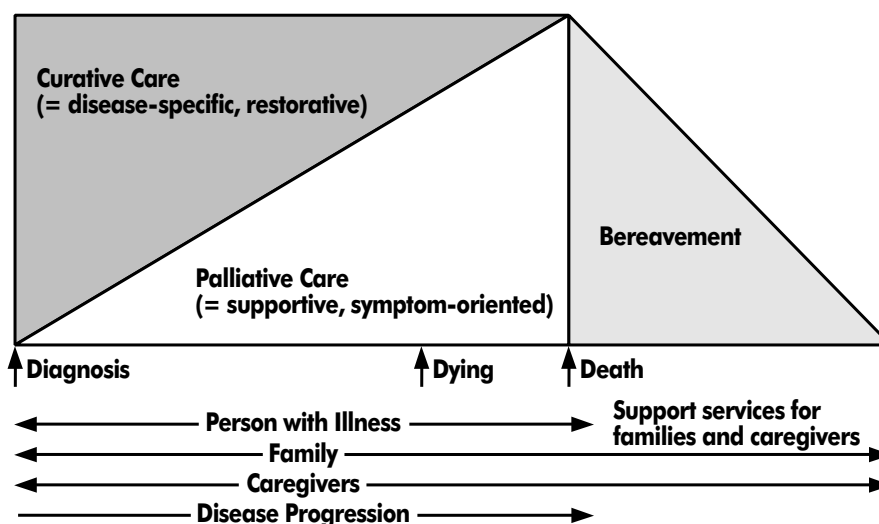
Why is palliative care still needed for people with HIV/AIDS, now that antiretroviral therapy (ART) is so successful?

AIDS, originally considered a terminal illness, has transitioned to a chronic disease for those who are able to use ART. However, there is still a steady death rate in the United States of 15,000 to 16,000 per year. While the numbers are low compared with the epidemic in the early years, persons living with HIV disease continue to experience pain, body habitus changes, and other physical and emotional symptoms that negatively impact their daily quality of life. Preventing and controlling these problems are as relevant as reducing viral load. Setting realistic goals and improving self-esteem allow the person with HIV disease to remain in control of his/her life and to be a productive member of society.

Figure 15-1a: Traditional Model of Care (first curative, then palliative)

Source: World Health Organization. *Cancer Pain Relief and Palliative Care, Report of a WHO Expert Committee*. Publication #1100804. Geneva: World Health Organization, 1990.

Figure 15-1b: Integrated Model of Care (curative and palliative together)



Source: World Health Organization. *Cancer Pain Relief and Palliative Care, Report of a WHO Expert Committee*. Publication #1100804. Geneva: World Health Organization, 1990.

What does palliative care focus on?

The following are essential elements of palliative care:

- Goals of care are patient- and family-driven and frequently revised.
- Relationships with an interdisciplinary team provide the mechanism for care.
- Truth-telling and support for realistic decisionmaking are the norm.
- Aggressive prevention and control of bothersome symptoms are paramount.
- It is understood that psychosocial, emotional, and spiritual needs significantly impact symptoms.
- Integration of a palliative care approach throughout the disease trajectory improves quality of life.
- Early identification of and communication with a proxy decisionmaker is a priority.
- Evaluation and treatment decisions are modified based upon prognosis.
- Near the end of life, unnecessary drugs are eliminated and comfort measures provided.
- Assisting the dying person to achieve psychosocial and spiritual closure is a goal of care.
- Family and friends are provided with care techniques and communication skills.
- Care of the caregiver and of the provider are essential aspects of providing supportive care.

- Legal, ethical, and cultural aspects are acknowledged and respected.
- It is recognized that dying is an inevitable part of life, not an enemy to be denied.
- Anticipatory grieving and bereavement support for the family are included in care.

How can palliative care be incorporated into primary HIV care?

A palliative approach to HIV disease management begins by obtaining an accurate assessment of the patient's support system, life goals, and preferences early in the disease process. Then the following activities are incorporated into the care plan:

- Open appraisal of stage of disease with appropriate goal setting
- Yearly review of goals (more frequently if symptomatic)
- Anticipation of and prophylaxis for side effects of ART
- Education regarding advance care planning well before patient is symptomatic
- Use of standardized questionnaires to assess presence of symptoms and their impact on quality of life
- Provision of separate medical appointments to manage symptoms such as pain or weight loss

- Reduction of diagnostic studies and number of medications as prognosis shortens
- Regular review of health power of attorney and support of patient wishes
- Discussions of prognosis with patient and family soon enough to allow closure near the end of life
- Referral to hospice/palliative home care when office visits become burdensome for patient
- Maintenance of contact with family during bereavement period
- Acknowledgement of staff members' feelings of loss when patients die

What are some common symptoms experienced by persons with advanced HIV disease?

In surveys, patients receiving ART report experiencing the same symptoms as patients reported in the earlier years of the epidemic, but the frequencies of symptoms have changed (Mathews et al, 2000; Vogl et al, 1998). Fatigue, sadness, diarrhea, and fever continue to plague patients even when disease is controlled by ART. Pain is still experienced by up to 75% of patients and may be present in multiple areas at once, including the extremities and oral, esophageal, abdominal, or rectal sites. Adequate treatment for one type of pain may only expose another. This often raises the specter of “drug-seeking behavior” when in fact the patient is simply able to be aware of the secondary pain after the greater pain is relieved (see Chapter 13, Management of Substance Abuse). Peripheral neuropathy can be caused by ART, HIV disease itself, or unrelated disease such as diabetes. This pain does not seem to be related to the degree of control of viral burden, and cause must be sought through historytaking as many patients seem to overlook early manifestations such as numbness. Refer to Chapter 8, Symptom Management, as well as resources under Suggested Resources for management of pain and symptoms.

How important is pain control in advanced HIV disease?

Pain, as with any symptom, should be described, quantitated, treated, and promptly reevaluated with appropriate dose modification of therapy (see Table 15-1). In the *Guidelines for Management of Cancer Pain*, pain experienced by those with HIV disease is compared with the chronic pain experienced by persons with cancer, which often requires management with opioids (AHCPR, 1994). Unlike blood pressure, which might be regulated over weeks, pain should be controlled within the shortest time possible to prevent the development of long-term symptoms such as depression and anhedonia.

Table 15-1. Mnemonic for Assessment of Pain

A	A sk about pain regularly; A ssess systematically
B	B elieve the patient and family
C	C hoose treatment options appropriate to patient and setting
D	D eliver medications on an “around-the-clock” basis with adequate “breakthrough” doses
E	E valuate results frequently; E mpower patients and families to control pain

The following guidelines are helpful in prescribing pain medication (American Pain Society, 1999):

1. Use a grading system (such as the scale of 0–10) to document pain severity and compare the number obtained to a second number following treatment to evaluate response.
2. Start with a dose that will acutely relieve the pain. This may be given intravenously or subcutaneously to achieve a rapid response. Care should be taken to observe for any signs of respiratory depression in opiate-naïve patients who receive parenteral opioids.
3. Next, begin a low dose every 3–4 hours (based on the half-life of the drug) “around-the-clock,” **not** on an as-needed, basis. The initial dose should be chosen based on the age, size, and renal/hepatic function of the patient. (See Suggested Resources for additional guidance on pain management.)
4. A “breakthrough dose” should also be prescribed every 1–2 hours prn equal to a sixth of the total daily opioid dose. This allows for development of a steady state drug level and avoids alternation of great pain intensity with somnolence. This is the same approach used to control hyperglycemia with a sliding scale of regular insulin based on glucometer readings; doses are based on pain scores.
5. When pain is fairly well controlled, it is appropriate to change the patient to a long-acting pain medication for ease of administration. The dose is calculated by adding together the total dose taken in 24 hours and dividing by the half-life of the new preparation. For example, for a medication meant to be given every 12 hours: divide the total dose by 2, and this number will be the dose every 12 hours. Don't forget the breakthrough dose. This is a short-acting opioid, preferably of the same type as the long-acting one for use at times when the pain is not adequately controlled.
6. Other forms of administration include liquid formulations for persons with difficulty swallowing, rectal suppositories, “sprinkles” that can be mixed with soft food, and patches that allow absorption of the medication through the skin.

What is advance care planning?

Advance care planning is an attempt to clarify patient wishes near the end of life. Identification of a “health care proxy,” a person who makes decisions if the patient becomes unable to communicate his or her own wishes, should be encouraged and documented in the medical record with contact information. Even when formal directives have not been written the patient should discuss his or her thoughts and concerns about the end of life with that person. Hosting a family meeting to discuss the issues might also be useful. A “living will” may be difficult to write because it is not possible to anticipate every event that might occur when one is critically ill. It may be better for the person to clarify general thoughts about the use of ventilators or other intensive support mechanisms for sustaining life. Permanency planning should be included in this discussion whenever children are involved.

Family members feel inadequate when confronted with end-of-life decisionmaking. Realistic guidance provided to the health care proxy can minimize that emotional burden (see Table 15-2). The provider should discuss in detail what a resuscitation effort means and give a specific description of what might happen during the use of “life supports” (eg, one cannot talk and may not be able to communicate when on a respirator; the combination of early dementia and an episode of hypoxia might result in significant diminution of mental capacities).

What is hospice care?

Hospice can be a philosophy, a place, a type of home care, or a reimbursement mechanism (EPEC Curriculum, 2003). The goal of hospice care is to reduce suffering by controlling symptoms, consolidating medications, and supporting the patient and family in living fully until death. However, in the United States obtaining hospice care for any individual often depends on insurance coverage. For a person on Medicare a referral to hospice care requires that the patient have a life expectancy of less than 6 months if the disease runs its normal course. This is a complex determination in any chronic illness. Patients who have decided to forego restorative therapy or who no longer want to be admitted to a hospital are not the norm in HIV disease, but working with a local hospice program may make this transition less burdensome. For financial reasons the patient may be offered “palliative” rather than “hospice” care.

Table 15-2. Useful Questions for Exploring Patient and/or Family Concerns

Domain	Question
Physical comfort	Tell me about your pain. Can you rate it on a 10-point scale?
	How much do you suffer from physical symptoms like shortness of breath, fatigue, or bowel problems?
Continuity with one's self	What makes life most worth living for you at this time?
	If you were to die sooner rather than later, what would be left undone?
Maintaining and enhancing relationships	How are your family (or loved ones) handling your illness?
	Have you had a chance to tell your family (or loved ones) how they are important to you?
Making meaning of life and death	What kind of legacy do you want to leave behind?
	What would allow you to feel that going through this illness has a purpose?
	Do you have spiritual beliefs that are important in how you deal with this illness?
Achieving a sense of control	How would you like your death to go?
Confronting and preparing for death	How much are you thinking about dying now? What are you thinking about it?

Source: Alexander C, Back A, Perrone M. Medical Care at the End of Life. In O'Neill JF, Selwyn PA, Schietinger H, eds. *A Clinical Guide to Supportive and Palliative Care for HIV/AIDS*. Rockville MD: Health Resources and Services Administration. 2003.

CARE AT THE END OF LIFE

What are the challenges of end-of-life care for the provider?

Deciding when to make the transition from curative/restorative mode to one of comfort measures only and having the skills to communicate this to the patient are probably the greatest challenges facing the provider (see Table 15-3). While guidelines exist for having difficult conversations effectively, avoiding conveying

a message of abandonment is the real difficulty. Being adept at managing symptoms such as pain can give the provider confidence when initiating this conversation. Reassuring the patient and family that comfort measures are always possible and isolating one problem at a time may minimize their sense of being overwhelmed. Simply asking the patient what goals are important helps refocus on concrete issues that can be successfully mastered.

Another significant challenge for the provider may be foregoing invasive diagnostic studies when the patient is moving closer to death. The astute practitioner needs to rely on physical assessment and knowledge of probabilities to surmise the cause of a symptom. Using one medication for multiple outcomes minimizes pill burden. For example, steroids may be employed for relief from dyspnea; this same drug might also improve appetite and sense of well-being, suppress fever, and relieve achiness related to prolonged bedrest.

Table 15-3. Mnemonic for Breaking Bad News	
S	S etting and listening S kills
P	P atient and family P erception of condition
I	I nvitation to patient to determine how much I nformation he/she wants to know
K	K nowledge; reviewing the facts
E	E xplore E motions and E mpathize
S	S ummary & S trategy

Source: Adapted from Baile W, Buckman R. *Practical Guide to Communication Skills in Clinical Practice*. Niagara Falls, NY: Medical Audio Visual Communications, Inc, 1998.

What roles do culture and spirituality play in end-of-life care?

Culture and spirituality are significant factors affecting how end-of-life care should be delivered to each individual patient and family. Lack of clarification of cross-cultural differences can be a barrier to patients' receiving appropriate end-of-life care. Spirituality, connection with a higher power, or a sense of meaning can provide tremendous comfort and support. Not recognizing these issues or the impact of AIDS-related stigma might even add to suffering. It is useful to ask the patient if he/she has a faith and how important it is to him/her. If the provider does not feel comfortable

addressing these issues, every attempt should be made to have someone on staff or for easy referral to address this need. It has been clearly documented in medical literature that spiritual concerns might be involved in exacerbation of all types of illness.

How do you provide reality-based hope for the person with advanced AIDS?

Hope is an intrinsic value that allows the human spirit to persevere even against great difficulty. When a person is nearing the end of life, it may not be reasonable to want to live until a certain birthday that will not occur for several months. In this case, the health care staff needs to help with a redefinition of hope that is more achievable. Some families in hospice programs have celebrated religious holidays a month ahead of time, held ceremonies before they were originally scheduled, and made videotapes of the dying person to be played during an up-coming event.

How do you conduct a family meeting?

Prior to a family meeting, the provider must prepare a mental agenda to identify internal and external barriers to achieving a clear and therapeutic picture of the goals important to all involved (see Table 15-4).

What does the patient need to accomplish before death?

There are multiple physical, psychosocial, and spiritual issues that deserve attention in order for the patient to die peacefully and to leave satisfactory memories for family and friends. The patient and family need to:

- Appoint a health power of attorney and talk with that person about support preferences
- Make a will to avoid conflict following death, including guardianship issues
- Attempt to resolve previous misunderstandings or estrangements
- Encourage family and friends to openly discuss the patient's deterioration to avoid a "conspiracy of silence"
- Express love and appreciation to family, friends, and staff
- Engage family, friends, and staff in a life review (eg, telling stories about accomplishments, regrets, funny things that have happened along the way)
- Create a memory book or video tape, or write letters for children left behind
- Discuss plans or preferences regarding funeral or memorial service
- Say goodbye to family, friends, and caregivers (the patient needs reassurance that those left behind will be cared for and that he or she will be remembered)

Table 15-4. Components of a Discussion about End-of-life Care

I. Making preparations prior to a discussion about end-of-life care:

- Review previous knowledge of the patient and/or their significant others
- Review previous knowledge of the patient's attitudes and reactions
- Review your knowledge of the disease prognosis, treatment options
- Examine your own personal feelings, attitudes, biases, and grieving
- Plan the specifics of location and setting: a quiet, private place
- Have advance discussion with the patient or family about who will be present

II. Holding a discussion about end-of-life care:

- Introduce everyone present
- If appropriate, set the tone in a non-threatening way: "This is a conversation I have with all my patients..."
- Find out what the patient or significant other understands
- Find out how much the patient or significant other wants to know
- Be aware that some patients do not want to discuss end-of-life care
- Discuss prognosis frankly in a way that is meaningful to the patient
- Do not discourage all hope
- Avoid temptation to give too much medical detail
- Make it clear that withholding life-sustaining treatment is NOT withholding caring
- Use repetition to show that you understand what the patient or the significant other is saying
- Acknowledge strong emotions and use reflection to encourage patients or their significant others to talk about these emotions
- Tolerate silence

III. Finishing a discussion of end-of-life care:

- Achieve common understanding of the disease and treatment issues
- Make a recommendation about treatment
- Ask if there are any questions
- Ensure basic followup plan and make sure the patient and/or significant others know how to reach you for questions

Source: Curtis JR. Patient-Clinician Communication. In O'Neill JF, Selwyn PS, and Schietinger H, Eds. *A Clinical Guide to Supportive and Palliative Care for HIV/AIDS*. Rockville, MD: Health Resources and Services Administration, 2003.

Table 15-5: Life's End

The following mnemonic may be helpful when writing DNR orders: LIFE'S END. This stands for

L	Keep the L ips and mouth moistened with ice chips
I	Expect urinary and fecal I ncontinence when patient is too weak to get out of bed; insert a catheter/use bed pad
F	Expect F evers and use around-the-clock antipyretics possibly by the rectal route
E	Eliminate all but E ssential medications
'S	Be aggressive about S ymptom management
E	E ating decreases; substitute other supportive activity for family members who want to continue feeding
N	N ursing call orders should be revised
D	D ecubitus ulcer prevention requires turning every 2 hours

Source: Copyright Palliative Care Program, University of Maryland, Baltimore, MD; 1999. Reprinted with permission.

What can the family expect as their loved one is dying?

Many people have little experience with the actual process of dying. At a time when family members feel grief and a loss of control, it is comforting to have a simple description of what to expect as they sit at the bedside. The provider needs to offer this information (see Table 15-6) as well as to suggest activities the family can do to offer comfort and to alleviate their feeling of helplessness.

What must the provider do after the patient dies?

At the time of death, those present need verification that in fact their loved one has died. It is useful to review what has happened and to offer supportive comments to those present as they adjust to this new information. It is comforting for them to remain with the deceased and say their goodbyes. Cultural beliefs will dictate behavior, and it is helpful to have discussed these practices ahead of time. Providers can:

- Reassure the family that they provided good and loving care
- Allow family members to remain at the bedside as long as necessary to bring closure

What steps should you take after writing a Do Not Resuscitate (DNR) order?

After writing an order for "No CPR" the provider should reverse these letters to offer family and friends "RPC" - Reassurance, Presence, and Caring. Facilitate conversations that acknowledge the role of family and friends in care. Be present for family even if only briefly. For hospitalized patients, write orders to intervene that assure comfort measures will be provided even when antibiotics or pressors might be discontinued (see Table 15-5).

- In the hospital, place something on the bed to honor the space recently vacated
- Tell family when to expect autopsy findings if autopsy is requested
- If an autopsy is performed, schedule time to discuss this with the family
- Notify other staff members who may have cared for this patient
- Send a condolence card
- Call family 1-2 weeks after the death to listen

Table 15-6: What the Family Should Expect of the Patient Prior to Death

1–2 weeks prior to death	• <i>Withdrawal from people</i> • <i>Decreased food and liquid intake</i> • <i>Talking with those who are already dead</i> • <i>Sleeping longer periods</i> • <i>Picking at clothing</i> • <i>Feeling very fatigued</i>
Days to hours prior to death	• <i>Surge of energy; seems like “himself”</i> • <i>Cheyne-Stokes respirations</i> • <i>Decreased urine output</i> • <i>Acral and large joint cyanosis</i> • <i>“Death rattle”</i> • <i>Weak pulse and decreased blood pressure</i>

Source: Adapted from Kearnes, *Gone from My Sight*. Depoe Bay OR: BK Books; 1995.

How can a primary care practice or clinic avoid staff burnout when several of the patients have died?

Providers who suffer from the death of more than one patient over a short time period may experience symptoms of multiple loss syndrome which, if unattended, can lead to symptoms found in post-traumatic stress disorder. They need to take the time to effectively grieve. How this is accomplished is a personal matter for each individual, but the clinic or health care facility must recognize the importance of allowing each person to come to a sense of closure after a patient's death. For some, attending the wake or funeral may be helpful. For others, a clinic-based time for remembering the individual(s) can provide a structured outlet for feelings of grief.

The focus of providers tends to be on caring for others. Primary care providers often have not received formal training in preventing and identifying burnout. With an ever increasing work load and shrinking time for office visits and administrative responsibilities it is easy to miss signs of stress (see Table 15-7). O'Neill and McKinney describe a 2-pronged approach to preventing and managing burnout. This involves developing more effective individual coping skills as well as creating a less stressful work environment (O'Neill and McKinney, 2003). Examples of personal coping strategies include: 1) being mindful of eating, exercise, and sleep patterns, 2) keeping a daily journal to record the events that cause stress, and 3) discussing personal experiences with someone else. A less stressful work environment includes a choice of mechanisms for 'taking a break' from the steady emotional drain of patient care.

Table 15-7: Common Signs of Stress for Caregivers

Physical	Psychological	Behavioral
Backaches	Anger and frustration	Emotional outbursts
Change in eating patterns	Loss of self-confidence and self-esteem	Withdrawal from friends and family
Diarrhea	Loss of interest in and commitment to work	Loss of punctuality and neglect of duty
Elevated blood pressure	Feelings of inadequacy, helplessness, and guilt	Decrease in judgmental ability
Fatigue	Feelings of restlessness	Inability to focus on tasks
Gastrointestinal problems	Depression	Tearfulness
Headaches	Sense of being overwhelmed or overloaded	Increased use of alcohol or other drugs
Insomnia	Mood swings	Difficulty getting along with people
Muscle tension	Sense of failure	Impaired work performance
Weight loss	Anxiety about the future	Resistance to change

Source: O'Neill JF, McKinney M. Caring for the caregiver. O'Neill JF, Selwyn PA, and Schietinger H, Eds. *The Clinical Guide to Supportive and Palliative Care for HIV/AIDS*. Rockville, MD: Health Resources and Services Administration, 2003.

KEY POINTS

Palliative medicine is the discipline devoted to the relief of suffering and the promotion of quality of life. Palliative care has often been thought to be limited to end-of-life or hospice care; it is rather a more general term for the type of supportive care needed throughout the trajectory of HIV disease.

Advance care planning is an attempt to identify a decisionmaker should the patient become unable to communicate his or her own wishes.

Deciding when to make the transition from curative/restorative mode to one of comfort measures only and having the skills to communicate this to the patient are probably the greatest challenges facing the provider.

There are multiple physical, psychosocial, and spiritual issues that need resolution in order for the patient to die peacefully and to leave satisfactory memories for family and friends.

The focus of providers tends to be on caring for others. Providers who suffer from the death of more than one patient over a short time period can experience symptoms of post-traumatic stress disorder. They need to take the time to effectively grieve.



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Chapter 16:

Clinic Management

*Jonathan Allen Cohn, MD, MS, FACP**PATIENT RECRUITMENT AND RETENTION**CLINICAL SERVICES NEEDED FOR HIV CARE**SUPPORT SERVICES AND LINKAGES NEEDED FOR HIV CARE**KEY POINTS**SUGGESTED RESOURCES*

PATIENT RECRUITMENT AND RETENTION

How can primary care clinics recruit patients with HIV into care?

The persons who were easy to recruit and retain in care are already enrolled; the more challenging patients await recruitment. Every clinic should 1) be linked to agencies providing HIV testing and services for persons with HIV and 2) make clinic access easy for the clients of those outside services.

Many clinics establish referral linkages with community services that provide HIV counseling and testing services (CTS), AIDS service organizations (ASOs), STD treatment facilities, family planning agencies, drug treatment facilities, local health departments, regional HIV/AIDS hotlines, and local hospitals and emergency rooms. Many clinics also offer free confidential or anonymous CTS using State or Federal funding.

Clinic personnel should build personal relationships with agencies that may provide referrals, invite staff of community agencies to visit the clinic, or hold an open house. Providers from ASOs, such as case managers, can be invited to accompany patients on clinic visits. Referring agencies must know what services the clinic provides and which patients it serves, as well as those it cannot serve. Clinics with Ryan White Care Act (RWCA) funding should be able to accept patients regardless of health insurance or ability to pay. Primary care clinics can benefit from having a brochure describing their programs and array of services, along with information about making appointments, hours of service, and so forth.

Clinics differ based on the characteristics of the people living in their catchment area and the expertise of clinic staff. Some successful clinics target a narrow but underserved population and concentrate on

meeting the needs of that population. A youth-friendly environment may differ from one targeting the working poor.

How do clinics retain patients in care?

Respect, cultural competence: Respecting patients and providing them with effective care builds trust and keeps them coming back. New clinic attendees may have strong feelings related to HIV infection (fear of death) or how they acquired it (issues of shame or of secrecy). They may lack trust in medical care (prior personal experiences or the legacy of the Tuskegee syphilis experiments) or in current treatments (“Everyone I knew who took AZT died...”). Patients encounter barriers where there are cultural differences or language barriers between themselves and the staff. Staff members should be trained to anticipate, recognize, and work with these issues.

Welcoming staff attitude: Patients should always be made to feel that they came to the right place (even when it is not true, and they must be referred on). Patients should receive understanding and support, even when they arrive in clinic without obtaining the required managed care referral form (at least the first few visits). Providers must know the target population and build a system that will make patients feel welcome. Many RWCA-funded clinics employ patient advocates, persons from the target community who may or may not themselves be HIV-infected. Advocates directly assist patients in negotiating the clinical care system and help patients ask questions or make their needs known to clinical staff. Advocates or peer support persons can be instrumental in helping patients build self-esteem and acquire new habits that will enable them to use health care services in a proactive manner. It is very helpful for patients to be able to forge a personal connection with at least one staff member.

Welcoming environment: Physically comfortable waiting and examination areas, with linguistically and culturally appropriate decoration and reading material, are important for patient retention. A clinic that serves parents or children should make available toys or children's books.

Orientation to clinic systems and rules: New patients need a brief description of clinic staff and services, routine and emergency procedures, prescription refill procedures, and after-hours followup. They must understand about requirements for referrals from managed care providers, and new patients may need help with such requirements. Patients must also be oriented to what is expected of them (eg, coming on time, calling to cancel or reschedule appointments) and the consequences of not fulfilling their responsibilities (eg, clinic rules regarding late arrivals). A handout or pamphlet with staff names, clinic hours and phone numbers, and emergency procedures can be very helpful.

Systems to support attendance: Patients should receive reminders (by phone or mail) about 48 hours before each appointment. It is also useful to have a staff member contact patients who have missed appointments to find out what prevented them from attending and offer to reschedule. ASOs may have funding for transportation (eg, door-to-door taxi service for selected patients, van service, vouchers for use on public transportation). Other barriers may require a coordinated effort by the clinic staff, case manager, and others. Clinic sessions should be scheduled at times convenient for the patients; mid-to-late afternoon is best for school-age children, occasional evenings or weekends are good for working people.

CLINICAL SERVICES NEEDED FOR HIV CARE

What is the optimum array of services that an HIV clinic should provide?

All patients with HIV need a similar array of services that must be provided either directly or through referral. Patients need providers knowledgeable in the diagnosis and treatment of HIV infection and its complications, including state-of-the-art use of antiretroviral therapy (ART). Services must address the clinical conditions associated with patients' current or prior risk behaviors. Given improved life expectancy, patients need age-appropriate general preventive and screening services. The high rates of premorbid mental health problems in persons with HIV and mental health problems related

to HIV disease make mental health services a key component of HIV care. Substance abuse treatment is crucial. Confronting the epidemic by including HIV prevention activities in clinical care sites is a new activity, challenging and critically important (see Chapter 4).

The HIV/AIDS Bureau of the Health Services and Resources Administration (HRSA) lists basic services required for agencies to receive funding through the RWCA Title III (Early Intervention/Primary Care) Program (Table 16-1). Some States have produced more detailed lists for agencies wishing to receive special State-level funding for HIV care; see the New York State list for comparison (Table 16-2). Funded programs generally must demonstrate continuity in primary care, 24-hour access to emergency care, ongoing staff training, an administrative apparatus adequate to manage the program and its funding, a reporting system to meet the grantors' requirements, and quality management. Programs that do not receive explicit funding for clinical care and/or support services need to rely more on referral networks.

**Table 16-1: HIV/AIDS Bureau
Requirements for Title III-funded Early
Intervention/Primary Care Programs**

- HIV counseling, testing, and referral
- Counseling and education on living with HIV disease, including availability and use of treatment therapies
- Appropriate medical care and monitoring, including CD4 cell monitoring, viral load testing, antiretroviral therapy, and prophylaxis and treatment of opportunistic infections, malignancies, and other related conditions
- Oral health care, outpatient mental health care, substance abuse treatment, nutritional services, and specialty care either directly or through a formal referral mechanism
- Appropriate referrals for other health services
- Perinatal care including therapy to reduce mother to child transmission (MTCT)
- Screening/treatment of TB

Source: Adapted from Ryan White C.A.R.E. Act Title III Manual. Rockville, MD: HIV/AIDS Bureau, Health Resources and Services Administration. 1999(Section II):5. Available at <http://www.hab.hrsa.gov/CATIE/> Accessed 2/04. Table 16-2. Comprehensive Ambulatory HIV Programs from the New York State AIDS Institute

Monitoring and treating the long-term complications of ART, such as insulin resistance, lipodystrophy syndromes, dyslipidemia, and osteopenia, are of increasing importance. Instituting formal activities to assist patients in behavior change is increasingly recognized as an essential component of HIV care. Hepatitis C diagnosis and management are of particular importance for patients who have had blood product

exposures or who were drug injectors. Screening for premalignant human papillomavirus (HPV) disease in men using anal Pap smears is potentially valuable, although it has not become a universal standard of practice.

Clinics should also have a system in place to protect the safety of their employees in regard to occupational HIV exposure (See Chapter 10 as well as Suggested Resources below).

Table 16-2. Comprehensive Ambulatory HIV Program Standards of the New York State AIDS Institute

Clinical services that must be provided by ambulatory HIV programs	
On site	
• Age appropriate, confidential HIV counseling and testing • Initial and annual comprehensive medical evaluations, including substance abuse and mental health assessments • Cognitive function testing • Ongoing clinical HIV disease monitoring • HIV-specific therapies and prophylactic treatments, including treatment education and adherence monitoring • Routine gynecologic care and followup (including reproductive counseling, pelvic examinations, and Pap smears) • Routine family planning services • Case management • Patient health education, including risk reduction and nutrition counseling	
On site or via linkage	
• Access to consultations by specialists in infectious diseases • Core diagnostic and therapeutic services - laboratory, including early diagnostic methods to establish the infection status of children - radiology, including MRI - pharmacy - dental services - mental health services, including clinical social work, clinical psychology, and psychiatry as clinically appropriate • Other primary care, specialty, and subspecialty services - obstetrics - pediatrics, adolescent medicine, and pediatric subspecialties - ophthalmology - dermatology - outpatient surgery - clinical pharmacy - subspecialties of internal medicine, including gastroenterology, hematology, pulmonology, and oncology	

Source: New York State AIDS Institute. Comprehensive Ambulatory HIV Program Standards. Part 490 of Title 10 NYCRR. November 1994.

What is different about providing HIV care compared with other types of medical care?

HIV care is new; the epidemic was recognized in 1981, and potent therapy became available in 1996. Therapeutic options are much improved, but there is little room for error. Drug resistance may occur rapidly and is irreversible. The ongoing development of new therapeutic agents is impressive, yet is not rapid enough to ensure future therapies to persons who received inappropriate prescriptions, or who did not receive the requisite education, support, and counseling to succeed with their therapy. With therapies that have been in use for less than 10 years, much is still unknown about long-term outcomes.

Juxtaposed against the need for expertise in HIV care is the need to expand access. The only prerequisite to developing expertise in HIV care is commitment. A wide range of providers may be the HIV experts for their communities: midlevel practitioners and physicians, generalists and subspecialists. Providing infected persons with the tools to succeed in their treatment and to avoid future HIV transmission may require stepwise behavior change. A persistent and nonjudgmental approach is most likely to be effective (for more on adherence see Chapter 7). Providers may have to change their own behaviors so they can be more effective in patient care.

Most persons receiving HIV care reduce their transmission behaviors, lowering the risk of HIV infection for others. Others do not change their behaviors, or do so only partially, or relapse. Providing prevention interventions in a clinic protects the public health. Clinic staff may know sex and drug using partners of patients, and find themselves with a duty to warn those who may be unknowingly exposed. These issues will be familiar to those in tuberculosis and STD treatment settings; but for many these challenges are new (see Chapter 4 on HIV prevention and Chapter 13 on substance abuse).

HIV/AIDS is associated with discrimination and stigma because of its association with sexual behavior and with drug injection, and because HIV is incurable and may still be eventually fatal. Historically, there has been discrimination because of fear of contagion based on misconceptions regarding transmission. Discrimination may still be encountered in families and communities experiencing HIV for the first time.

What can clinics do to ensure that patients receive the necessary array of services?

Clinic forms can be designed to remind providers of care standards, simplify data collection, and serve other purposes as well. Sample forms for initial and followup visits are posted on the HRSA HIV/AIDS Bureau (HAB) website (<http://www.hab.hrsa.gov>). They include reminders regarding clinical standards, reminders of services required for billing levels, checklists built around definitions used by RWCA grantees for reporting to HRSA, and other data for quality management. Staff members may rebel when confronted with new forms; however, using checklists often saves time by listing required elements of the visit and by reducing the amount of writing. Including clinical, data, and quality management staff in the process of designing forms eases the transition.

Information systems can produce reports useful to providers, for example listing a patient's prior diagnoses, medications, and sequential plasma HIV RNA levels and CD4 cell counts (see again the HAB website for examples). Similar flow sheets can be generated from electronic medical record systems; some commercial services also provide such services, but confidentiality must be assured. Periodic reports of achievement of clinical standards (viral load targets, opportunistic infection prophylaxis, vaccination, cancer screening, and other health maintenance activities) can easily be provided to individual providers, and to the clinic medical director, linking implementation of the chronic care model (see Chapter 1) and quality management (see Chapter 17).

What enhancements can make an HIV clinic more effective?

Clinics can enable patients to better care for themselves by providing them with information about HIV and by building a community among them. Patients should be given education materials; a separate area with HIV-related materials may help maintain confidentiality. Some clinics display male and female condoms with instructions about their use and have available other information on safer sex and birth control. Much information is available for patients, including publications on medications, side effects, and adherence. Free materials are available from Federal and State web sites, and the pharmaceutical industry also produces some excellent materials.

Many ASOs and clinics host support groups for interested patients. Participation must be voluntary, and only patients comfortable with revealing their status

to other patients will be willing to participate. Some groups target specific populations. Groups may be more successful if an experienced counselor or mental health provider leads them.

Some clinics hold classes on HIV and adherence. Clinics serving pregnant women and parents may include classes on birth preparation and parenting. Other clinics provide periodic symposia to keep patients up-to-date on treatment advances. For clinics that have a community advisory board, the board can be the organizing force for these community updates. Both public grants and the pharmaceutical industry support these events.

Some youth-oriented clinics arrange social events and outings for their patients. Some programs for children or mothers provide support services for both infected and affected children, ranging from formal psychological care to supportive recreational activities after school or during school breaks.

How can clinics implement interdisciplinary care?

It is not enough to have staff from many disciplines on the payroll; rather, systems have to be created that allow staff to function as a team. Training with followup by supervisors is essential. Specific tasks of each staff member need to be assigned (Table 16-3). Ideally, the staff can meet for a few minutes prior to each clinic session to anticipate special needs and allocate personnel resources. Some clinics place a checklist on each chart at each visit, to indicate which team members a patient is meant to see that day and to confirm that all intended interactions have occurred.

The team's potential can best be utilized if there is a regular opportunity to meet and discuss patients outside of clinic sessions, often called multidisciplinary team meetings. When all members participate, the discussions can range from selecting antiretroviral regimens based on genotype or phenotype results for one patient to addressing chronic mental illness for another. Services for infected and affected family members can be coordinated at these sessions.

Should clinics have a stated policy regarding controlled drugs?

Controlled drugs are needed as part of comprehensive care of HIV-infected patients, for treatment of psychiatric conditions and pain. At the same time, many patients with HIV have had prior or have current issues with substance abuse. The clinic should have policies in place regarding prescription of controlled

medications: how many prescription refills are provided at a time, how new refills are provided, access to controlled drug prescriptions or refills outside of normal clinic hours, and refills of lost medication or lost prescriptions. To avoid confusion or disagreement some clinics have patients sign copies of the clinic policy regarding use of controlled medications before they are given prescriptions. It may be necessary to provide formal notification to a substance abuse program or parole officer that the clinic is prescribing a controlled medication, specifying the drug, dose, and duration of treatment.

Table 16-3. Clinic Staff Responsibilities

Tasks prior to a clinic visit
• Remind every patient of appointments via phone call or postcard • Review charts to list items to address during the visit
Tasks during a clinic visit
• Verify patient's current contact information and current insurance status • Orient new patients • Assist with insurance gaps (teaching about need for referrals, help with insurance application or ADAP, etc) • Assess other barriers to care and psychosocial needs • Assess medication adherence • Teach and provide behavior change counseling about medications and self-care • Assess ongoing transmission behaviors • Teach and provide behavior change counseling about transmission behaviors • Educate about clinical trial opportunities (if applicable) • Make referrals for psychosocial services • Make referrals/appointments for medical, dental, mental health care
Tasks following clinic sessions
• Make followup calls regarding new medication regimens or referrals • Call or mail postcards to patients who miss their visits • Help patients overcome barriers to clinic attendance • Extract data and enter it into the information system (not necessary with electronic medical records)

SUPPORT SERVICES AND LINKAGES NEEDED FOR HIV CARE

How do support services enhance the clinical care of persons with HIV?

It is a rare clinic that has the funding, personnel, and expertise to address all of its patients' psychosocial issues. Most patients need services from an array of agencies. Case managers assist patients in accessing the range of services and entitlements that can help them succeed in treatment. This includes assistance in applying for insurance; accessing support groups; accessing supplemental food, housing, homemaker and other concrete services; accessing mental health and substance abuse services. Case managers should perform periodic assessments of clients' needs and update comprehensive care plans every 6 months. Home visits can be very useful as part of the assessment. Some case managers or their agencies will provide selected direct services themselves; these may include short-term counseling, transportation for clinic visits, accompanying patients to clinic visits, and providing financial assistance for specific emergencies. Excellent case managers help motivate patients.

Close coordination between clinic staff and case management is important to avoid duplication of effort and services. Periodic case conferences between clinic staff and case managers are ideal. Written communication, for example sharing case management care plans, can be useful. Case management agencies and clinical sites need to obtain written consent from patients to share the information that allows coordination.

How do clinics create useful linkages with community-based services?

Clinics can develop relationships with community-based case managers or directly with providers of specific services, such as mental health, substance abuse, or housing. Personal contact between clinic and agency is important to establish the relationship, and ongoing contacts are necessary for coordination. Community organizations are often pleased to give in-service education to clinic staff in order to streamline the referral process. Clinics should make their expectations clear to community-based agencies. Clinics can function as advocates to ensure that their patients receive the attention and services for which they were referred. Periodic interdisciplinary meetings of clinic staff with representatives of community-based agencies, including case managers, are very useful.

How should consumers be involved in the provision of HIV clinical care?

Many clinics have created consumer advisory boards to participate in planning and quality management. Experiences have varied greatly, with some advisory board members educating themselves about the issues and providing expert input to these processes. Other boards act more as social event or support groups. Clinics are likely to have to train board members in technical background regarding HIV and care provision, and in the role of advisors. Board members must agree to confidentiality policies, even though information about individual patients or staff members should not be discussed. Clinics have to create meaningful opportunities for advisory board members to provide input: this may involve discussion of workplans in writing grant applications, planning outreach activities, modifying clinics to enhance recruitment and retention of patients, and participating in quality management teams. When consumers are living in poverty or otherwise difficult conditions, obtaining ongoing participation of volunteers may require providing transportation to meetings, meals at meetings, and reimbursement for childcare or similar expenses. Some clinics find it useful to pay officers of their advisory boards in order to enable the officers to devote adequate amounts of time to the project. If this seems contradictory to the spirit of volunteerism, we should remember how much continuing education of medical and nursing professionals relies on enhancements to recruit participation. Creating effective advisory boards takes time, but can be a valuable investment. Advisory board members, while providing an outside view of the clinic to the clinic management, often provide useful community outreach and improve public relations.

Less intensive consumer input involves the use of periodic satisfaction surveys or questionnaires of clinic patients, confidential or anonymous mechanisms for eliciting suggestions, and a publicly accessible grievance procedure. Clinics with advisory boards use these mechanisms as well.

What resources are required to provide comprehensive HIV/AIDS care?

Financial: Patient access is maximized in clinics that can accept Medicare, Medicaid (including Medicaid managed care), and county insurance programs. Clinics should have a sliding fee scale. Clinics should assist appropriate patients to enroll in the AIDS Drug Assistance Program (ADAP), to access the drug coverage or other clinical services that vary by State.

Within designated metropolitan areas, RWCA Title I funding may be available. Clinics planning to serve a moderate-to-high volume of HIV patients can apply for a RWCA Title III planning grant. Clinics serving women, pregnant women, youth, and families are eligible to apply for Title IV funding. Clinics may collaborate with other agencies in seeking RWCA funding.

Personnel: A lone provider whose patients are self-sufficient or can access community-based services can “provide” comprehensive HIV/AIDS care. For most patients, care is more effective if multiple team members are available at the clinical site.

Facilities: In addition to the usual office layout, other facilities are useful. An examination room suitable for gynecologic exams is important. An apparatus for pulse oximetry is very useful in assessing patients with respiratory symptoms. Easy access to facilities for collecting venous blood, urine, and stool specimens should be available. On-site access to rapid tests that do not require CLIA certification may be useful, such as urine pregnancy tests, capillary blood glucose, and perhaps the newly licensed rapid whole blood HIV antibody screening test. Laboratory certification to perform urine analysis and microscopic examination of vaginal fluid specimens is very useful. Refrigeration to maintain vaccines and material for tuberculin skin testing is necessary. Refrigeration also enables the clinic to provide patients with on-site injection of medications required once a week or less frequently and to instruct patients in the use of more frequent injections.

Training and technical assistance: Patients look to nontechnical staff to corroborate information given by physicians and midlevel providers. Further, patients expect the same accepting attitude from all staff members. Thus, all staff need training in both technical and cultural matters. One important resource is the local performance site of the AIDS Education and Training Center (AETC) funded by HRSA to provide training and technical assistance to clinics. The local AETC and the National Clinicians’ Consultation Warmline provide detailed and patient-specific education to assist clinicians in making treatment decisions. Written educational materials for staff, such as national and regional treatment guidelines, are available free on the web and are frequently updated. Many regional and national meetings provide training in both clinical care and prevention. Assistance with enhancing and implementing systems of care, including instituting a quality management program, is also available from the AETCs. Chapter 18 provides other resources for training and information.

KEY POINTS

In order to recruit persons with HIV who are not in care, clinics need to establish referral linkages with community agencies such as HIV testing services, AIDS service organizations that provide case management, STD and drug abuse treatment facilities, family planning agencies, local health departments, regional HIV/AIDS hotlines, and local hospitals and emergency rooms.

Clinics can retain patients in care by respecting patients, providing them with effective care, and addressing cultural and language differences between patients and staff. Providing a welcoming staff attitude and physical environment are also important.

Orienting patients to the clinic systems and rules and telling them what is expected of them can improve attendance and adherence to care.

Primary care clinics must be able to provide, either directly or through referral, an array of clinical and psychosocial services that includes mental health and substance abuse services, support for HIV prevention and adherence to care, and close medical monitoring. Some issues that differ in HIV disease from other medical conditions include that there is little room for error in providing treatment, that providers may need to change their own behaviors and attitudes to provide effective care, that preventing HIV transmission is a critical component of patient care, and that patients continue to suffer discrimination and stigma.

Patient services can be enhanced in primary care clinics through the introduction of mechanisms for reminding staff of clinical standards, simplifying data collection, and monitoring quality improvement. These can include forms, checklists, and flowsheets, on paper or in electronic databases, and can result in feedback such as reports to individual providers. In addition, educational materials and support activities for patients can enhance their care.

An interdisciplinary care team, which is an important component of HIV primary care services, can be developed by creating systems for staff collaboration and communication, such as training, assignment of tasks with checklists on patient charts designating responsible team members, and multidisciplinary team meetings at which the issues of individual patients are discussed.

Resources needed to provide comprehensive HIV care include the capacity to accept Medicare, Medicaid, and county insurance programs and access to the AIDS Drug Assistance Program for coverage of antiretroviral drugs. In addition, the Ryan White Care Act makes a variety of funding programs available for direct funding to clinics for care. Ongoing training and technical assistance are critical to keep the expertise of staff up to date.



SUGGESTED RESOURCES

National HIV/AIDS Clinicians' Consultation Center (Free and confidential advice from a multidisciplinary team)

Warmline: 1-800-933-3413
Monday-Friday, 9 am to 8 pm EST

PEP Hotline: 1-800-448-4911
24 hours a day/7 days a week

Website: <http://www.ucsf.edu/hivcntr>
Accessed 2/04.

HIV/AIDS Bureau: <http://www.hab.hrsa.gov>
Accessed 4/04 (An array of technical assistance tools for clinic management are available at this HRSA website)

Chapter 17:

Quality Improvement

Bruce D. Agins, MD, MPH

OVERVIEW

DATA COLLECTION

KEY POINTS

SUGGESTED RESOURCES

REFERENCES

“Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

(Institute of Medicine, 1990)

“All health care organizations, professional groups, and private and public purchasers should pursue six major aims; specifically, health care should be safe, effective, patient-centered, timely, efficient, and equitable.”

(Institute of Medicine, 2001)

OVERVIEW

Quality Improvement: Why Bother?

An open letter to clinic directors:

You may have dismissed quality improvement from your agenda for many reasons. You may think it is someone else's job, or it's a lot of extra work with no benefit, or think that you've already got a quality program in place. You may think that your current system of monitoring the charts in your clinic and giving feedback to the providers who aren't doing the right thing is a quality improvement (QI) program. You may also think that your clinic is doing a fantastic job and that you don't need to monitor its quality. Here's why it's worth investing the time and effort:

- Data generated from your QI program showing improvements over time demonstrate that the program is worth its funding
- QI provides an opportunity to solve problems that are part of the system and not dependent on one individual
- Focus on performance measurement and improvement usually stimulates employees to maximize their performance
- Clinicians have the opportunity to provide leadership through championing best outcomes for patient care
- Innovative problem-solving techniques lead to better care and promote a positive working environment
- QI projects demonstrate compliance with accreditation authorities and grant sponsors
- Quality improvement activities that lead to better outcomes provide a competitive edge when competing for alliances with purchasers
- Monitoring systems that are dependent on single individuals will not last when these key players leave the clinic or are absent for long periods, whereas a fully functioning quality improvement program that involves staff working in teams with a clearly defined infrastructure will keep going when even the most dynamic individuals depart.

This chapter describes how your clinic can develop, implement, and maintain a QI Program and what your role in it might be, whether part of a QI Project Team, the Quality Committee, or simply a customer of the performance measurement and quality improvement processes.

• • • • •

What is Quality Improvement (QI)?

Quality improvement (QI) includes regular measurement of care processes and outcomes to analyze processes and systems of care. It involves implementation of solutions to improve care and monitor their effectiveness with the goal of achieving optimal health outcomes for patients. Ongoing cycles of change and remeasurement are implemented to test and try different ideas to determine which result in improved care. QI activities in clinics can range from a single team focusing on improving one aspect of care to a comprehensive QI program with many teams working on a wide variety of improvement projects, with a well-established plan and an oversight committee.

The methods of QI are based on core principles that are readily translated into a practical approach and integrated into the clinical care delivery system (see Table 17-1). Successful implementation of QI involves actions at 2 different levels: the QI activities and the HIV program processes that provide the structural backbone for them. This section will articulate the core principles and describe activities that can be easily adapted into the HIV ambulatory care setting to implement a sustainable QI program.

Table 17-1: Core Principles of Quality Improvement

- *Focus on the customer: improvement activities result in improved patient health*
- *Measurement: collect and use data to improve care*
- *Emphasis on systems of care: improve processes that link to desired outcomes*
- *Involvement of participants: encourage direct participation in teams by those individuals who implement the processes being evaluated*

Descriptions of the chronic care model that serves as an important application of QI principles to HIV care can be found in Chapter 1, Figure 1-1, and Chapter 18, the section on Integrating HIV Specialty into Practice. A training manual developed from an HIV/AIDS collaborative is available from the Institute for Healthcare Improvement (see Suggested Resources).

Why aren't chart audits sufficient for QI – Why can't management just conduct QI?

Measurement alone is not sufficient to improve quality. A common pitfall in implementing QI programs is to rely solely upon performance data, the medical or program director's interpretation of it, and one person's decisions about how to make changes. Successful improvements

most often result when staff members from the systems being assessed work together in teams. When they are engaged in the process, they are more likely to generate ideas to try and to accept changes.

Which personnel should be involved in QI?

The size of the clinic will determine who participates in quality-of-care activities. In small HIV clinics with a primary care provider, case manager, nurse, and support staff, most of the staff are involved in all aspects of QI work. Larger institutions usually establish an HIV Quality Committee that includes senior management staff of the HIV clinic, designated QI staff if there are any, and other key players who work in the clinic. A member of this committee represents the group in the agency-wide quality committee. The Quality Committee identifies the priorities for improvement or agrees to use priorities identified by staff or patients in the clinic. The Quality Committee also charters improvement teams, identifying potential members who are key stakeholders in the process under investigation or their representatives.

Who should be on the teams?

Teams are formed to address the specific care processes or systems undergoing improvement. Team members should be selected to represent the different functions involved in these processes or to represent the components of the system under focus. The size of a team varies according to the size of the clinic and the process under study. In small clinics, the few dedicated HIV program staff may constitute the project teams, with added representation from different departments as needed, such as from the lab, or from other medical disciplines. In larger clinics, teams often include 6-10 members. Membership should include representatives from the different groups in the clinic who are involved in the care process. In addition to the clinical and case management representatives, scheduling clerks and medical records staff are often important representatives, especially when followup appointments and documentation are important components of the care process or have been identified as areas that need to be improved.

What are the responsibilities of the team?

Teams are expected to identify areas of change, implement pilots to test the change, review data assessing the change, and ultimately make recommendations about improvements. Team meetings should be kept flexible and adapt to the working environment of the clinic as much as possible, although a few specific guidelines will help keep things running

smoothly. These include designating a leader for the team, developing clear and specific aims and goals, and ensuring that a clear line of accountability is defined pointing back up to the Quality Committee. Sometimes, short impromptu meetings keep the momentum of the project going and enable rapid decisionmaking based on results as soon as they become available.

As the Project Team conducts its work and gains experience, it will become more independent and assume more responsibility for ongoing measurement, data collection, and implementation of steps toward improvement.

DATA COLLECTION

How do you select which components of care should be measured?

Indicators are measurable aspects of care that evaluate the extent to which a facility provides a certain element of care. Indicators should be based on standards or guidelines, meet the primary goals of QI, and reflect priorities specific to the community and the clinic. For example, in HIV clinics where the population includes a large number of women, indicators may include rates of routine Pap smears, rates of preconception counseling, or other aspects of care specific to women. In clinics that care for a high volume of patients with severe immunosuppression and advanced HIV disease, indicators may include rates of prophylaxis for specific opportunistic infections, such as PCP and MAC. Some indicators should be selected by soliciting input from patients who attend the clinic (see Table 17-2). Staff members also often know what aspects of care would benefit from being measured and improved and should be consulted to determine priorities. If routine data collection systems already exist in the clinic, data should be reviewed to determine which components of care would be prime candidates for improvement (see Table 17-3 for sample indicators).

Table 17-2: Methods for Obtaining Input from Patients

- Suggestion box
- Surveys
- Focus groups
- Consumer advisory board

Table 17-3: Sample HIV Quality Indicators

Element Of Care	Quality Of Care Indicator
HIV staging	CD4 cell count test performed every 4 months Viral load measurement test performed every 4 months
Antiretroviral therapy	ART drug usage for stable and unstable patients
Tuberculosis screening	Annual PPD testing
OI prophylaxis	PCP prophylaxis (CD4 count <200 cells/mm ³) MAC prophylaxis (CD4 count <50cells/mm ³) Pneumococcal vaccination
Gynecological care	Annual pelvic exam with Pap smear
Syphilis screening	Annual syphilis serology
Substance abuse education	Annual discussion of substance use Annual discussion of tobacco use
Coordination of care	Annual dental exam

Once the aspect of care has been selected, how do you develop and measure the indicators?

Three major activities constitute the process of indicator development:

- 1) Define the measurement population: location, gender, age, clinical condition, visits.
- 2) Define the measures.
- 3) Develop the data collection plan.

The measurement population is defined by determining the location of care being studied, whether both men and women are eligible, the applicability of the indicator to different age groups, whether any clinical conditions are necessary to determine whether the indicator is applicable, and whether the patient must have been in treatment or visited the clinic more than once.

After defining the population, the measure needs to be defined. For each measure, specific criteria must be developed to define the “yes” response and the “no” response (see Table 17-4). Often this involves deciding during which time period an activity has been performed. For example, an indicator measuring viral load monitoring must include the frequency with which that test should be performed. One simple way to construct this measure would be to ask “Was viral load measured within the last 4 months?”

Table 17-4. Examples of Specific Measures with Definitions of Responses

Measure	Definition of measure	Yes/No response
TB screening (Eligibility: HIV-infected patients without a history of previous TB treatment or a history of a positive PPD)	Was PPD testing performed (placed and read within 72 hours) in the past 12 months?	Yes: PPD screening was performed (placed and read) No: PPD screening was not performed (or it was placed but results were not documented)
PCP prophylaxis	Did the patient with <200 CD4 cells/mm ³ and no sustained CD4 cell increase to >200/mm ³ during the last 6 months of the review period receive PCP prophylaxis?	Yes: The patient received PCP prophylaxis No: The patient did not receive PCP prophylaxis

The data collection plan includes determining the source of information, such as whether medical records or an electronic database will be used, how the data will be recorded, who will record the data, and how a sample will be selected. A representative sample will allow inferences to be made about the clinic population based on observations of the smaller sample. Some form of random sampling should be used, either from a random numbers table, or a selection of every nth record from the list of eligible patients.

A common pitfall at this point is to think of the measurement sample as a research project. For the purposes of QI, a sample just needs to be current, representative, and readily obtained (ie, sample size calculations and the achievement of statistically significant results are not necessary).

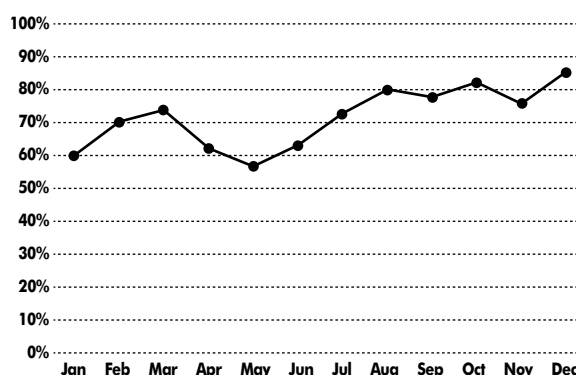
Should you measure only one indicator at a time?

Definitely not. Several indicators should be measured simultaneously, whether abstracted from medical records or analyzed through administrative databases. Indicators reflecting different aspects of patient management should be selected, as well as those involving different populations. Indicators should also be selected to evaluate different components of the health care system, such as the different components of the chronic disease model.

How should you analyze and display data?

Data should be reviewed and distributed to all members of the team and others involved in the care process under evaluation. Whenever possible, data should be displayed in graphic format. Once data from several time periods have been collected (eg, rates of patients with viral load performed every 4 months collected in 2 different time periods), a simple line graph (run chart) can be constructed with each point representing a performance rate (percentage) for a given period of time. This is usually the simplest and most effective way to show performance data (see Figure 17-1).

Figure 17-1: Sample Run Chart: Percentage of Patients PPD Tested, by Month

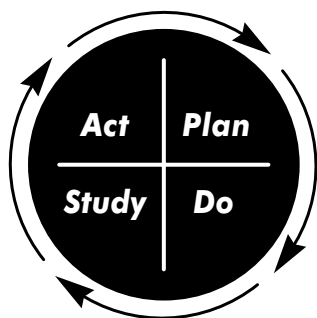
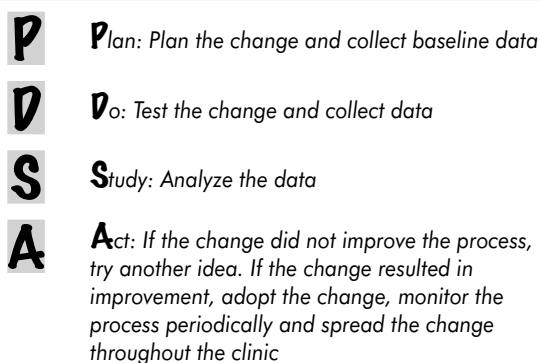


Source: *Measuring Clinical Performance: A Guide for HIV Health Care Providers*. New York, NY: New York State Department of Health AIDS Institute. April, 2002.

How does improvement occur?

Once the data have been reviewed by the team and the process for improvement identified, the next step is to decide where opportunities for improvement exist. This process is described as the PDSA (Plan-Do-Study-Act) or PDCA (Plan-Do-Check-Act) cycle (see Figure 17-2).

The first step is to investigate this care process in greater detail. Several techniques are often used to accomplish this goal. The simplest is brainstorming, in which individuals offer their suggestions for which processes are the best candidates for change. Another easy method is flowcharting, in which the group breaks down the process into its components to identify how it is coordinated and how its parts fit together. Then, the areas that would be most likely to benefit from improvement are selected for change (see Figure 17-3).

Figure 17-2. Plan-Do-Study-Act Cycle

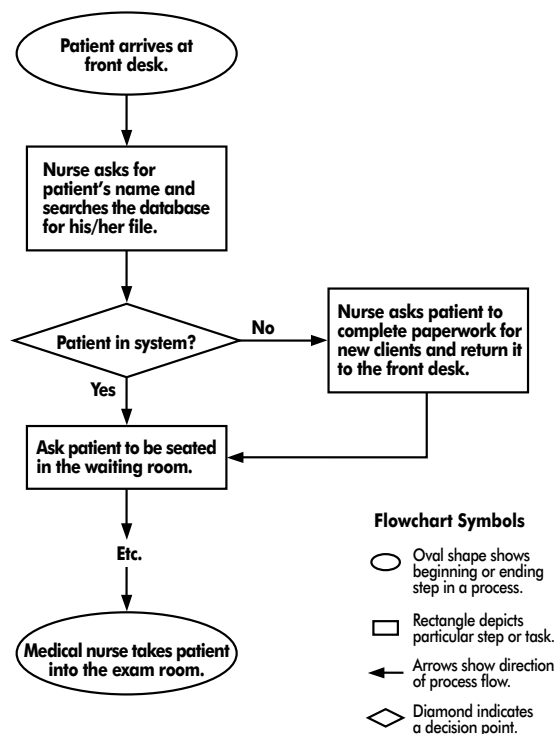
Source: Institute for Healthcare Improvement. HIV/AIDS Bureau Collaborations: Improving Care for People Living with HIV/AIDS Disease. Boston: Institute for Healthcare Improvement; 2002. Available at <http://www.ihl.org/collaboratives/breakthroughseries/HIV/ChronicCare.pdf>.

Once a change in a particular step of the process has been selected, a pilot test of the change can be quickly implemented and evaluated. A limited implementation of the proposed change can be tested – perhaps with just the next few patients, or those attending on the next day, or those seen by a particular clinician. If the pilot does not work, another change can be selected and quickly implemented. If the change is feasible and improvement is noted, then the change can be adopted more widely, before formal remeasurement occurs, and a regular period of remeasurement adopted. If the change was not successful, then another one can be chosen and tested.

What systems need to be established to support QI?

The key to sustaining QI in the clinic is development of an infrastructure that supports ongoing QI activities. The central components of this infrastructure include:

- A QI Plan with goals and a process to prioritize these goals
- An organizational framework that displays clear lines of accountability for QI in the organization

Figure 17-3. Sample Flow Chart

Source: New York State Department of Health AIDS Institute. HIVQUAL Group Learning Guide: Interactive Quality Improvement Exercises for HIV Health Care Providers. Available at <http://www.hivguidelines.org>.

- Commitment of senior management staff to support the program, allocate resources, and celebrate its successes
- Creation of a culture that supports quality in the program and that values the activities of QI as part of the regular work of the clinic (see Table 17-5)
- Establishment of a formal QI Committee to oversee quality activities, monitor the Quality Plan, and evaluate its effectiveness

Table 17-5. Tips for Promoting a Culture of Quality Improvement: Integration of Quality into the Regular Work of the Clinic

- Educate staff about QI and provide them with the skills to participate in QI activities
- Communicate results from improvement projects throughout the clinic
- Display data and storyboards
- Celebrate successes
- Articulate the values of QI in meetings
- Provide opportunities for all staff to participate in QI teams
- Reward staff members through performance evaluation for their contributions to the QI Program

The regular, ongoing work of the QI Committee, supported by the clinic's leadership, constitutes the backbone of the infrastructure that supports ongoing QI activities. The committee oversees the dynamic process of planning, implementation, and evaluation that involves:

- Analysis of data from the QI projects
- Solicitation of feedback from participating staff
- Decision-making based on the information from its analysis

These activities contribute to sustaining the QI Program and its activities in the clinic.

Will improvements last?

Sustainability is probably the biggest challenge that clinics face in the field of QI. All too often, improvements do not last once initial projects are completed, because the structure and culture to support QI is not present or is not supported. The challenge of sustainability is therefore two-fold – not only to maintain the successes of QI work and its clinical outcomes, but also to maintain the systems of QI and to keep the QI program vital. By asking questions about how care systems can be improved and how QI activities are progressing, clinicians play an important role in both catalyzing and supporting QI activities.

What are the key components of a quality plan?

The key elements of a quality plan include a quality statement that describes the purpose and goals of the QI program, priorities of the program, a description of the organizational systems needed to implement the program, including committee structure and functions, definitions of accountability, roles and responsibilities, the process for obtaining consumer input, core measures, data collection processes, and a description of how the plan will be evaluated.

KEY POINTS

Providers play an active role in the activities of QI and can lead these efforts by asking questions to determine how improvements can be made. Although the QI program may require extra work from busy providers, the opportunities to systematically measure clinical performance will provide useful information that leads to better care for the patients they serve.

QI includes regular measurement of care processes, analysis of processes and systems of care, and implementation of solutions to improve care and monitor their effectiveness. The goal of QI is to achieve optimal health outcomes for patients.

QI teams identify areas of change, implement pilots to test the change, review data assessing the change, and ultimately make recommendations about improvements. When staff members from the systems being assessed work together in teams and are engaged in the QI process, they are more likely to generate ideas and to accept changes.

Indicators, measurable aspects of care that evaluate the extent to which a facility provides a certain element of care, should be based on standards or guidelines, meet the primary goals of QI, and reflect priorities specific to the community and the clinic.

Once data have been reviewed by the team and the process for improvement identified, the next step is to decide where opportunities for improvement exist. This process is described as the PDSA (Plan-Do-Study-Act) process. The first step is to investigate this care process in greater detail. Once a change in a particular step of the process has been selected, a pilot test of the change can be quickly implemented and evaluated. If the pilot is successful, the change can be adopted widely. If the pilot is not successful, another change can be selected and tested.

Sustainability is probably the biggest challenge that clinics face in the field of QI. The key to sustaining QI in the clinic is development of an infrastructure that supports ongoing QI activities.



SUGGESTED RESOURCES

AETC National Resource Center and New York State Department of Health AIDS Institute.

Measuring Clinical Performance: A Guide for HIV Healthcare Providers. Available at http://www.hivguidelines.org/public_html/center/quality-of-care/perform_guide/perform-guide-intro.htm Accessed 1/04.

Berwick D, Godfrey AB, Roessner J. *Curing Health Care.* San Francisco: Jossey-Bass; 1990.

HIV/AIDS Bureau. *Quality Management Technical Assistance Manual.* Rockville, MD: Health Resources and Services Administration; 2003. Available at <http://hab.hrsa.gov>.

Institute for Healthcare Improvement. *HIV/AIDS Bureau Collaborations: Improving Care for People Living with HIV/AIDS Disease.* Boston: Institute for Healthcare Improvement; 2002. Available at <http://www.ihl.org/collaboratives/breakthroughseries/HIV/ChronicCare.pdf>.

Institute of Medicine Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington DC: National Academy Press; 2001.

Langley GJ, Nolan KM, Norman CL, Provost LP, Nolan TW. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* San Francisco: Jossey-Bass; 1996.

McGlynn EA, Asch SM. *Developing a Clinical Performance Measure.* *Am J Prev Med.* 1998;14(3 Suppl):14-21.

New York State Department of Health AIDS Institute. *HIVQUAL Group Learning Guide: Interactive Quality Improvement Exercises for HIV Healthcare Providers.* http://www.hivguidelines.org/public_html/center/quality-of-care/performance_measurement_materials/glg/group_learning_guide.

Scholtes PR, Joiner BL, Streibel BJ. *The Team Handbook* (3rd Ed). Madison: Oriel, Inc; 2003.



WEBSITES *

HIV-Specific Examples

<http://hab.hrsa.gov/special/qualitycare.htm>

<http://hab.hrsa.gov/tools/QM>

<http://www.hivguidelines.org>
Quality of Care Section.

<http://www.qualityhealthcare.org/QHC/Topics/HIVAIDS>

<http://www.ihl.org/collaboratives/breakthroughseries/hiv>

<http://www.qaproject.org>

General QI Websites

<http://www.qualityhealthcare.org/qhc>

<http://www.ihl.org>
(Institute for Healthcare Improvement)

<http://www.isqua.org.au> (International Society for Quality in Health Care)

<http://www.asq.org>
(American Society for Quality)

<http://www.mytapestry.com>
(contains many links to other websites)

<http://www.ahrq.gov> (Agency for Healthcare Research and Quality)

<http://www.jcaho.org> (Joint Commission on Accreditation of Healthcare Organizations)

<http://www.nahq.org>
(National Association of Healthcare Quality)

http://www.musc.edu/fm_ruralclerkship/
(Family Medicine/Rural Clerkship CQI)

* Websites accessed 1/04.

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*HIV/AIDS Bureau Collaborations: Improving
Care for People Living with HIV/AIDS
Disease*. Boston: Institute for Healthcare
Improvement; 2002.

Institute of Medicine. *Medicare: A Strategy
for Quality Assurance*. Vol.1. Washington:
National Academy Press; 1990.

Institute of Medicine. *Crossing the Quality
Chasm*. Washington: National Academy
Press; 2001.

Institute of Medicine. *Measuring What Matters:
Allocation, Planning, and Quality Assessment
for the Ryan White CARE Act*. Washington, DC:
The National Academies Press; 2004.

New York State Department of Health AIDS
Institute. *HIVQUAL Group Learning Guide:
Interactive Quality Improvement Exercises for
HIV Health Care Providers*. New York,
NY: New York State Department of Health
AIDS Institute.

New York State Department of Health AIDS
Institute. *Measuring Clinical Performance:
A Guide for HIV Health Care Providers*. New
York, NY: New York State Department of
Health AIDS Institute; April 2002.

Chapter 18:**Keeping Up-To-Date: Sources of Information for the Provider***OVERVIEW**HUMAN RESOURCES**WRITTEN RESOURCES**ELECTRONIC AND WEB-BASED RESOURCES**INTEGRATING HIV SPECIALTY INTO PRACTICE**KEY POINTS**SUGGESTED RESOURCES**Bruce D. Agins MD, MPH**Renslow Sherer, MD**Caroline J. Teter, PA-C, MPH***OVERVIEW****Doesn't the Guide itself provide sufficient information about HIV care?**

At a pace unlike that in any other field, rapid change characterizes the field of clinical HIV medicine. Fortunately, opportunities to stay current with the fast-paced changes in science and practice are available through a variety of sources.

What kinds of resources are available for keeping up-to-date?

One approach to identifying educational resources for providers is to consider them an expanding circle of information sources, starting at the local level, and finally reaching the globally available web of information on the Internet. Resources can also be grouped by type of information delivery:

Human Resources Conferences, training workshops, case-based presentations, educational consultations (in-person, telephone, distance-learning), preceptorships, audio tapes, video tapes

Written Materials Books, journals, newsletters, self-assessment, slides, handouts

Web-Based Information Downloadable articles, webcasts, resource directories, search engines, listserves, e-newsletters

What kind of standards are available to assure that HIV providers are keeping up-to-date?

Professional associations and State governments have developed policies defining HIV specialists that specify the number of patients that providers should directly manage in order to qualify for this experience-driven classification, reinforcing through regulations and requirements the simple notion that providers need to

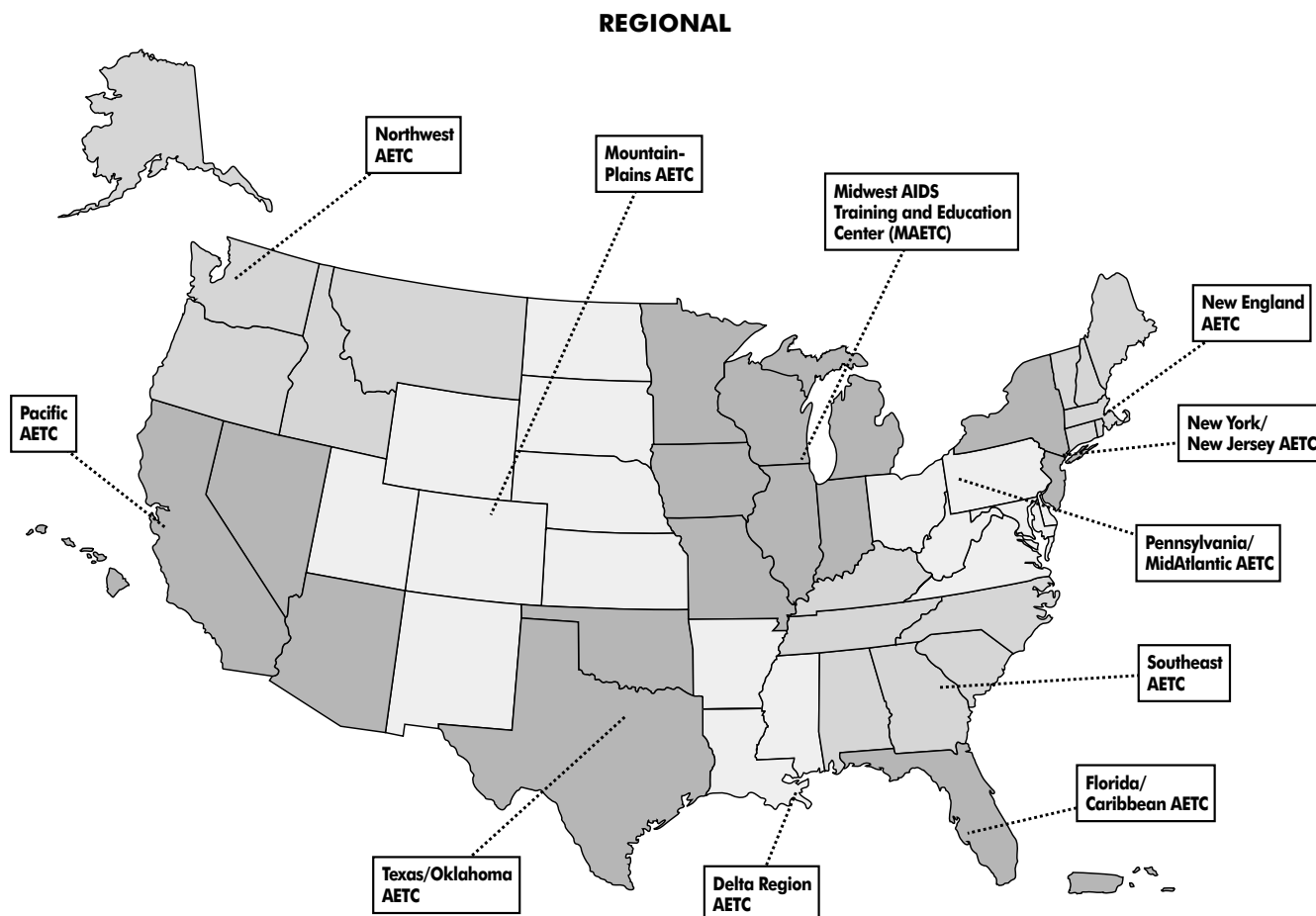
keep current in order to provide good care. See last section, Integrating HIV Specialty into Practice, for details.

HUMAN RESOURCES**How do you identify what's available in your own community?**

The single most important step in obtaining current information is to identify local resources. The first step is to determine whether any HIV experts are practicing nearby who provide care to with HIV in the community. HIV specialists are an important source of information – not only about clinical practice, but also about educational opportunities in the area. Local hospitals or clinics may offer grand rounds on topics in HIV clinical care or continuing education programs. Local infectious disease societies or HIV medical associations may sponsor meetings at which new information is disseminated. Every region in the United States is targeted by a regional AIDS Education and Training Center (AETC), funded by the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA), that offers a menu of educational programs designed to fit the specific needs of practicing providers, including physicians, mid-level practitioners, nurses, and dentists (see Figure 18-1).

AETC educational sessions also present excellent opportunities to make personal contact with clinical experts. Establishing relationships with local experts can lead to ongoing communication about advances in care, telephone consultations when needed, and the potential for referrals when patient management becomes especially complicated, such as when drug resistance occurs or salvage therapy is required, prompting changes in antiretroviral therapy (ART).

Figure 18-1. AIDS Education and Training Centers



Contact information for regional as well as national and international centers is available at <http://www.aidsetc.org/>. Accessed 3/04.

Table 18-1. Major AIDS Conferences

Name	Website*
International AIDS Conference; biannual	http://www.ias.se/
Conference on Retroviruses and Opportunistic Infections; annual	http://www.retroconference.org
Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC); annual	http://www.icaac.org
Infectious Diseases Society of America (IDSA); annual	http://www.idsociety.org
International AIDS Society Conference on HIV Pathogenesis and Treatment; biannual (Rio de Janeiro, July 2005)	http://www.ias2003.org
UCSF: Medical Management of AIDS; annual (San Francisco)	http://medicine.ucsf.edu/cme/
International Association of Physicians in AIDS Care (IAPAC) Sessions; biannual	http://www.iapac.org/
Association of Nurses in AIDS Care (ANAC) Annual Conference; annual	http://www.anacnet.org/

* Websites accessed 1/04.

Are AIDS conferences useful for providers who are not HIV experts?

A number of national conferences provide opportunities to obtain cutting-edge information (see Table 18-1). The range of offerings usually meets the needs of providers just learning about HIV as well as providers who are already HIV experts.

What if you practice in a remote area?

In remote geographic areas, the nearest HIV expert may actually be far away and attendance at conferences and meetings may not be feasible. In this situation, the regional AETC can be contacted to determine how to obtain direct educational programming. When distance prevents on-site attendance at educational programs, newer technologies may enable long distance participation. Satellite broadcasting and down-linking to local facilities may be available and has been a useful approach in various parts of the United States. Distance learning and web-based information also provide important sources of education when other programming is unavailable. Many sessions are videotaped or audiotaped. Videocassettes and audiocassettes may be distributed or purchased for a modest price.

Is clinical consultation possible even if you are not affiliated with an HIV specialty practice?

In areas of the country with no HIV clinical experts, a number of consultative and co-management options are available through the AETCs or statewide education initiatives to assure that patient care is of the highest quality. Informal discussions with experienced providers in the region are probably the easiest way to access expertise, especially since these providers may be available for formal clinical consultation when decisions are made about ART, such as when to initiate, modify, or discontinue therapy.

Clinical consultations are available not only through the regional AETCs, but also from the National HIV Clinical Consultation Center, based at the University of California San Francisco (UCSF). This service provides a “warmline” — a toll-free phone number staffed from 6:00 a.m. to 5:00 p.m. PST by physicians, nurse practitioners, and pharmacists who are available to answer providers’ questions. During other times, or when the phone line is busy, voicemail messages can be left and calls returned. The HIV experts discuss options with callers, presenting pros and cons of various approaches with the goal of improving the capability of the provider to manage the current situation and others like it. The Center also refers callers to their local resources for expertise, consultation and training.

**National HIV/AIDS Clinical Consultation
Center Warmline: 1-800-933-3413**

WRITTEN RESOURCES

What books and journals are most useful for primary care providers?

Although a basic textbook of HIV/AIDS medicine provides a basic reference of core knowledge, it becomes outdated nearly as quickly as it is published, particularly in relation to ART. Small books such as the Pocket Guide included in this guide contain quick reference materials, are more frequently updated, and provide summaries that can be useful at the point of care. Other books provide specialized information related to the care of specific groups of persons with HIV. For example, *A Guide to the Clinical Care of Women with HIV* offers an excellent comprehensive overview of issues pertaining to the care of women, with useful tables, photographs, and practical information for the provider.

Most major journals include articles about HIV. Clinical trials and review articles periodically appear in the major internal medicine journals. Two important peer-reviewed HIV-specific journals, *AIDS* and *JAIDS (Journal of the Acquired Immune Deficiency Syndromes and Human Retrovirology)*, include studies and review articles in the domains of basic science, epidemiology, clinical care, and HIV prevention. Other regularly published bulletins and journals offer review articles on basic aspects of clinical management that are useful summaries for the primary HIV care provider. *The Johns Hopkins HIV Report* provides summaries of current issues and controversies in HIV care authored by experts from the Hopkins HIV Service. Question and answer sessions with experts are often included as part of these publications. See Table 18-2 for a list of recommended publications. Also, a comprehensive list of HIV professional journals can be found at http://www.mednets.com/index.cfm/fuseaction/articles_aids_aidsjournals Accessed 3/04.

Can journal articles be accessed on the internet?

To keep up with all of the HIV journals is impossible, especially when a practice is not exclusively devoted to HIV care. Several websites post information about newly published articles and can easily be scanned to seek relevant or noteworthy information (see Table 18-3). *Medscape*, which has a specific section dedicated to HIV, and *HIVinSite* are two good sources of news. An abstract of almost any article can be retrieved through the National Library of Medicine’s website at *PubMed*. A useful list of websites, references and news may also be found at Medline Plus. The Kaiser Daily HIV/AIDS Report offers a daily news summary that includes both newspaper articles and major clinical or scientific releases that anyone can subscribe to by registering at the website. The Aegis website links to news summaries that can be quickly accessed to obtain the desired summary.

Table 18-2. Printed Resources and Associated Websites*

Title	Website	Availability
<i>Annals of Internal Medicine</i>	http://www.annals.org	Subscription
<i>AIDS</i>	http://www.aidsonline.com/	Subscription includes online access
<i>AIDS Clinical Care</i>	http://www.medscape.com/viewpublication/880	Online at no charge through Medline
<i>The AIDS Reader</i>	http://www.medscape.com/viewpublication/93	Online at no charge through Medline
<i>AIDS Patient Care & STDs</i>	http://www.liebertpub.com/apc/default1.asp	Subscription includes online access
<i>A Guide to the Clinical Care of Women with HIV</i> edited by Anderson, JR.	http://www.hab.hrsa.gov	Online and printed book at no charge
<i>The Hopkins HIV Report</i>	http://www.hopkins-aids.edu/publications/report/report_toc.html Accessed 2/04.	Online at no charge
<i>JAIDS</i>	http://www.jaids.com/	Subscription includes online access
<i>Journal of the International Association of Physicians in AIDS Care</i>	http://www.iapac.org/	Online at no charge
<i>The Lancet</i>	http://www.thelancet.com	Subscription or pay per article for online access
<i>The Medical Management of HIV</i> by Bartlett JG, Gallant JE.	http://www.hopkins-aids.edu/	Printed book can be purchased online
<i>New England Journal of Medicine</i>	http://www.nejm.org	Subscription includes online access
prn Physicians Research Network Notebook	http://www.prn.org	Online at no charge

* Websites accessed 3/04.

Are there guidelines for HIV care?

The Department of Health and Human Services has sponsored several guidelines panels composed of HIV clinical experts to develop evidence-based and consensus-driven practice recommendations for the provision of HIV care. These guidelines are updated regularly, and are posted on the official website of AIDSInfo, a service of the U.S. Department of Health and Human Services at <http://www.aidsinfo.nih.gov>. Currently available Federal guidelines address the following topics:

- ART for adults and adolescents
- ART for pediatric HIV
- Perinatal screening, prevention, and care
- Healthcare worker exposure
- Nonoccupational exposure
- Prevention of opportunistic infections
- Management of tuberculosis
- Incorporation of HIV prevention into care
- Nutrition

New York State has sponsored an HIV Guidelines Program since 1985 through which independent guidelines are developed that specifically target frontline providers and contain concise recommendations for primary care physicians, nurse practitioners,

and physician assistants. In addition to guidelines for adults and children, other guidelines specifically address mental health and oral health for persons with HIV. These guidelines, along with information about implementation strategies, including best practices, quality improvement methods, and success stories, can be found at <http://www.hivguidelines.org>.

ELECTRONIC AND WEB-BASED RESOURCES

Which web-based resources are most useful?

Numerous websites provide useful information about HIV. While it is beyond the scope of this chapter to provide a comprehensive listing of all HIV-related websites, Table 18-3 is a partial listing of some particularly useful ones. Websites in the Search Engines category allow the user to enter a topic of interest and obtain a list of other websites or resources from which to choose. There are search engines that are general as well as medical. Websites in the Resource Listings category provide lists of HIV resources, including agencies, other websites, and informational materials. The General HIV Resources category contains some of

Chapter 18: Keeping Up-To-Date: Sources of Information for the Practicing Clinician

the websites that are most useful when specific HIV information is being sought. One important example is the database of antiretroviral drug interactions that is part of the HIV InSite website. The HIV CME websites provide continuing medical education and award CME

credits, usually at no cost. The Specific HIV Topics category lists some of the websites addressing focused issues related to HIV care, such as drug dependency and treatment adherence.

Table 18-3. Selected Sources for Information on the Web*

Search Engines	Resource Listings
General Searches Google http://www.google.com Medical Searches PubMed http://www.ncbi.nlm.nih.gov/entrez/query.fcgi AIDS MedLine (National Library of Medicine) http://www.nlm.nih.gov/medlineplus/aids.html MedBioWorld (links to journals and government resources) http://www.sciencekomm.at	AIDS InfoNet Internet Bookmarks on AIDS http://www.aidsinfonet.org/ Health Care Information Resources (McMaster University) http://hsl.mcmaster.ca/tomflem/aids.html Pangaea Global AIDS Foundation http://www.pgaf.org/links.html AIDS Treatment News Internet Directory http://www.aidsnews.org About AIDS http://www.aids.about.com MedNets (listing of AIDS journals) http://www.mednets.com/index.cfm HIV/AIDS Resources http://www.sph.uth.tmc.edu/library/aids.htm CBEL DOT COM (listing of AIDS websites) http://www.cbel.com/AIDS/
General HIV Resources	
HIV InSite http://hivinsite.ucsf.edu AIDS Education Global Information Services http://www.aegis.com . AETC National Resource Centers http://www.aids-etc.org AIDS Info (formerly AIDS Treatment Information Service) http://www.aidsinfo.nih.gov/ Kaiser Daily HIV/AIDS Report http://www.kaisernetwork.org/daily_reports/rep_hiv.cfm U.S. Food and Drug Administration (therapies, clinical trials, Fraud Task Forces) www.fda.gov/oashi/aids/hiv.html CDC Div HIV/AIDS Prevention (news, guidelines, fact sheets, FAQ, slide sets, surveillance reports, policy documents) http://www.cdc.gov/hiv/dhap.htm Johns Hopkins AIDS Service (news, medical education, interactive forums) http://Hopkins-aids.edu New York State AIDS Institute (guidelines, quality of care information, best practices, slide sets) http://www.hivguidelines.org National AIDS Treatment Advocacy Project (NATAP) http://www.natap.org Canadian AIDS Treatment Information Exchange (CATIE) http://www.catie.ca World Health Organization (WHO) http://www.who.int/hiv/en/	
HIV CME Websites	Resources on Specific HIV Topics
Medscape http://www.medscape.com University of Alabama Center for AIDS Research http://main.uab.edu/uasom/show.asp?durki=30529 HIV Clinical Education Initiative http://www.upstate.edu/cei hivcme.com (cme portal site and elibrary, slidesets available) http://www.hivcme.com	Drug Dependency National Institute on Drug Abuse http://www.nida.nih.gov Substance Abuse and Mental Health Services Administration http://www.samhsa.gov Pediatric Care National Pediatric & Family HIV Resource Center http://www.pedhivaid.org http://www.womenchildrenhiv.org/ Patient Information The New Mexico AIDS Infonet http://www.aidsinfonet.org Clinical Trials AIDS Info http://www.aidsinfo.nih.gov/ The AIDS Community Research Initiative of America (ACRIA) http://www.acria.org Treatment Adherence HIV/AIDS Project Development and Evaluation Unit http://www.hapdeu.org New York State AIDS Institute HIV Clinical Resource http://www.hivguidelines.org aidsmap http://www.aidsmap.com

* Websites accessed 1/04.

Chapter 18: Keeping Up-To-Date: Sources of Information for the Practicing Clinician

Websites targeting consumers enable them to directly access scientific and clinical information and to pose questions to experts. These websites empower patients by helping them to better understand their disease and its manifestations and by enabling them to advocate for their own health and to more fully participate in decisionmaking about their care. See Table 2-1, Information Resources for Patients, in Chapter 2.

Thinking ahead: can personal digital assistants (PDAs) help you keep up?

A revolution in healthcare information technology has begun that brings information resources directly to the provider at the point of care, whether at the bedside or during the clinic visit. Mobile computing through handheld devices, such as personal digital assistants (PDAs), are now available and have begun to change the practice of medicine by facilitating capture of data and retrieval of information. PDAs (eg, Palm, Pocket PC, Visor) are now used as clinical tools for reference, prescribing, coding and patient education (see Table 18-4).

Table 18-4. Useful PDA References*

General medical references (available commercially)	Harrison's On-Hand: http://harrisons.accessmedicine.com Merck Manual: http://www.merck.com Washington Manual™ of Medical Therapeutics, 30th edition, for PDA: http://www.lww.com DSM-IV: http://www.appi.org/pda.cfx Bellevue Guide to Outpatient Medicine: http://www.bmjpg.com/Bellevue
Drug prescribing databases, including drug interaction data (available at no cost)	ePocrates: http://www2.epocrates.com mobilePDR: http://www.pdr.net Tarascon ePharmacopoeia: http://www.tarascon.com
Antibiotic prescribing guides (available at no cost)	Johns Hopkins Antibiotic Guide: http://www.Hopkins-abxguide.org ePocrates ID: http://www2.epocrates.com
Prescriptions	Ephysician.com: http://www.ephysician.com Advanced PCS: https://physician.advancedpcs.com/ ZIXCorp: http://www.zixcorp.com/caredel/
Compiled abstracts and CMEs	JournaltoGo: http://www.journaltogo.com eMedicine: http://www.emedicine.com (also has patient education materials)

* Websites accessed 1/04.

Currently, the greatest advantage of carrying a PDA is having medical resources at your fingertips. Through a function that uses a cradle to connect with a website via a personal computer, the provider's PDA can "synch" with a master database that is maintained and updated regularly.

Transfer of information is easily accomplished with PDAs through "beaming." By pointing the PDA at another

PDA and tapping on the appropriate prompts, data are quickly transported into the other PDA database. Similarly, information can be beamed to a printer, which is a particularly useful feature for quickly printing patient information or prescriptions.

As PDA technology rapidly evolves, the utility and efficacy of handheld computing will similarly expand. Potential new uses of PDA technology include portable access to MEDLINE, full text journal articles, information searches, comprehensive information storage, and point-of-care access to guidelines, algorithms, and other decisionmaking tools to enhance the quality of care.

PDA versions of patient tracking systems and coding references (<http://www.meistermed.com>) have also been developed. Ultimately, PDAs will be used in conjunction with electronic medical record systems, with information being "beamed" between the two systems. This powerful application of PDA technology will permit comprehensive individualized patient data files that can include current and past medical information, laboratory data, and even reminders for providers to perform periodic preventive health or monitoring tests. Providers who have not already taken the first step, purchasing and using a PDA, should become acquainted with this important new technology as an important source of clinical information and aid to patient management (see Table 18-5).

Table 18-5. Websites for Learning More about PDAs or Obtaining Software*

Websites that categorize resources/libraries
University of Alberta http://www.library.ualberta.ca/subject/laboratory/pdahealth/index.cfm Or click on PDA Resources at http://www.library.ualberta.ca/
Duke University Medical Center Library http://www.mclibrary.duke.edu/respub/guides/pda/index.html Or look up PDAs at http://www.mclibrary.duke.edu
Arizona Health Sciences Library http://educ.ahsl.arizona.edu/pda/index.htm
U VA Health System PDA Support http://www.healthsystem.virginia.edu/internet/library/services/computing/pda/ Or look up PDA support at http://www.healthsystem.virginia.edu/internet/library
E Carolina University Laupus Library PDA Support http://www.hsl.ecu.edu/departments/outreach/pda.cfm
Websites for downloading of software (often at no cost)
American College of Physicians PDA Portal http://www.acponline.org/pda/clinical_references.htm
Healthy Palm Pilot http://www.healthypalmpilot.com
Palmgear.com http://www.palmgear.com
PocketGear.com http://www.pocketgear.com
Handango http://www.handango.com
tucows http://pda.tucows.com/

* Websites accessed 1/04.

INTEGRATING HIV SPECIALTY INTO PRACTICE

Making it stick: how can you integrate new information into clinical practice?

Numerous resources at the fingertips of providers enable them to obtain up-to-the-minute information about new developments or management strategies for HIV care. However, even the best-educated provider cannot assure that quality of care will be achieved through access to the most recent standards and current information unless the system in which care is provided has been adapted to integrate that information. Strategies for developing and sustaining systems to support information can be implemented at the local level through individual actions and through quality improvement programs.

A variety of resources provide assistance in successfully integrating current information into HIV care. Most notably, the decision support framework of the chronic care model developed by the University of Washington has been used to improve care delivered by Ryan White CARE Act-funded clinics (see Figure 1-1 in Chapter 1). Quality improvement strategies based on this model include the following principles:

- Embed current guidelines in the care delivery system.
- Establish linkages with key specialists to ensure that primary care providers have access to expert support.
- Provide continuous skill-oriented interactive training programs for all staff to update knowledge of current guidelines.
- Provide feedback to providers on their use of guidelines.
- Incorporate community-based staff (social workers and case managers) into decision support.
- Educate patients about guidelines.

One example of the application of these strategies is conducting chart audits in order to benchmark practices and feed the information back to providers. Other examples are using flow sheets or checklists to embed guidelines into practice and developing simplified versions of guidelines for providers and patients. The most successful strategies to incorporate guidelines into systems of care are those that include reminders at the point of care or decisionmaking. An important rule of thumb is that multiple interventions work better than just one. For more information on quality improvement, see Chapter 17.

How do you develop the experience needed to qualify as an HIV specialist?

Multiple studies show better outcomes when providers managing patients have expertise in HIV (see Table 18-6). In the absence of a formally recognized subspecialty society devoted to HIV medicine, government agencies, professional societies, and academic institutions have developed definitions of HIV specialization in order to develop policies, standards, and regulations, and to monitor the quality of care provided to persons with HIV (see Table 18-7). Definitions of HIV specialists generally focus on two major areas, experience and HIV CME credits, and also require that experience be current and that knowledge be updated annually. Generally, requirements for experience in the care of patients with HIV range from 10 to 20 patient-years of experience. All definitions emphasize currency of experience and education, given the rapid pace at which HIV clinical management standards change.

Table 18-6. Resources on HIV Expertise and Patient Outcomes

Gerbert B, Moe JC, Saag MS, et al. Toward a definition of HIV expertise: a survey of experienced HIV physicians. *AIDS Patient Care STDS*. 2001;15:321-330.

Keitz SA, Box TL, Homan RK, Bartlett JA, Oddone EZ. Primary care for patients infected with human immunodeficiency virus: a randomized controlled trial. *J Gen Intern Med*. 2001;16:573-582.

Kitahata MM, Koepsell TD, Deyo RA, Maxwell CL, Dodge WT, Wagner EH. Physicians' experience with the acquired immunodeficiency syndrome as a factor in patients' survival. *N Engl J Med*. 1996;334:701-706.

Kitahata MM, Van Rompaey SE, Shields A. Physician experience in the care of persons with HIV infection is associated with earlier adoption of new antiretroviral therapy. *J Acquir Immune Defic Syndr*. 2000;24:106-114.

Stone VE, Mansourati FF, Poses RM, Mayer KH. Relation of physician specialty and HIV/AIDS experience to choice of guideline-recommended antiretroviral therapy. *J Gen Intern Med*. 2001;16:360-368.

Willard CL, Liljestrand P, Goldschmidt RH, Grumbach K. Is experience with human immunodeficiency virus disease related to clinical practice? A survey of rural primary care physicians. *Arch Fam Med*. 1999;8:502-508.

Table 18-7. HIV Specialist Definitions

Agency	Requirements
American Academy of HIV Medicine (AAHIVM)* http://www.aahivm.org/new/revised_definition.htm	Current and valid state licensure (MD, DO, PA, NP) Experience: Direct, continuous, ongoing care to at least 20 patients within the past 2 years CME: 30 hours within the past 2 years Exam: AAHIVM exam at application
Association of Nurses in AIDS Care (ANAC) and HIV/AIDS Nursing Certification Board (HANCb) http://www.anacnet.org/certification/hancb/index.html Certification as an Advanced HIV/AIDS Certified Registered Nurse (AACRN); there is also the HIV/AIDS Certified Registered Nurse (ACRN) for nurses not functioning in advanced practice roles	Current Registered Nurse licensure with master's degree or higher in nursing Experience: At least 2,000 hours of HIV/AIDS nursing experience and 3 years experience as an RN within 5 years prior to application CME: 70 hours every 4 years Exam: HANCb exam at application
California (State law, effective January, 2004)	Demonstrated expertise in treating a condition or disease involving a complicated treatment regimen that requires ongoing monitoring of the patient's adherence to the regimen
Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) Factsheet on Experienced HIV/AIDS Providers*: http://www.cms.hhs.gov/states/letters/smd10699.asp	Experience: active caseload of 25 patients (rural) or 50 patients (urban) within the past 24 months, with a minimum of 12 patients within the past year.
HIV Medicine Association (HIVMA) [HIVMA is part of the Infectious Diseases Society of America*. Click on HIVMA at: http://www.idsociety.org/ Accessed 3/04.]	Experience: Direct, continuous medical care to at least 20 patients within the past 2 years CME: 30 hours within the past 2 years; Category I in the areas of diagnosis and treatment of HIV OR Board certification or recertification in infectious diseases within the past 36 months
Johns Hopkins University Moore Clinic	Experience: 50 patients a year CME: 50 HIV-related credits a year Chart Audits Examination (not required)
New York State Department of Health AIDS Institute* (Click on Policy at http://www.hivguidelines.org/ for HIV Specialist Policy)	New York State licensure Experience: Ambulatory care management of at least 20 patients a year who are receiving ART CME: 10 hours per year AAHIVM or HIVMA qualification plus ambulatory care requirements
TennCare Tennessee	Experience: active caseload of 50 patients each seen at least twice a year CME: 20 AIDS-related category I credits annually

* Websites accessed 2/04.

KEY POINTS

While rapid change characterizes the field of clinical HIV medicine, opportunities to stay current are available through a variety of human, written, and electronic resources.

The most important step in obtaining current information is to identify local resources, including local HIV specialists and regional AIDS Education and Training Centers (AETCs). The regional AETCs offer continuing education programs, distance learning for remote geographic areas, and clinical consultation for providers in the area. The National HIV Clinical Consultation Center also provides telephone consultation to providers.

A basic textbook of HIV/AIDS medicine can provide core knowledge, but it quickly becomes outdated. Books can be supplemented with newsletters, journals, and frequently updated pocket guides. Websites post summaries of newly published journal articles as well as noteworthy information. Clinical guidelines for various aspects of care and prevention are updated regularly and are available on internet websites.

The personal digital assistant (PDA) is a new healthcare information technology that enables providers to have a wealth of clinical information at the point of care. PDAs can be used in conjunction with electronic medical records for patient management.

Numerous websites provide access to information about HIV through search engines, sites that provide listings of resources including other websites, sites that provide HIV-specific information for providers and consumers, and sites that offer CME credits for providers.

Several government agencies and professional societies have developed definitions for the HIV specialist. Two major areas of qualification are experience in clinical management of patients with HIV and completion of HIV CME credits.

New clinical information must be continuously integrated into the system in which care is provided. Strategies for developing and sustaining systems to support information can be implemented through individual actions and through quality improvement programs.

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EXHIBIT BB



HHS 
@HHSGov



We delivered a clear message: federal funds must be used responsibly. California's Personal Responsibility Education Program grant was revoked today because it failed to remove delusional gender ideology that isn't part of the program's mission. We stand firm on doing the right thing for children.

5:48 PM · Aug 21, 2025 · **12.5K** Views



30



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7



Relevant 

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EXHIBIT CC



At the United Nations General Assembly, on behalf of @POTUS and the United States, @SecKennedy:

- Reaffirmed the Trump Administration's commitment to exit the World Health Organization
- Rejected the divisive and controversial Political Declaration on Non-Communicable Diseases
- Asserted that there is no constitutional or international right to abortion
- Opposed destructive gender ideology

The United States will walk away from the WHO, but we will never walk away from the world—or our commitment to end chronic disease.

We stand ready to lead, to partner, and to innovate with every nation committed to a healthier future.



9:00 AM · Sep 27, 2025 · 92.8K Views



68



222



852



42



EXHIBIT DD



Donald J. Trump

@realDonaldTrump

Iowa, a beautiful State that I have won BIG every time, has a Bill to remove Radical Gender Ideology from their Laws. Iowa should follow the lead of my Executive Order, saying there are only two genders, and pass this Bill – AS FAST AS POSSIBLE. Thank you Iowa!

5.85k ReTruths **32.8k** Likes

Feb 27, 2025, 9:37 PM



EXHIBIT EE

 Donald J. Trump Retruthed



Team Trump

@TeamTrump · January 20, 2025, 10:04 PM

 Original Post

Thanks to President Trump, American women are hereby protected from radical gender ideology 🔥

