IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL DECLARATIONS IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs respectfully move for leave to file five supplemental declarations in further support of their Motion for Preliminary Injunction: (1) Dr. Georges C. Benjamin (attached as Exhibit A); (2) Dr. Suzanne Berman (attached as Exhibit B); (3) Dr. Fiona Havers (attached as Exhibit C); (4) Dr. José Romero (attached as Exhibit D); and, (5) Dr. Jason Goldman (attached as Exhibit E). The supplemental declarations of Dr. Benjamin and Dr. Berman provide the Court with updates regarding the ongoing and worsening harms to Plaintiffs and their members from the Defendants' challenges actions. The declarations of Dr. Havers, Dr. Romero, and Dr. Goldman respond directly to the two May 12, 2025 memoranda that Defendants produced for the first time as exhibits to their Opposition brief filed just last Friday (ECF Nos. 273-1 & 273-2). In support of their Motion, Plaintiffs state:

1. On January 26, 2026, Plaintiffs filed their Motion for Preliminary Injunction challenging Defendants' May 19, 2025 Directive, June 2025, September 2025, and December 2025 ACIP Actions, January 5, 2026 Childhood Schedule change and the upcoming ACIP

meeting. *See* ECF 237. The Court bifurcated the preliminary injunction proceedings into two hearings: the first addressing the January 5 Childhood Schedule Change and the then-impending ACIP meeting, and the second addressing Plaintiffs' remaining claims concerning the May 19, 2025 Directive and the June, September, and December 2025 ACIP Actions that each made changes to the CDC immunization schedules. In advance of the first hearing, Plaintiffs sought, and the Court granted, leave to file supplemental declarations responding to arguments raised in Defendants' Opposition. *See* ECF No. 241. The Court exercised its discretion to permit supplementation so that the record would accurately reflect the developing factual landscape at the time it considered preliminary relief. *See Id.*

2. The proceedings now stand at the second phase of the bifurcated preliminary injunction. On Friday, February 27, 2026, Defendants filed their opposition brief attaching, for the first time, two May 12, 2025 memoranda that allegedly support the Secretary's decision-making related to the May 2025 Directive changing the CDC immunization schedules recommendations for Covid-19 vaccination for pregnant individuals and children: (i) a memorandum dated May 12, 2025, from Matthew Memoli, Principal Director, NIH, and Sara Brenner, Principal Deputy Commissioner, FDA, to the Secretary titled "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age"; and (ii) a memorandum dated May 12, 2025, from Tracy Beth Hoeg to Secretary Robert F. Kennedy, Jr., concerning "COVID-19 vaccine safety in pregnant women". Because these materials were newly introduced through Defendants' Opposition, Plaintiffs did not previously have an opportunity to respond to them. In addition, Defendants dispute that the May 19 Directive and the June, September, and December ACIP Actions warrant injunctive relief. The consequences of those actions are not static. They are unfolding in real time. Because the challenged conduct is

ongoing, the harms are ongoing, and the factual record relevant to irreparable harm has continued to develop. The supplemental declarations submitted here address these developments and ensure that the Court evaluates Plaintiffs' remaining claims on a current and complete record.

3. District courts possess broad discretion to manage the evidentiary record in preliminary injunction proceedings. *See Rice v. Wells Fargo Bank, N.A.*, 2 F.Supp.3d 25, 31 (D. Mass. 2014) ("[T]his court has broad discretion in deciding what evidence to consider in connection with a motion for preliminary injunction, including hearsay."). Preliminary injunction proceedings are inherently flexible and may rely on affidavits and supplemental submissions. *See Asseo v. Pan. Am. Grain Co., Inc.*, 805 F.2d 23, 26 (1st Cir. 1986) (holding affidavits and hearsay materials are often received in preliminary injunction proceedings, particularly where the type of evidence is appropriate "given the character and objectives of the injunctive proceeding"). Courts routinely allow supplementation where it promotes judicial economy and allows the Court to consider developments relevant to the issues presented. *See Alan L. v. Lexington Pub. Schs.*, 2025 WL 3767420, at *6 (D. Mass. 2025) (court granted plaintiff's motion for leave to file supplemental declaration in support of motion for preliminary injunction five weeks after plaintiff filed motion for preliminary injunction and three weeks after defendant opposed the motion for preliminary injunction).

4. The declaration of Dr. Georges C. Benjamin (Exhibit A) updates the Court on ongoing harms to Plaintiff APHA and APHA members (including health clinics, clinicians, and, public health officials, and, immunization programs) resulting from the May 19 Directive and June, September, and December ACIP Actions. Dr. Benjamin attests that, as of this week, APHA members are actively undertaking ongoing adjustments to staffing, scheduling, allocation of limited resources, public outreach materials, clinical guidance, workforce training, and infectious

disease preparedness and response in direct reaction to the May, June, September, and December challenged changes to the CDC immunization schedule. These real-time operational disruptions demonstrate the continuing and ongoing impact of Defendants' actions on APHA members who are the public health providers, agencies, clinics, and practitioners responsible for managing infectious disease prevention nationwide. The harms are occurring now, not hypothetically, and require the immediate diversion of scarce public health resources away from core disease-prevention activities to address uncertainty and instability created by Defendants' May, June, September, and December alterations to the CDC immunization schedule, thereby reinforcing the ongoing and irreparable nature of Plaintiffs' injuries.

5. The declaration of Dr. Suzanne Berman (Exhibit B) provides updated testimony regarding the impact of the challenged May, December, and January 5 changes to the CDC childhood immunization schedule on her pediatric practice. Dr. Berman attests to the ongoing, increasing confusion among patients and families, heightened counseling burdens, and operational strain on her medical practice that must reconcile evolving federal guidance with established standards of care. She further explains how the challenged May 2025 changes to the CDC childhood immunization schedule recommendation for Covid-19 vaccination and the December 2025 and January 5 changes to the CDC childhood immunization schedule for Hepatitis B vaccination continue to cause her and her practice ongoing harm, impacting her provider decision-making regarding counseling, billing, reimbursement expectations, staffing, and patient communications, matters that directly affect her day-to-day clinical operations.

6. Dr. Fiona Havers is a former epidemiologist at the CDC and served as the Lead, Respiratory Virus Hospitalization Surveillance Network (ESP-NET) Team prior to resigning on June 16, 2025. Dr. Havers declaration (Exhibit C) attests to her presentation at the April 15, 2025

ACIP meeting, the data she presented on Covid-19 related pediatric hospitalizations, as well as additional presentations delivered by CDC scientists and the ACIP Covid-19 Vaccines Work Group members. Her declaration explains that these presentations reflected the data that had undergone the CDC's established scientific clearance process prior to public dissemination consistent with longstanding agency practice governing ACIP deliberations on the CDC immunization schedule recommendations. Dr. Havers further attests that she had no knowledge of the May 12, 2025 memoranda, did not receive or review them during her time at the CDC, and is unaware of any CDC colleagues who were provided those memoranda.

7. Dr. José Romero, former Chair of the ACIP (2018-2021), attests in his declaration (Exhibit D) based on his years of leadership on ACIP to the longstanding processes governing ACIP membership selection, committee balance requirements, and the development of CDC immunization schedule recommendations. He explains that, during his tenure, vaccine recommendation decisions consistently proceeded through structured ACIP deliberative processes and that the Secretary did not bypass those procedures. Dr. Romero further attests that the two May 12, 2025 memoranda relied upon by Defendants reflect a significant and highly irregular departure from established ACIP practices, as he has never known NIH or FDA officials to provide unilateral recommendations used to alter CDC immunization schedules outside the ACIP process.

8. Dr. Jason Goldman, President of American College of Physicians and a longtime liaison to the ACIP Covid-19 Vaccines Work Group, attests in his declaration (Exhibit E), based on nearly eight years of participation in ACIP meetings and Work Group deliberations, that the two May 12, 2025 memoranda submitted with Defendants' Opposition were never shared with, discussed by, or incorporated into the ACIP Covid-19 Vaccines Work Group's established deliberative processes, and that he first saw them only in this litigation. His declaration further

explains that bypassing ACIP's established scientific EtR framework has created ongoing uncertainty and operational burdens for ACP and its physician members, reinforcing the continuing irreparable harms to Plaintiffs and their members resulting from Defendants' actions.

9. These supplemental declarations do not introduce new legal claims and do not expand the scope of requested relief. They update the factual record in light of continuing developments, are in direct response to new evidence introduced by Defendants, and address questions the Court had at the February 13, 2026, hearing. Allowing Plaintiffs to supplement their Motion for Preliminary Injunction here promotes judicial efficiency and ensures that preliminary relief is evaluated on a complete record. *See also D.V.D. v. U.S. Dep't of Homeland Sec.*, 784 F.Supp.3d 401, 412 n. 2 (D. Mass. 2025) ("The Court has 'broad discretion in deciding what evidence to consider in connection with a motion for preliminary injunction.'") (quoting *Rice v. Wells Fargo Bank, N.A.*, 2 F.Supp.3d 25, 31 (D. Mass. 2014); *see also Alan L.*, 2025 WL 3767420, at *6 (noting supplemental declarations were allowed in preliminary injunction proceedings). Where, as here, the Court has not yet ruled and the challenged conduct is ongoing, supplementation promotes judicial efficiency and provides the Court with a more fulsome record. Furthermore, any perceived prejudice can be cured by permitting Defendants to file a response. Plaintiffs would not object to such a filing.

9. Counsel for Plaintiffs conferred via email with counsel for Defendants on March 2, 2026. Defendants oppose this Motion. Plaintiffs' Local Rule 7.1 Certification is attached hereto.

For the foregoing reasons, Plaintiffs respectfully request that the Court grant leave to file the Supplemental Declarations of (1) Dr. Georges C. Benjamin (attached as Exhibit A); (2) Dr. Suzanne Berman (attached as Exhibit B); (3) Dr. Fiona Havers (attached as Exhibit C); (4) Dr. José Romero (attached as Exhibit D); and, (5) Dr. Jason Goldman (attached as Exhibit E).

Dated: March 2, 2026

Respectfully submitted,

By: */s/ James J. Oh*

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LOCAL RULE 7.1 CERTIFICATE REGARDING PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL DECLARATIONS IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION

Per Local Rule, 7.1, counsel for Plaintiffs state that they conferred with counsel for Defendants by email on March 2, 2026, and counsel for Defendants oppose the filing of Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction.

/s/ James J. Oh
James J. Oh

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 2nd day of March 2026:

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF GEORGES C. BENJAMIN, MD

I, Georges C. Benjamin, MD, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I make this declaration based on personal knowledge and if called as a witness, I could and would testify competently to the statements contained herein. I am over the age of 18. I am the Executive Director of the American Public Health Association ("APHA"). I have served in this role since December 2002. I previously submitted a declaration in this matter. I submit this supplemental declaration to update the Court on the ongoing operational harms that APHA and its members are experiencing as a result of the challenged actions, including: (1) the May 19, 2025 Directive issued by Secretary Robert F. Kennedy, Jr., reclassifying pediatric Covid-19 vaccination as "Shared Clinical Decision-Making" ("SCDM") (the "May 19 Directive"); (2) the June, September, and December 2025 ACIP votes (the "ACIP Actions") altering the CDC immunization schedule without adherence to the GRADE and Evidence-to-Recommendation ("EtR") framework that were adopted by the CDC; (3) the January 5, 2026 revised CDC Childhood Immunization

Schedule and accompanying decision documents (the "January 5 Schedule Change"); and, (4) the upcoming March 18-19, 2026 ACIP meeting. These actions continue to inject chaos and confusion into the public health practice provided by APHA and APHA members, forcing APHA and its members into a perpetual crisis-response mode and compelling the diversion of limited resources away from disease prevention to address these challenged actions.

2. The harms to APHA and APHA members described in my prior declarations filed in this matter are ongoing and compounding. Each successive agency action by the Secretary, ACIP, and CDC making changes to the CDC immunization schedule has required (and continues to require) APHA to divert additional resources, destabilized the operational work of APHA's members, and weakened the coordinated national public health system and prevention framework upon which APHA and APHA members depend on for disease prevention strategies, treatment, counseling, and outbreak response. The Secretary's Directive, followed by ACIP and CDC changes to the CDC immunization schedule including the June vote removing thimerosal, the September vote downgrading the Covid-19 vaccine recommendation for essentially all adults to SCDM, the December vote changing the childhood schedule hepatitis B recommendation, and the January 5 Childhood Schedule Change, has (and continues to) disrupt the public health system that APHA and its members rely upon and support through their guidance documents, outreach materials, clinical care, and strategies and response plans for infectious disease control and management.

3. APHA is a national organization representing more than 23,000 public health professionals and affiliated state, local, tribal, and territorial health departments, health organizations, and public-health–focused institutions across the United States. APHA members (including clinicians, epidemiologists, public health officials, public health service providers,

health clinics, nurses, researchers, and emergency preparedness professionals) operate within every level of the nation's public health system and rely on the CDC immunization schedule as national benchmark governing vaccine practice, outbreak prevention, standards of care, and federally mandated reimbursement structures. Because the CDC immunization schedule is embedded throughout the coordinated federal, state, and local public health infrastructure, sudden and unsupported changes disrupt clinical operations, create confusion among providers and patients, undermine trust in vaccine safety and efficacy, and increase the risk of preventable infectious disease outbreaks. Consistent with the harms described in my prior declarations, APHA received additional reports from its members this week describing ongoing operational disruption, uncertainty in vaccine delivery and counseling, and heightened professional and public health risks resulting from each of the May, June, September, December, and January 5 challenged changes to the CDC immunization schedule.

4. Since the May 19 Directive and subsequent June, September, December, and January 5 changes to the CDC immunization schedule, APHA members across multiple jurisdictions report a sustained and measurable increase in phone calls from healthcare providers, community members, and parents seeking clarification regarding the Secretary, ACIP, and CDC changes to the CDC immunization schedule changes and how to apply the new vaccination recommendations in practice.

5. For example, APHA members running immunization programs in Texas reported this week that their clinics continue to receive numerous calls from healthcare providers and community members requesting clarification on the May, June, September, December, and January 5 changes to the CDC immunization schedule and how each of these changes to the CDC immunization schedule affect the vaccines the clinic is providing and offering to the public. The

immunization program leadership reports that these calls from healthcare providers and the community to the clinic now require substantially more time per inquiry than similar questions in prior years because staff must explain not only the recommendation itself but also the procedural and scientific irregularities underlying the changes to the CDC immunization schedule, which is complicated by the failure of the Secretary, ACIP, and CDC to follow the evidence to recommendation (EtR) framework prior to making the vaccination recommendation changes to the CDC immunization schedule. APHA members running immunization programs and health clinics report that answering the increase in patient and community calls inquiring about the May, June, September, December, and January 5 changes to the CDC immunization schedule requires them to shift resources and staff away from providing care to patients and the public to respond to the calls. This diversion of clinical staff and public health personnel reduces staff capacity to provide care or for immunization outreach; this reduction in care and prevention capacity cannot later be restored.

6. APHA continues to divert staff time and organizational resources to assess and respond to the consequences of the May 19 Directive, June, September, and December ACIP Actions, and January 5 Schedule Change. For example:

a. As a direct result of the Secretary's May Directive, the June, September, and December ACIP votes changing the CDC immunization schedule recommendations for thimerosal containing influenza vaccines, Covid-19 vaccines, and Hepatitis-B vaccines, and the January 5 Childhood Schedule Changes, APHA continues to divert substantial organization resources to unplanned revisions of its flagship infectious-disease publications, including the Control of Communicable Diseases Manual, which APHA has published for over a century, and its companion, Control of Communicable Diseases: Clinical Practice. These volumes are relied on

by APHA members (including state and local health departments, epidemiologists, public health practitioners, and clinicians) nationwide and their content is built around the evidence-based immunization framework historically produced through the CDC and ACIP evidence-based review process. As a result of each of the Secretary, ACIP, and CDC's actions (in May, June, September, December, and January 5) that depart from the established GRADE and EtR evidence review framework and created new confusion about the basis for the changes to the CDC immunization schedule recommendations, APHA has (and continues to have to) reconvene its editorial contributors, reassess affected chapters, and update the guidance to reconcile the scientific evidence with the Secretary, ACIP, and CDC's changes to the CDC immunization schedule. This work requires the reallocation of APHA staff time, editorial ownership, and expert contributors away from other public health priorities that APHA would otherwise be pursuing. These are compelled and ongoing diversion of resources that APHA would not have undertaken but for these May, June, December, September, December, and January 5 actions by the Secretary, ACIP, and CDC that each made changes to the CDC immunization schedule recommendations without following the evidence-based EtR process.

b. APHA members rely on the GRADE and EtR analyses to understand the scientific basis, strength, and scope of the CDC immunization schedule recommendations. Without those analyses, APHA members (including clinicians, public health practitioners, health clinics, and public health officials) lack the methodological foundation necessary to interpret and explain the changes accurately to their patients and community. The failure of the Secretary, CDC, and ACIP to follow the established evidence-based framework prior to making changes to the CDC immunization schedule in May, June, September, December, and January 5 has therefore required

APHA to expend additional resources filling explanatory gaps for APHA members that should have been addressed through the ordinary federal process.

c. I, along with other APHA senior scientific staff, policy analysts, and communications professionals have been forced to divert our time away from APHA planned public health initiatives (including infectious disease prevention campaigns, monitoring, and response planning) to respond to APHA members and the public on questions related to how to interpret and apply the Secretary, ACIP, and CDC changes in May, June, September, December, and January 5 to the CDC immunization schedule. Specifically, APHA has convened emergency internal meetings, hosted member calls, issued clarifying advisories, and developed explanatory materials to address confusion created by May Directive, ACIP June, September, and December Actions, and January 5 Schedule Change.

d. APHA continues to have to divert staff time and institutional resources to assess and respond to the operational consequences of the June ACIP vote, which occurred against the backdrop of longstanding scientific consensus that thimerosal, a preservative containing ethylmercury, is safe and not associated with autism. After the June ACIP vote, APHA became aware that CDC website materials continued to state that thimerosal is safe, while other federal communications surrounding the vote suggested renewed concern. This conflicting federal messaging created confusion among APHA public health practitioner members in the field. In response, APHA staff continue to have to divert their time away from other necessary public health initiatives to review federal materials for inconsistencies on influenza vaccines and prepare responses to member inquiries regarding the June ACIP vote on thimerosal containing influenza vaccines.

e. APHA continues to divert APHA staff time away from necessary public health initiatives to develop public communications and education materials to counter the ongoing widespread confusion caused by the May Directive and September ACIP vote downgrading the Covid-19 vaccine to SCDM. APHA staff field inquiries from APHA members seeking guidance on now to navigate the conflicting and unexplained actions by the Secretary, ACIP, and CDC and coordinating with other public health administrators throughout the country on Covid-19 vaccine guidance to address the changes to the CDC immunization schedule. These efforts are essential to mitigate the ongoing harm, and they represent a continued unplanned burden for APHA. APHA has also continued to have to divert resources to publish materials and statements to APHA members and the public on the safety and efficacy of the Covid-19 vaccine as a direct result of the Secretary's Directive and ACIP's change to the Covid-19 vaccine recommendation to SCDM.

7. APHA's long-standing role as a reliable disseminator of evidence-based public health guidance has been undermined by the Secretary, ACIP, and CDC's unexplained changes to the CDC immunization schedule. APHA's ability to carry out its mission depends on the trust placed in it by the public health professionals, policymakers, and the communities they serve. For decades, APHA's recommendations and educational materials have been grounded in the transparent, evidence-based federal vaccine review framework established by ACIP and the CDC. The Secretary's Directive and ACIP and CDC's abrupt departure from that evidence based EtR review framework have directly undermined APHA's reputation as a reliable conduit of authoritative, evidence-based public health guidance. APHA has had to expend additional resources addressing questions from partners and members on APHA materials on Covid-19 vaccination, Hepatitis B vaccination, and influenza vaccination, that contradict these sudden, unexplained federal cations. The new doubt in APHA guidance caused directly by the Secretary,

ACIP, and CDC unfounded changes to the CDC immunization schedule erodes APHA's standing in the public health community, weakens perceived reliability of its communications, and diminishes the effectiveness of its educational initiatives. APHA continues to have to expend additional resources to rebuild credibility with APHA members and the public, which are resources that would otherwise be directed toward advancing necessary core public health priorities. This loss of trust and impairment of APHA's reputation directly obstructs APHA's ability to fulfill its mission and educate, coordinate, and lead national public health efforts.

8. APHA members continue to report that the May Directive and September ACIP and CDC change from the routine recommendation for Covid-19 vaccination to SCDM has required APHA members to update standing orders, review patient educational materials, change staffing models, and incorporate additional time into clinicians' schedules for the SCDM discussions on Covid-19 vaccinations with their patients. For example, APHA members who run metropolitan health clinics reported this week that their health clinics have to change staffing models to ensure the practitioners are staffed correctly each shift to engage in the SCDM discussions for Covid-19 vaccines. An APHA member health clinic previously relied on licensed practical nurses ("LPNs") for routine vaccine counseling; now the health clinic must staff and schedule LPNs with registered nurses or physicians to engage in the SCDM discussions with the clinic's patients to comply with the changes to the CDC immunization schedule recommendations that now require SCDM for Covid-19 vaccines.

9. An APHA member that operates mobile public health services and mobile health clinics reported this week that it is experiencing a measurable increase in vaccine hesitancy for influenza and hepatitis B following the challenged CDC and ACIP actions changing the recommendations for influenza vaccines (in June) and hepatitis B (in December and January 5).

This APHA mobile public health service provider and clinic member further reported these additional alterations to its allocation of time and resources to respond to the CDC and ACIP actions:

a. As a direct result of increased hesitancy attributable to these June, December, and January 5 changes to the CDC immunization schedule recommendations for influenza vaccination and Hepatitis B vaccination, the APHA member clinic has implemented mandatory motivational interviewing training for all registered nurses to address patient resistance and confusion. This training has increased staff training and labor costs by approximately two additional hours per registered nurse per year.

b. The APHA member clinic has also developed and incorporated a structured motivational interviewing process into routine patient encounters. As a result, each patient encounter involving vaccination now requires approximately three additional minutes of counseling time.

c. Despite this increased counseling time and labor investment, the APHA member clinic receives fewer billable vaccine administration fees per patient because vaccine uptake has declined following the changes to the CDC immunization schedule. The mobile clinic has therefore incurred increased labor costs as a result of the changes to the CDC immunization schedule while simultaneously experiencing decreased vaccine administration revenue.

d. The APHA member clinic has also had to redesign its public-facing website to remove references to prior CDC immunization schedules and replace outdated links to CDC webpages that no longer reflect longstanding evidence-based guidance.

e. In addition, the APHA clinic has been required to revise its standing orders to remove references to the prior CDC schedule language and to incorporate the SCDM

terminology used in the May Directive, September ACIP vote, and January 5 Schedule Change. Revising these standing orders required substantial leadership and staff labor hours, including administrative review, clinical sign-off, retraining of nursing staff, and electronic medical record updates.

f. The APHA member clinic reports that these operational burdens and financial costs would not have occurred but for the May Directive, the June ACIP vote on influenza vaccines containing thimerosal, the September ACIP vote on Covid-19 vaccine, the December ACIP vote on Hepatitis B, and the January 5 Childhood Schedule Change; and these harms are compounding and ongoing. Increased counseling time, staff retraining, staffing model changes, protocol revisions, and revenue loss to the APHA member clinics continues as long as instability and confusion in the May, June, September, December, and January 5 CDC immunization schedule recommendations persist.

10. APHA members continue to report that following the June ACIP vote, they have experienced increased patient questions regarding flu vaccine safety. For example, APHA members have reported modifying flu vaccine messaging campaigns to rebuild confidence and address confusion generated by the June ACIP vote removing thimerosal from influenza vaccines. These changes to messaging campaigns and outreach materials require additional staff time, printing and communications expenses, and expanded community engagement efforts by APHA members. Increased counseling time by clinic staff on the changes to the CDC immunization schedule recommendations for influenza vaccines directly affect APHA members' clinic workflow, patient throughput, and staffing allocation.

11. The December ACIP hepatitis B vote and January 5 Schedule change have destabilized universal birth-dose prevention strategy that APHA and APHA members have

implemented across the public health system nationwide and supported through outreach materials, guidance, counseling, and public health campaigns. APHA members report increased parental refusal of hepatitis B vaccination in birthing hospitals citing December ACIP change and January 5 Childhood Schedule change for hepatitis B vaccination. Universal birth-dose vaccination was adopted because screening-only approaches previously failed in the United States' fragmented healthcare system. That structural reality remains unchanged. Once a newborn leaves a hospital unvaccinated, the prevention opportunity may be lost permanently. Chronic hepatitis B infection carries lifelong increased risk of cirrhosis and hepatocellular carcinoma. APHA and APHA members continue to have to shift resources and staff time to respond to inquiries related to the December ACIP and January 5 changes to the childhood schedule recommendation for hepatitis B vaccination and prepare new outreach materials, strategies for hepatitis B public health awareness and prevention campaigns, and coordinate with public health practitioners across the country to execute the new campaigns. For example, APHA members running maternal child health programs report that as a result of the December ACIP vote and January 5 Childhood Schedule Change for the hepatitis B recommendation, they are shifting their staff members' time and the program's limited resources away from other necessary maternal health initiatives so that the program's staff can spend more time counseling women on the risk of not getting vaccinated for hepatitis B and developing post-delivery programs for the women who are now choosing to forgo hepatitis B vaccination.

12. The next ACIP meeting has been rescheduled for March 18-19, 2016. The March 18-19 ACIP Meeting is imminent, and is causing operational disruption to APHA and APHA members. APHA is preparing contingency communications and internal briefings in anticipation of additional destabilizing actions by ACIP that may make additional changes to the CDC

immunization schedule without following the relied upon evidence-based GRADE and EtR process. APHA members report delaying vaccine procurement and planning decisions pending potential additional changes to the CDC immunization schedule at the March 18-19 ACIP Meeting. Even absent a specific vote, statements made during the ACIP proceeding include vaccine confidence immediately. Each additional meeting and change to the CDC immunization schedule conducted without adherence to the established evidence-based GRADE and EtR framework compounds instability in the CDC immunization schedule recommendations that are embedded in APHA and APHA member guidance, protocols, standing orders, and operations, which APHA and APHA members must address and respond to immediately. Permitting the March 18-19 ACIP Meeting to proceed under these circumstances will cause immediate, concrete, and ongoing harm to APHA and APHA members by further destabilizing the CDC immunization schedule recommendations that are embedded in the nation's public health system and the protocols, disease prevention strategies, outbreak response plans, counseling provided by APHA and APHA members.

13. The harms described here resulting from the Secretary, ACIP, and CDC changes to the CDC immunization schedule (in May, June, September, December, and January 5) are ongoing and cannot later be remedied in the normal course of APHA's operations or recovered. APHA has diverted staff time and financial resources away from its mission-critical public health initiatives to respond to each of the Secretary's, ACIP's, and CDC's May, June, September, December, and January 5 changes to the CDC immunization schedule that each bypassed the evidence-based EtR framework it and its members rely on to understand and then implement the changes across the nation's public health system. APHA members have incurred increased labor costs, reduced vaccine administration revenue, expanded training obligations, website redesign expenses, and

substantial standing-order revision burdens as a result of the Secretary, ACIP, and CDC May, June, September, December, and January 5 changes to the CDC immunization schedule. APHA members have also experienced increased patient counseling time and reduced vaccination uptake as a result of these challenged changes to the CDC immunization schedule. Preventable infectious disease does not pause while litigation proceeds. Missed vaccinations, reduced herd-immunity thresholds, and the avoidable infections that result cannot be restored retroactively. These all threaten the individuals served by APHA members as well as the general public. Absent emergency relief, APHA and APHA members will remain in sustained crisis-response mode, sustaining ongoing injury to their missions and to the public health infrastructure they serve.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C.§ 1746, and the laws of Washington D.C., that the foregoing is true and correct.

Executed on March 1, 2026, in Washington, D.C.

Georges C. Benjamin, MD
Executive Director, American Public Health Association

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF SUZANNE BERMAN, M.D.

I, Suzanne Berman, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I make this declaration based on personal knowledge and if called as a witness, I could and would testify competently to the statements contained herein. I am over the age of 18. I previously submitted a declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction describing the immediate harms resulting from Defendants' challenged agency actions. This supplemental declaration updates the Court on the ongoing, escalating, and compounding harms to my practice arising from: (1) the May 19, 2025 Directive issued by Secretary Robert F. Kennedy, Jr., reclassifying pediatric Covid-19 vaccination as "Shared Clinical Decision-Making" ("SCDM") (the "May 19 Directive"); (2) the June, September, and December 2025 ACIP (the "ACIP Actions") actions altering the CDC immunization schedule without adherence to the GRADE and Evidence-to-Recommendation ("EtR") framework; and (3) the January 5, 2026 revised CDC Childhood Immunization Schedule and accompanying decision

documents (the "January 5 Schedule Change"). These actions have and continue to destabilize vaccine delivery in my practice and community, impair the physician-patient relationship, materially increase uncompensated labor, create direct and imminent financial exposure for my practice, and force operational changes that cannot easily be reversed.

2. I co-own Plateau Pediatrics in Crossville, Tennessee. I oversee the business, compliance, and operational aspects of the practice. Approximately 70–75% of my pediatric patients are insured through Medicaid. The financial stability of my practice depends heavily on the Vaccines for Children ("VFC") program and Medicaid reimbursement structures, which rely on the CDC childhood immunization schedule recommendations. I am a current member of the American Academy of Pediatrics (AAP).

3. Since the May 19 Directive downgraded pediatric Covid-19 vaccination to SCDM, vaccine counseling time with my patients and their parents has increased substantially, which is an ongoing strain on the operations of my practice. SCDM requires individualized, documented discussions. These conversations frequently add 10 minutes to each patient visit and are rarely reimbursed. The time spent engaging in SCDM is not separately reimbursable, and generally SCDM counseling cannot be reimbursed if the patient declines vaccination. Although there are new CPT codes that allow us to bill for this type of discussion, only one insurer is paying for them so far and even then, they are only reimbursing these codes 8% of the time if the patient declines vaccination. As a result, my colleagues and I are spending increasingly more time counseling patients and their parents and performing work that is uncompensated as a result of the May 19 Directive and January 5 childhood schedules changes of childhood vaccines from routine to SCDM. This extra time aggregates and amounts to significant time for which my colleagues and I do not receive compensation, which we cannot later recover.

4. The May 19 Directive also caused and continues to cause significant administrative burden on my practice. For example, because of the lack of a universal definition for SCDM, our practice had to discuss this during weekly administration meetings to determine the meaning of SCDM and develop a standard protocol for our practice. This in turn led to the development of written practice guidance to assist clinicians on navigating these encounters. We have also had to dedicate additional time to training staff, creating new consent forms, and finding and updating resources for clinicians. Overall, the adoption of SCDM has proved very disruptive to our practice and our ability to provide care, vaccinations, and treatment to our patients. The time spent our staff has spent and continues to spend on developing new workflow, protocols, and guidance as a result of the May Directive and January 5 changes to the CDC childhood immunization schedule from routine recommendations to SCDM is not something our practice can recover later on.

5. Because SCDM counseling consumes appointment time, our pediatricians must either shorten discussions about other medical issues or see fewer patients per day. Both options result in lost revenue and reduced access to care. Many parents now refuse to engage in SCDM discussions altogether. If they do engage with us, they frequently cite distrust in medical experts and confusion due to the messaging on childhood vaccines by the CDC, ACIP, and Secretary. I, along with other pediatricians in my practice, therefore, continue to be placed in an untenable position: either push the discussion and escalate conflict or move on and risk professional liability exposure for failing to satisfy SCDM expectations now required by May Directive and January 5 Childhood Schedule Change.

6. My colleagues and I continue to have to address the Secretary, CDC, and ACIP changes to the childhood immunization schedule in real time, every day, with the patients and parents in my practice; the increased questioning from parents and time spent during a wellness

visit on previously routine vaccination counseling, continues to directly impact the operations of my practice, staffing, finances, and relationship with our patients. Each change to the CDC immunization schedule for children by the Secretary, CDC Director, and ACIP since May 2025 has created even more confusion amongst the parents in my practice that I have to address in real life without the supporting evidentiary support for the vaccination recommendation change that I rely on.

7. With each change by the Secretary, CDC, and ACIP to the CDC childhood immunization schedule, I have also experienced (and continue to experience) an increase in the number of parents in our practice who are becoming emotionally charged and adversarial during vaccine counseling discussions. Mothers have broken down in tears during visits, expressing fear and confusion due to vaccine recommendations by the Secretary, HHS, CDC, and ACIP. At least 4 to 5 parents per day question our practice's vaccine recommendations due to the changes to the CDC childhood immunization schedule by the Secretary, HHS, CDC, and ACIP, which increases the time spent on vaccine counseling by as much as 10 additional minutes per patient visit. This additional counseling time is rarely, if ever, reimbursed and diverts time away from very important aspect of the wellness visit that I no longer have time to focus on because of the increased time I am spending on the changes to the childhood vaccine recommendations. As a result of the increase in time I, along with other physicians at my practice now have to spend on vaccination counseling, we continue to have to change our staffing and operations models.

8. This year, some of our clinicians have asked to work fewer hours, in part so they can take a break from the constant moral injury of patient distrust caused by the Secretary, HHS, CDC, and ACIP actions changing CDC childhood immunization schedule. Although we are not turning any patients away due to lack of provider availability, these reductions have required us to

adjust in other ways. Other clinicians are seeing more patients per day, one clinician has added more hours to her schedule seeing patients that has diverted her time away from doing necessary administrative work such as quality improvement projects, and we ultimately had to hire a new nurse practitioner to maintain coverage. The total reduction in hours across clinicians is about 60% of a full-time position. However, it is not feasible to hire a nurse practitioner at 60% capacity, so the nurse practitioner was hired as a full-time employee. This means paying for the full cost of salary, benefits, medical malpractice insurance, loan repayment, payroll taxes, and other related expenses, adding up to $130,000 annually. Given that we only needed 60% of this capacity, roughly 40% of the cost, or $52,000 annually, represents excess expense driven by the need to replace lost hours rather than truly growing my practice. In addition, the Secretary, ACIP, and CDC changes to the CDC childhood immunization schedule in May, December, and January 5 continue to produce significant administrative burden for me and our practice as I and our staff have to shift around schedules, renegotiate clinician days off, and review provider contracts that are impacted by these childhood schedule changes.

9. Prior to the December ACIP Action, Hepatitis B vaccination was routinely recommended beginning at birth. Counseling on was HepB focused on continuation of the series. ACIP removed the routine recommendation in December 2025, and the January 5 Schedule Change eliminated the birth-dose option entirely and shifted initiation to two months under SCDM. Now newborns increasingly present to my practice unvaccinated against HepB. Initiating HepB counseling at two months is significantly more time-consuming than counseling parents about continuing a vaccine series that began in the hospital. Parents who have already refused the vaccine once are more likely to refuse again. Because newborns appear healthy, some parents treat that observation as evidence that vaccination is unnecessary. Following the ACIP and CDC changes to

the childhood schedule for HepB, parents in my practice have become increasingly confrontational during vaccine counseling on HepB, which adds more time to the consultation. For example, in one recent visit, a father became confrontational when HepB vaccination was recommended; despite extended counseling, the family ultimately declined vaccination. The visit consumed substantially more time than it would have prior to the schedule change and was not reimbursed because no vaccine was administered. These types of encounters are becoming more common. This reflects real-world, ongoing behavioral consequences of the schedule changes that significantly impact the physician-patient relationship and operations of my practice.

10. The Secretary's May 19 Directive, December ACIP Action, and the January 5 Schedule Change that each made changes to the CDC childhood immunization schedule have materially altered the way vaccine discussions occur in my exam rooms. These actions signaled to parents that prior childhood vaccine recommendations may have been unsound or politically influenced. That perception, whether accurate or not, is directly affecting clinical operations in my practice. Prior to these changes to the CDC childhood immunization schedule, vaccine administration during well-child visits followed an established, efficient workflow. Vaccines were discussed within a predictable counseling framework grounded in evidence-based ACIP guidance. Since the Secretary's May Directive and additional ACIP and CDC childhood schedule revisions, made without relying on the evidence-based review framework, routine patient visits have become unpredictable and frequently adversarial. The May Directive and January 5 changes to childhood immunizations from routine to SCDM directly increased confusion and fear in our patients and their families, which has increased the amount of time I along with other physicians in my practice must now spend on vaccine counseling. My practice continues to adjust our clinic workflow to

address this increased vaccine counseling time spent on the SCDM changes to the CDC childhood immunization schedule.

11. Parents in my practice now increasingly request that vaccine vials be opened and doses drawn up in the exam room in front of them because they do not trust what is being administered. These types of requests began after the Secretary, ACIP, and CDC began making changes to the childhood schedule in May last year and increased following the January 5 Schedule Change. These requests disrupt established safety and efficiency protocols for vaccination, extend room turnover time, delay subsequent appointments, and reduce the total number of patients we can safely see each day. These operational slowdowns are a direct downstream effect of the Secretary's, ACIP's, and CDC's actions that have changed the CDC childhood immunization schedule.

12. The Secretary, CDC, and ACIP's public framing of vaccines as subject to reconsideration or reclassified from "routine" to "SCDM" status, without transparent adherence to the GRADE and EtR framework, has created a perception among parents in my practice that childhood vaccine recommendations are "not important." That instability is manifesting in my clinic as increased questioning, repeated second-guessing of clinical advice, and heightened skepticism toward vaccines and physicians at my practice. These actions by the Secretary, CDC, and ACIP changing the childhood immunization schedule have imposed a real, operational burden on my practice: longer visits, increased staff time per patient, and physician burnout so severe it has required us to hire additional practitioners. In a Medicaid-dependent practice operating on narrow margins, even small reductions in daily patient volume have meaningful financial consequences.

13. The Secretary's May Directive and the ACIP and CDC actions changing the childhood immunization schedule have also altered the emotional environment of my clinic and physician-patient relationship. What were once collaborative vaccine conversations with parents at my practice, are now frequently tense and confrontational. Pediatricians in my practice have experienced encounters in which parents question whether they can "trust" physicians at all due to the childhood schedule changes. These interactions require substantially more time and emotional labor, often result in vaccine refusal, and increase the likelihood of future follow-up visits dedicated solely to revisiting the same disputes. These changes did not arise organically within my community; they followed and correlate directly with the May Directive and the highly publicized ACIP schedule revisions and January 5 Schedule Change. For example, due to the May Directive, a parent has told a pediatrician in my practice "because you pushed Covid vaccination, I won't trust your advice now on any vaccination." Other patients directly cite Denmark's immunization schedule, referenced in the materials accompanying the January 5 Schedule Change, as a reason not to vaccinate their children, which I then have to spend time explaining during the consult (without the benefit of a robust evidentiary review framework for the January 5 Schedule Change).

14. Newborn visits, which historically were among the most rewarding aspects of pediatric practice, are now among the most stressful. The December ACIP Action removing the routine Hepatitis B recommendation, coupled with the January 5 elimination of the birth-dose option, has transformed these visits into high-conflict encounters requiring extra time to discuss the conflicting HepB recommendations. Physicians in my practice increasingly anticipate confrontation when recommending vaccines that were routine and uncontroversial for decades. This pattern has measurably affected clinician morale. Pediatricians in my practice now avoid newborn visits when possible because of the high probability of vaccine conflict. This represents

a significant shift in staffing preferences and professional satisfaction that began after the Secretary's Directive and continued following the ACIP and CDC changes to the childhood immunization schedule in December and January. Physician burnout at my practice has increased, and retention risk has correspondingly risen.

15. The cumulative effect of these actions by the Secretary, ACIP, and CDC changing the childhood immunization schedule (by the May Directive, December ACIP Action, and January 5 Schedule Change) is not merely an inconvenience on me and my practice. It is an ongoing and worsening structural strain on my practice: longer visits, lower daily capacity, increased uncompensated labor, rising emotional fatigue, and a deteriorating physician-patient relationship that cannot easily be repaired. Each of these successive actions that changed the CDC childhood immunizations schedule (the May 19 Directive, the December HepB ACIP vote, and the January 5 Schedule Change) has compounded distrust with my patients rather than alleviating it. These harms to me and my practice are cumulative and ongoing. Each of these modifications by the Secretary, ACIP, and CDC to the childhood immunization schedule has and will continue to prolong vaccine counseling time, impede my physician-patient relationship, and destabilize childhood vaccine delivery in my practice.

16. The downstream consequences to me and my practice flowing from the Secretary's May 19 Directive, the ACIP's changes to the CDC childhood immunization schedule, and the January 5 Schedule Change include uncompensated clinical labor, direct financial exposure from potential loss of vaccines through the VFC program, deterioration of physician-patient trust, increased liability risk under expanded SCDM obligations, and rising clinician burnout. Each day that the challenged changes to the CDC childhood immunization schedule remain in effect compounds those harms. Professional goodwill and parental trust, once eroded, cannot simply be

restored. Structural staffing and inventory decisions at our practice made as a result of these changes to the childhood immunization schedule by the Secretary, ACIP, and CDC cannot be immediately reversed without further disruption and expense. The Secretary's May Directive and additional changes to the CDC childhood immunization schedule by ACIP in December and the January 5 Schedule Change have transformed stable pediatric vaccine delivery into an unstable and financially precarious system in my community and my practice. These harms that my practice and I are experiencing as a result of these actions by the Secretary, ACIP, and CDC changing the childhood immunization schedule are immediate, compounding, and ongoing.

17. Prior to these May, December, and January 5 actions by the Secretary, ACIP, and CDC changing the childhood immunization schedule, vaccine counseling with my patients and their parents followed stable, evidence-supported guidance supported by the GRADE and EtR framework. The abrupt reclassification of long-standing childhood immunization recommendations, without adherence to established scientific review processes, introduced confusion and distrust that now manifests daily in my exam rooms. Because the Secretary, ACIP, and CDC did not follow the evidence-based review framework before issuing these changes to the CDC childhood immunization schedule, I do not have the evidentiary support to understand the childhood schedule changes, which further disrupts the physician-patient relationship by interfering with my ability to answer questions from my patients in real time on the changes.

18. The March 18-19, 2026 ACIP meeting notice states that "agenda items are subject to change as priorities dictate." There is a likelihood that the next ACIP Meeting will still include a vote to "align" the VFC program with the January 5 revised childhood immunization schedule and there is a very real risk that vaccines moved to SCDM will be removed entirely from the VFC program. As I stated in my prior declaration, the consequences of such a vote would be immediate

to me and my practice. VFC providers may not administer federally supplied vaccine outside the VFC program. If these vaccines are removed from the program, my practice must immediately stop using VFC inventory for those vaccines. That would require us either to cease offering the vaccines to Medicaid-insured children or to purchase private stock at our own expense.

19. Vaccine procurement requires advance ordering, minimum purchase quantities, and upfront payment. Because the next ACIP Meeting is still imminent and the agenda remains subject to change based on ACIP's undisclosed priorities, I must divert my time and resources to prepare for a VFC vote on the January 5 revised childhood immunization schedule and make purchasing decisions now without knowing whether these vaccines will remain covered under VFC. That uncertainty itself is disruptive to me and my practice. If I reduce orders to limit financial exposure, I risk shortages for children who present for vaccination in the coming weeks. If I purchase additional private inventory in anticipation of removal from VFC, I assume significant financial risk that cannot later be undone.

20. If vaccines are removed from VFC, Medicaid reimbursement mechanisms are unlikely to immediately absorb those costs at market rates. Many vaccines cost my practice $100, $200, or more per dose outside the VFC program. My experience with non-VFC vaccines demonstrates that Medicaid reimbursement frequently falls below acquisition cost. For example, a vaccine costing $120 to acquire may be reimbursed at $80; a vaccine costing $30 may be reimbursed at $20. When multiplied across a high-volume pediatric population, those losses compound rapidly. If vaccines are removed from VFC following the next ACIP Meeting, each administration to a Medicaid-insured child would generate a direct financial loss. Those losses cannot later be recovered from families due to federal billing restrictions–as a Medicaid-participating provider, I am prohibited from charging Medicaid families more than a nominal co-

pay. They also cannot realistically be recouped through retroactive reimbursement adjustments. Once vaccine inventory is purchased or administered at a loss, the financial harm is complete. If I attempted to charge TennCare patients the full cash price of the vaccine to make myself whole, I could be excluded entirely from the Medicaid program. Opting out of TennCare, or risking exclusion from the program, would leave the county my practice serves with no practical medical care for most children. These harms cannot be reversed by a later court ruling.

21. If a provider serves both VFC-eligible and privately insured patients, VFC rules state that the provider must stock both VFC and private inventory for the same vaccine. In rural areas like mine, where access to pediatric care is already limited, many surrounding practices operate on narrow margins and may choose not to stock private inventory of vaccines that cannot also be obtained through VFC. If multiple practices reduce vaccine offerings, families may have no practical local option. My practice cannot absorb unlimited overflow from other providers. In an outbreak situation, I would be forced to ration supply and prioritize existing patients, creating immediate public health risk and operational strain.

22. As a practicing pediatrician responsible for ordering, counseling on, and administering vaccines, many of them through the VFC program, I rely on ACIP's published GRADE evidence summaries, EtR analyses, and explanatory MMWR guidance to guide my conversations with patients and their families and defend my clinical decisions. When a vaccine recommendation changes, I use these resources to understand how to apply the updated guidance to my patients and how to clearly explain the change to them. The GRADE and EtR framework were not followed prior to the issuance of the May Directive, December ACIP Action, and January 5 Schedule Changes that each made changes to the CDC childhood immunization schedule. As a result, I do not have the scientific review framework and underlying evidentiary support and

analysis that I ordinarily use to counsel parents, address concerns, and justify my clinical decisions on the childhood vaccinations impacted by these actions. This lack of information is continuing to compromise my physician-patient relationship and operations of my practice as I do not have the evidentiary foundation to understand the changes to the childhood schedule and answer the questions that I receive from parents in my practice.

23. When CDC childhood immunization schedule recommendations are issued or altered without following the evidence-based review (GRADE and EtR) framework, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work. Instead, it is added on top of my existing clinical responsibilities and diverts from patient care. When this occurs repeatedly, as with the Covid-19 childhood schedule changes, December childhood schedule change, and the January 5 Schedule Change, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. The deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point.

24. The scientific assessment memo issued alongside the January 5 Schedule Change did not follow the established GRADE or EtR framework and cannot substitute for it. No supporting MMWR was issued. Without these materials, I lack the evidentiary tools I ordinarily use to explain changes to parents. If ACIP removes vaccines from VFC at the March 18-19 ACIP meeting based on this truncated process, I will be required to implement immediate programmatic

changes without being able to reference a recognized evidentiary framework. That undermines parental confidence and directly impairs my ability to practice evidence-based medicine. If ACIP votes to remove several vaccines from the VFC program using the scientific assessment and decision memo, the impact will worsen as I have to explain the changes to families in my practice seeking to understand why certain recommendations have shifted and why vaccine access through the VFC program has changed. This is especially disruptive for my practice where the vast majority of my patients are VFC-eligible.

25. Without GRADE tables, EtR analyses, or an MMWR explaining the rationale and scope of the January 5 Schedule Change, I cannot provide the level of evidence-based explanation that parents in my practice reasonably expect. If ACIP votes during its next meeting on March 18-19 to remove vaccines from VFC program based on the January 5 revised childhood schedule, the harm will escalate. I will be required to implement changes affecting VFC-eligible children in my practice while still lacking the robust, scientific analysis and written guidance necessary to explain the change and maintain parental confidence. That combination, mandatory programmatic change without the robust evidentiary foundation and review process that I can reference, creates immediate and serious disruption in the care I provide to the children and their parents in my practice.

26. If the ACIP votes to remove the vaccines that were downgraded as a result of the January 5 Schedule Change from the VFC program at the upcoming March 18-19 ACIP meeting, I will be forced to make immediate decisions about inventory, reimbursement risk, and whether I can continue offering these vaccines to the majority of my patients. Those consequences occur at the time of the vote and implementation (not months later); as a result, I have to continue to take action now to attempt to prepare my practice for this likely vote. In addition, missed vaccination

opportunities cannot be recreated. Financial losses incurred by my practice from unreimbursed vaccine administration cannot be recovered. Once my practice adjusts inventory, participation, or service offerings, those structural changes cannot be quickly reversed. If vaccines reclassified under the January 5 Schedule Change are removed from VFC, the financial and operational harms described above will escalate immediately. As a practicing pediatrician and practice owner, permitting the next ACIP Meeting to proceed under these circumstances will cause immediate, concrete, and devastating harm to me and my practice and to the stability of vaccine delivery in my community.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C.§ 1746, and the laws of Tennessee, that the foregoing is true and correct.

Executed on February 26, 2026 in Crossville, Tennessee.

/s/ Suzanne Berman

Dr. Suzanne Berman

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

I, Fiona P. Havers, M.D., MPH, FIDSA, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge.

2. I have a Bachelor's degree in Biology from Yale University, a Master's Degree from Harvard University in Regional Studies East Asia, a Masters in Health Science from Johns Hopkins Bloomberg School of Public Health, and a Medical Degree from the University of Washington – School of Medicine.

3. I am a Fellow of the Infectious Diseases Society of America.

4. For thirteen years, I served as an epidemiologist at the Centers for Disease Control and Prevention ("CDC"). The last position I held at CDC before I resigned on June 16, 2025, was Lead, Respiratory Virus Hospitalization Surveillance Network (RESP-NET) Team.

5. I gave an interview to the New York Times about why I resigned. The article reporting on my resignation is attached hereto as Exhibit A. The article accurately reports that I

resigned from the CDC because I "could no longer continue while the health secretary, Robert F. Kennedy Jr., dismantled the careful processes that help formulate vaccination standards in the United States." The article accurately quotes me when I told the reporter: "'If it isn't stopped, and some of this isn't reversed, like, immediately, a lot of Americans are going to die as a result of vaccine-preventable diseases.'"

6. The Advisory Committee on Immunization Practices ("ACIP") held a public meeting on April 14-15, 2025, at CDC headquarters in Atlanta. The agenda for the April 15-16, 2025, ACIP meeting is attached hereto as Exhibit B. Five presentations were given on COVID-19 vaccines on April 15. I gave a PowerPoint on April 15, 2025, titled "COVID-19 Associated Hospitalizations – COVID-NET, April 2025 Update." The PowerPoint deck that I presented at that meeting is attached hereto as Exhibit C. The YouTube video of the April 15, 2025, ACIP meeting can be found here: https://www.youtube.com/watch?v=Hra3xSJBOtk My presentation starts at 2:17:28 of the video.

7. Before I gave my presentation, Dr. Robert Schechter, the COVID-19 Work Group Chair, gave an introductory presentation on the COVID-19 vaccines. His presentation is attached as Exhibit D and starts at 1:43:20 in the YouTube video. The sixth slide of his presentation compares the disease burden of COVID-19 to influenza from October 1, 2024, through March 22, 2025, in four categories: illnesses, outpatient visits, hospitalizations, and deaths. For Covid, the slide estimated deaths due to Covid in this time period to be from 26,000 – 43,000; hospitalizations from 220,000 – 370; outpatient visits 1.9 – 3.2 million; and illnesses 7.7 – 13.5 million. Dr. Schechter commented at the meeting that: "However, looking at the more severe outcomes toward the right hand side of the table, the lower estimates for death is comparable between the two diseases reflecting that for a case of Covid-19, a severe outcome is more probable than for any

given case of influenza. A couple of other observations that even at lower levels, tens of thousands of Americans have perished with Covid-19 and that many of these [were] potentially vaccine preventable." (YouTube video at 1:47:27-1:48:03).

8. Dr. Schechter announced in his presentation that, at the June 2025 ACIP Meeting, there would be "[d]iscussion and vote on recommended use of the 2025-2026 vaccine." (Exhibit D, slide 10).

9. During my presentation, when slide 17 titled "~1 in 5 children and adolescents with COVID-19-associated hospitalization are admitted to the intensive care unit (ICU)" was shown, I stated: "Among children who are hospitalized for COVID-19, many continue to experience severe outcomes across all the pediatric age groups. From July 2023 through March 2024, approximately one out of five hospitalized children were admitted to the intensive care unit, 41% of whom had no underlying medical conditions, although the proportion with no medical conditions varied by age group. Also during this period, seven children with Covid-19 associated hospitalization died in hospital in the Covid-Net catchment area." (Exhibit C, slide 17; YouTube video at 2:25:17 – 2:25:46).

10. When I went to the next slide, I said: "This slide shows the vaccination status of children hospitalized for COVID-19 during the 2023-24 season. Fewer than 10% of children and adolescents hospitalized with COVID 19 had received any vaccine within the 12 months preceding their COVID-19 hospitalization. And additionally, fewer than 5% of the hospitalized children and adolescents had received the recommended 23-24 COVID vaccine for that season as shown in dark blue, suggesting that many of these hospitalizations were potentially preventable had the child received the recommended vaccine." (Ex. C, slide 18; YouTube video at 2:25:48 – 2:26-17).

11. I summed up my presentation as follows: "So in summary for pediatrics, rates of Covid 19 hospitalizations are highest among the youngest age groups, although among school age children, hospitalization rates are generally have been higher for influenza than for Covid -19. More than half of children and adolescents hospitalized with COVID-19 had more than one underlying condition. And this increased with increasing age, but a substantial proportion of children had no underlying medical conditions. And the most common underlying conditions also varied by age groups. And again, as we saw, the vast majority of children who were hospitalized with Covid had not received the most recently recommended Covid 19 vaccine during the 2023 – 24 season." (Ex. C, slide 19; YouTube video at 2:26:22 – 2:26:58)

12. After I presented, Dr. Ruth Link-Gelles of the CDC presented an update on "Interim Estimates of 2024-2025 COVID-19 Vaccine Effectiveness." Her PowerPoint is attached as Exhibit E, and her presentation starts at 2:33:13 on the YouTube video. Slide 14 of Dr. Link-Gelles' presentation states her conclusions. When showing this slide, she stated: "2024-2025 COVID-19 vaccination provided additional protection against COVID-19 associated emergency department and urgent care visits and hospitalizations compared to no 24-25 COVID-19 vaccine dose. 24-25 COVID-19 vaccination also provided additional protection against COVID associated hospitalizations among adults aged 65 years and up with immunocompromising conditions. Finally, just a reminder the VE should be interpreted as the added benefit of 24-25 COVID-19 vaccination in a population with high levels of infection induced immunity, vaccine-induced immunity, or both." (Ex. E, slide 14; YouTube video at 2:42:44 – 2:43:19).

13. After Dr. Link-Gelles' presentation, Dr. Edwin Asturias, a voting member of the ACIP at the time, commented: "I'm very encouraged that we are focusing more on children as I think one of the major myths that we have to debunk is that young children do not have a risk of

severe disease and hospitalization from COVID-19. And I think your data shows that these trends are not decreasing, so it's consistent that as we have new cohorts of unprotected infants being born every year, we probably have to adjust our current recommendation given that they don't specify the importance of vaccinating young infants and children to avoid this morbidity and mortality. I have to point out that 70% of your hospitalizations in children are occurring in less than four years of age and half of them don't have any associated medical condition. … I think it's so important for all of us to … make sure that we value children as a prime, you know, group that needs to be protected better than what we are doing so far." (YouTube video at 2:44:21 – 2:45:38).

14. Dr. Naima Joseph with the American College of Obstetricians and Gynecologists then commented: "I just wanted to highlight as has been mentioned by others the high rate of hospitalization in young children and especially you know the previous CDC data has shown a really high rate amongst infants 6 months and younger who are ineligible for vaccine which small studies have shown a benefit for boosting in pregnancy as a way to protect those infants who are not otherwise eligible for vaccination and would look forward to further data that might demonstrate the effectiveness of vaccination of maternal immunization against infant infection." (YouTube video at 2:50:01 – 2:50:37).

15. I responded to this comment at the meeting by stating "I do want to emphasize in this presentation we were largely focusing on children and infants who are older than six months. But you are correct and that the hospitalization rates for infants less than six months who are protected through maternal vaccination during pregnancy are by far the highest among all the pediatric age groups. So that is a very important point that I hadn't emphasized." (2:50:42 – 2:51:04; *see* Exhibit C, slide 10) I had not emphasized this point in my presentation because the recommendation was not a particularly controversial topic for the ACIP members and the

ACIP COVID-19 Work Group at the time. Data on pregnancy and hospitalization rates in infants <6 months, who depend on protection through transplacental transfer of maternal antibodies for protection from COVID-19, had been reviewed by the COVID-19 Work Group prior to the meeting. However, based on the evidence reviewed and the Work Group discussions before the April 2025 meeting, the recommendation for vaccination during pregnancy was not likely to be changed during the ACIP vote on COVID-19 recommendations that had originally been planned for the June 2025 meeting, and I thus did not focus on these data during my presentation.

16. After Dr. Link-Gelles' presentation, Dr. Lakshmi Panagiotakopoulos of the CDC and co-lead of the COVID-19 Work Group, presented a PowerPoint presentation titled "Use of 2025-2026 COVID-19 Vaccines: Work Group Considerations" (attached as Exhibit F). Her presentation starts at 2:51:05. When showing slide 24, Dr. Panagiotakopoulos said: "This graph shows the number of Covid-19 and influenza deaths among people ages 0 to 17 years between September 2023 and August 2024. For children less than one, the number of deaths from Covid-19 were higher than the number of deaths from flu." (Ex. F, slide 24; YouTube video at 2:59:41 – 2:59-54). The graph showed a total of 152 deaths of children 0-17 in this time period from COVID-19. (Ex. F, slide 24).

17. The data presented publicly by myself, Dr. Link-Gelles and Dr. Panagiotakopoulos had been previously presented to the ACIP COVID-19 Work Group in the months leading up to the April 2025 ACIP meeting and those presentations had gone through the CDC scientific clearance process prior to the public presentation of the data. The COVID-19 Work Group was in the months leading up to the April and June 2025 meetings contemplating recommending a risk-based approach for the COVID-19 vaccination for some population groups. Slides 60-68 of Dr.

Panagiotakopoulos summarize discussions and polling of the Work Group that had been done prior to the April 15 meeting about adopting a risk-based approach for the COVID-19 vaccination.

18. I have read the Memorandum from Matthew Memoli, Principal Director, NIH, and Sara Brenner, Principal Deputy Commissioner, FDA, to the Secretary, dated May 12, 2025, with the subject "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age." I have also read the Memorandum from Tracy Beth Hoeg to Secretary Robert F. Kennedy, Jr., dated May 12, 2025, with the subject of COVID-19 vaccine safety in pregnant women. The first time I saw these memos was on March 1, 2026, and I personally had no knowledge of these memos while I was at CDC. I am very confident that none of my colleagues at CDC who had responsibilities related to the control and prevention of the spread of the COVID-19 virus were consulted or knew about these memos in May 2025, because they would have told if they had. Plus, I am aware that no career CDC officials in CDC leadership were aware of the Secretarial Directive that is dated May 19, 2025, until the Secretary's video posted on X on May 27, 2025, announcing his decision to remove the CDC recommendations that pregnant women and children receive the COVID-19 vaccine.

19. In the May 27, 2025, video, the Secretary states: "Last year, the Biden Administration urged healthy children to get yet another COVID shot despite the lack of any clinical data to support the repeat booster strategy in children." I do not understand how the Secretary could say there is no clinical data to support children receiving a COVID-19 booster when I and three others presented substantial data just a month before that supported children continuing to receive the COVID-19 vaccine, especially vaccine-eligible infants >6 months and very young children. The Hoeg memo ignores the data on hospitalizations of children less than six months old.

20. In the months leading up to the April 15, 2025, meeting, the COVID-19 Work Group had robust debate about a cut-off for a routine vaccine recommendation for young children and was heading towards a changing the COVID-19 vaccine recommendations for children which would likely maintain a routine vaccine recommendation for children aged 6 – 23 months as well as older children with underlying medical conditions, among other nuanced recommendations.

21. When I told the New York Times reporter that I "could no longer continue while the health secretary, Robert F. Kennedy Jr., dismantled the careful processes that help formulate vaccination standards in the United States," two actions I was referring to were the Secretary's bypassing of the ACIP to change the COVID-19 recommendations and his firing of the entire ACIP on June 9, 2025.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on March 2, 2026.

FHavers

Fiona Havers, MD, MHS, FIDSA

EXHIBIT A

The New York Times https://www.nytimes.com/2025/06/18/health/havers-cdc-vaccines-kennedy.html

Why a Vaccine Expert Left the C.D.C.: 'Americans Are Going to Die'

Dr. Fiona Havers is influential among researchers who study immunizations. The wholesale dismissal of the agency's scientific advisers crossed the line, she said.

Listen to this article · 8:07 min Learn more

By Apoorva Mandavilli

June 18, 2025

In 13 years at the Centers for Disease Control and Prevention, Dr. Fiona Havers crafted guidance for contending with Zika virus, helped China respond to outbreaks of bird flu and guided safe burial practices for Ebola deaths in Liberia.

More recently, she was a senior adviser on vaccine policy, leading a team that produced data on hospitalizations related to Covid-19 and respiratory syncytial virus. To the select group of scientists, federal officials and advocates who study who should get immunizations and when, Dr. Havers is well known, an embodiment of the C.D.C.'s intensive data-gathering operations.

On Monday, Dr. Havers resigned, saying she could no longer continue while the health secretary, Robert F. Kennedy Jr., dismantled the careful processes that help formulate vaccination standards in the United States.

"If it isn't stopped, and some of this isn't reversed, like, immediately, a lot of Americans are going to die as a result of vaccine-preventable diseases," she said in an interview with The New York Times, the first since her resignation.

Dr. Havers, 49, cited an escalating series of attacks on federal vaccine policy by Mr. Kennedy. Three weeks ago, the health secretary announced in a minute-long video on X that the agency would no longer recommend Covid-19 vaccines for healthy children or pregnant women.

Last week, he fired all 17 members of the agency's Advisory Committee on Immunization Practices, saying without evidence that the group was beset with conflicts of interest and that a clean sweep was needed to restore public trust.

Mr. Kennedy went on to name eight new members, at least half of whom appear to share his antipathy to vaccines. Two have testified against vaccine makers in trials.

Senator Lisa Blunt Rochester, Democrat of Delaware, plans to introduce a bill on Wednesday that would reverse Mr. Kennedy's decision and make it impossible for future leaders to dismiss committee members without due cause.

The restocking of the committee may have enormous implications for the health of Americans. The panel's endorsements mean insurance companies must cover the costs of immunizations and help states decide which vaccines to mandate for school-age children.

"It's a very transparent, rigorous process, and they have just taken a sledgehammer to it in the last several weeks," Dr. Havers said.

"C.D.C. processes are being corrupted in a way that I haven't seen before," she added.

The agency was not consulted about any of it, Dr. Havers said. The C.D.C. has languished without a director since the new administration began.

Dr. Havers had been scheduled to present new data to the scientific advisers next week.

"I could not be party to legitimizing this new committee," she said. "I just no longer had confidence that the data that we were generating was going to be used objectively."

Andrew Nixon, a spokesman for the Department of Health and Human services, said, “Under Secretary Kennedy’s leadership, H.H.S. is committed to following the gold standard of scientific integrity.”

“Vaccine policy decisions will be based on objective data, transparent analysis and evidence — not conflicts of interest or industry influence,” he said.

Dr. Havers is at least the second official to resign because of what they perceive to be rising antagonism to vaccines at H.H.S. Dr. Lakshmi Panagiotakopoulos, who oversaw a work group on the Covid vaccine, resigned two weeks ago.

“Losing one more highly qualified and experienced C.D.C. public health expert, such as Dr. Fiona Havers, further weakens our national public health vigilance,” said Dr. Yvonne Maldonado, a pediatrician at Stanford University and one of the fired committee members.

“It also demonstrates the chaos and lack of support our federal health agencies are currently experiencing,” she said.

A walkout in Atlanta on June 10 protesting the firing of all 17 members of a C.D.C. scientific advisory panel. Melissa Golden for The New York Times

Until now, scientists at the C.D.C. gathered data on infections, hospitalizations, deaths and more, presenting the numbers to A.C.I.P. members and helping shape recommendations on the strategies needed to keep Americans healthy.

As head of the C.D.C.'s platforms for tracking hospitalizations related to Covid-19 and R.S.V., Dr. Havers oversaw analyses of data from 14 states, representing 10 percent of the U.S. population.

The research she presented informed the Food and Drug Administration's decision to authorize Covid-19 vaccines for children in 2021. The work also helped the C.D.C.'s advisers to recommend the shots to children, adolescents and pregnant women and to prioritize doses by age and underlying medical conditions.

The data led to more than 20 peer-reviewed publications and 15 reports from the C.D.C., and it fed online dashboards that drew millions of views. Dr. Havers herself has published more than 100 papers while at the agency, including R.S.V. vaccine recommendations for adults in 2023.

Early in the pandemic, Dr. Havers designed and led a national study to estimate the prevalence of antibodies to the coronavirus among Americans, a proxy for the number of infections.

She found that the number was anywhere from two to 13 times as high as the reported rates in a given region.

At the time, the first Trump administration muffled the C.D.C.'s scientists and sidelined them in making decisions. "That was a really rough time at C.D.C.," Dr. Havers recalled. "The last five, six months have been worse than that."

In an article published on Monday, the fired panelists wrote that "Secretary Kennedy's process blurs lines of legal authority" and that his decisions had "left the U.S. vaccine program critically weakened."

Dr. Camille Kotton, who served on the vaccine advisory committee until last year, said in an interview, "My whole career, I have relied on everything that came from the C.D.C. as the most powerful and best information available."

Now, "we're at a time where it seems increasingly likely that we will not be able to trust information coming from the C.D.C.," she said.

In April, the agency's advisers met and recommended that the R.S.V. vaccine be offered to everyone 50 and older at high risk of severe outcomes from the infection. But there is no permanent or acting director to sign off on those recommendations.

Mr. Kennedy did not endorse them. The decision will be reconsidered by the new committee next week.

"I think it is a very interesting ethical conundrum that we're at now," Dr. Kotton said, referring to scientists advising federal officials. "Do we continue to serve even though we feel like it's a very political leadership, or do we step away?"

Dr. Havers studied medicine at the University of Washington and specialized in infectious diseases and epidemiology at Johns Hopkins University. She joined the C.D.C. in 2012 as a member of the elite Epidemic Intelligence Service, training in the agency's flu division.

She has continued to see patients as an infectious-disease physician at the Atlanta Veterans Affairs Medical Center and is an adjunct associate professor at Emory University. But she does not yet know what she might do next, beyond gardening and spending time with her family.

When Mr. Kennedy was named to lead the Department of Health and Human Services, Dr. Havers had expected to see some changes to vaccine policy.

Thousands of her colleagues at the agency were fired. She held out hope even after Mr. Kennedy's recent decision to restrict Covid shots for children and pregnant women, because parents could still get healthy children vaccinated in consultation with a doctor.

But the dismissal of the entire vaccine advisory committee was too much to bear, Dr. Havers said.

"I have utmost respect for my colleagues at C.D.C. who stay and continue to try and limit the damage from the inside," she said. "What happened last week was the last straw for me."

Apoorva Mandavilli reports on science and global health for The Times, with a focus on infectious diseases and pandemics and the public health agencies that try to manage them.

A version of this article appears in print on , Section A, Page 16 of the New York edition with the headline: Vaccine Expert Warns 'a Lot of Americans Are Going to Die'

EXHIBIT B

Final Agenda

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
Atlanta, Georgia 30329

Tuesday, April 15, 2025

8:00	**Welcome & Introductions**	Dr. Keipp Talbot (ACIP Chair) Dr. Melinda Wharton (ACIP Executive Secretary, CDC)
8:15	**Mpox Vaccine**	
	Introduction	Dr. Faisal Minhaj (CDC/NCEZID)
	Presentation on immunogenicity and safety of JYNNEOS in 12-17 year olds	Dr. Buddy Creech (Vanderbilt University)
	EtR for JYNNEOS in outbreaks and due to the 2022 global outbreak	Dr. Faisal Minhaj (CDC/NCEZID)
9:55	**Lyme Disease Vaccine**	Dr. Grace Marx (CDC/NCEZID)
10:00	**Influenza Vaccines**	
	Introduction	Dr. Jamie Loehr (ACIP, WG Chair)
	Influenza vaccine effectiveness update	Dr. Aaron Frutos (CDC/NCIRD) Dr. Sophie Zhu (California DPH and CDC/PHIC), Dr. Joshua Quint (California DPH)
	FluMist self/caregiver administration	Dr. Allyn Bandell (AstraZeneca)
11:15	***Break***	
11:30	**COVID-19 Vaccines**	
	Introduction	Dr. Robert Schechter (ACIP, WG Chair)
	Moderna mRNA-1283 COVID-19 vaccine	Dr. Bishoy Rizkalla (Moderna)
	Epidemiology and risk factors for COVID-19 hospitalizations	Dr. Fiona Havers (CDC/NCIRD)
	Vaccine effectiveness update	Dr. Ruth Link-Gelles (CDC/NCIRD)
	Workgroup considerations for use of 2025-2026 COVID-19 vaccines	Dr. Lakshmi Panagiotakopoulos (CDC/NCIRD)
1:30	**Pneumococcal Vaccines**	
	Workgroup Next Steps and Proposed Work Plan	Dr. Miwako Kobayashi (CDC/NCIRD)
1:45	***Break***	
2:00	**Human Papillomavirus (HPV) Vaccines**	
	Introduction	Dr. Oliver Brooks (ACIP, WG Chair)
	Update on literature related to reduced number of doses for HPV vaccination	Dr. Carla DeSisto (CDC/NCIRD)
	KEN SHE trial	Dr. Ruanne Barnabas (Harvard University)
	HPV vaccination coverage	Ms. Cassandra Pingali (CDC/NCIRD)
	Modeling of reduced number of doses for HPV vaccination	Dr. Jane Kim (Harvard University)
	Modified EtR: wording of the age for routine HPV vaccination	Dr. Ruth Stefanos (CDC/NCIRD)
	Workgroup next steps and considerations	Dr. Lauri Markowitz (CDC/NCIRD)
4:00	**Cytomegalovirus (CMV) Vaccines**	
	Introduction	Dr. Denise Jamieson (ACIP, WG Chair)
	CMV and cCMV epidemiology and disease burden	Dr. Tatiana Lanzieri (CDC/NCIRD)
	CMV vaccine safety and immunogenicity data	Dr. Robert Paris (Moderna)
	Initial workgroup considerations for CMV vaccine policy	Dr. Tatiana Lanzieri (CDC/NCIRD)
5:00	**U.S. Measles Update**	Dr. David Sugerman (CDC/NCIRD)
5:30	**Adjourn**	

Final Agenda

Wednesday, April 16, 2025

8:00	**Welcome & Introductions**	Dr. Keipp Talbot (ACIP Chair)
8:15	**Meningococcal Vaccines**	
	Introduction	Dr. Jamie Loehr (ACIP, WG Chair)
	GSK pentavalent vaccine: update of EtR and workgroup considerations	Dr. Sarah Schillie (CDC/NCIRD)
	Updates to Meningococcal vaccines VFC resolution	Dr. Jeanne Santoli (CDC/NCIRD)
	Introduction to MenQuadfi label change for infants	Dr. Sarah Schillie (CDC/NCIRD)
	MenQuadfi in infants: safety and immunogenicity	Dr. Rachel Dawson (Sanofi)
	Workgroup considerations regarding MenQuadfi in infants	Dr. Sarah Schillie (CDC/NCIRD)
9:30	***Break***	
9:45	**Respiratory Syncytial Virus (RSV) Vaccines - Adults**	
	Introduction	Dr. Albert Shaw (ACIP, WG Chair)
	Manufacturer Presentation: mRNA-1345 (Moderna) Immunogencity in Adults 18-59 at Increased Risk; 24-Month Re-Vaccination	Dr. Frances Priddy (Moderna)
	Manufacturer Presentation: Arexvy (GSK) 36-Month Re-Vaccination	Dr. Susan Gerber (GSK)
	Economic Analysis of Adult RSV Vaccination, including benefits and risk discussion	Dr. Ismael Ortega-Sanchez (CDC/NCIRD)
	Comparison of Economic Analyses of Adult RSV Vaccination	Dr. Ismael Ortega-Sanchez (CDC/NCIRD)
	Evidence to Recommendations	Dr. Diya Surie (CDC/NCIRD), Dr. Michael Melgar (CDC/NCIRD)
	Clinical Considerations	Dr. Diya Surie (CDC/NCIRD)
12:15	***Break***	
12:30	**Chikungunya Vaccines**	
	Introduction	Dr. Edwin Asturias (ACIP/WG Chair)
	EtR for use of virus-like particle chikungunya vaccine among adolescent and adult travelers	Dr. Susan Hills (CDC/NCEZID)
	EtR for use of virus-like particle chikungunya vaccine among laboratory workers	Dr. Erin Staples (CDC/NCEZID)
	Surveillance for adverse events following use of live attenuated chikungunya vaccine and its use among travelers	Dr. Susan Hills (CDC/NCEZID), Dr. Erin Staples (CDC/NCEZID)
	Clinical guidance for use of virus-like particle chikungunya vaccine among pregnant and breastfeeding women	Dr. Susan Hills (CDC/NCEZID), Dr. Dana Meaney-Delman (CDC/NCBDDD)
3:00	***Break***	
3:10	**Public Comment**	
3:40	**VOTES**	
	Meningococcal Vaccines	Dr. Sarah Schillie (CDC/NCIRD)
	Meningococcal Vaccines VFC	Dr. Jeanne Santoli (CDC/NCIRD)
	RSV Adult	Dr. Michael Melgar (CDC/NCIRD)
	Chikungunya Vaccines	Dr. Susan Hills (CDC/NCEZID)
4:10	**Respiratory Syncytial Virus (RSV) Immunizations- Maternal/Pediatric**	
	Introduction	Dr. Helen Chu (ACIP, WG Chair)
	EtR: Clesrovimab	Ms. Danielle Moulia (CDC/NCIRD)
	Clinical considerations	Dr. Jefferson Jones (CDC/NCIRD)
5:10	**Adjourn**	

Acronyms

cCMV	Congenital cytomegalovirus
CDC	Centers for Disease Control and Prevention
CMV	Cytomegalovirus
COVID-19	Coronavirus disease 2019
DPH	Department of Public Health
EtR	Evidence to Recommendations Framework
HPV	Human papillomavirus
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NCIRD	National Center for Immunization & Respiratory Diseases
NCEZID	National Center for Emerging and Zoonotic Diseases
PHIC	Public Health Infrastructure Center
RSV	Respiratory Syncytial Virus
WG	Work Group
VFC	Vaccines for Children

EXHIBIT C

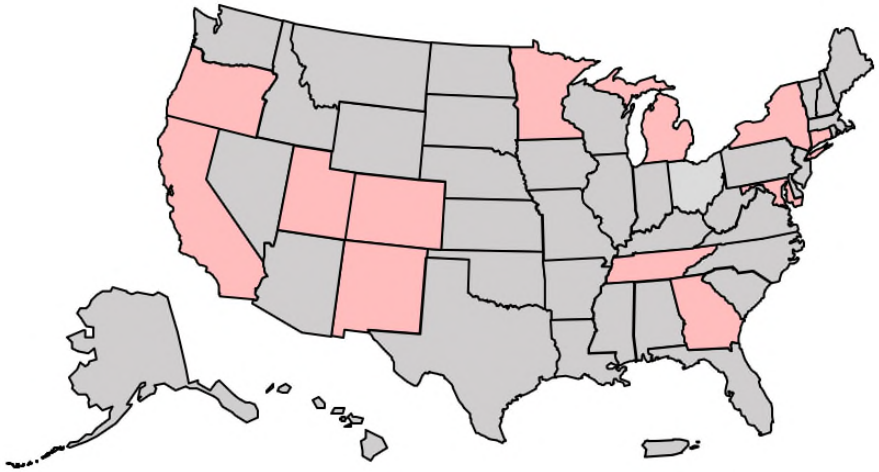
COVID-19–Associated Hospitalizations — COVID-NET, April 2025 Update

Fiona P. Havers, MD, MHS, FIDSA
RESP-NET Hospitalization Surveillance Team
Coronavirus and Other Respiratory Viruses Division

Advisory Committee on Immunization Practices (ACIP) Meeting
April 15, 2025

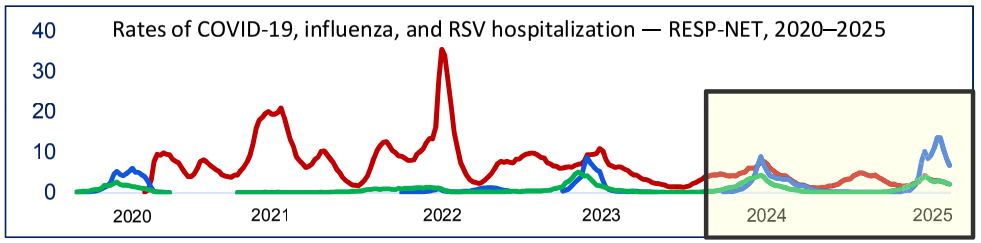
COVID-NET is a population-based hospitalization surveillance platform.

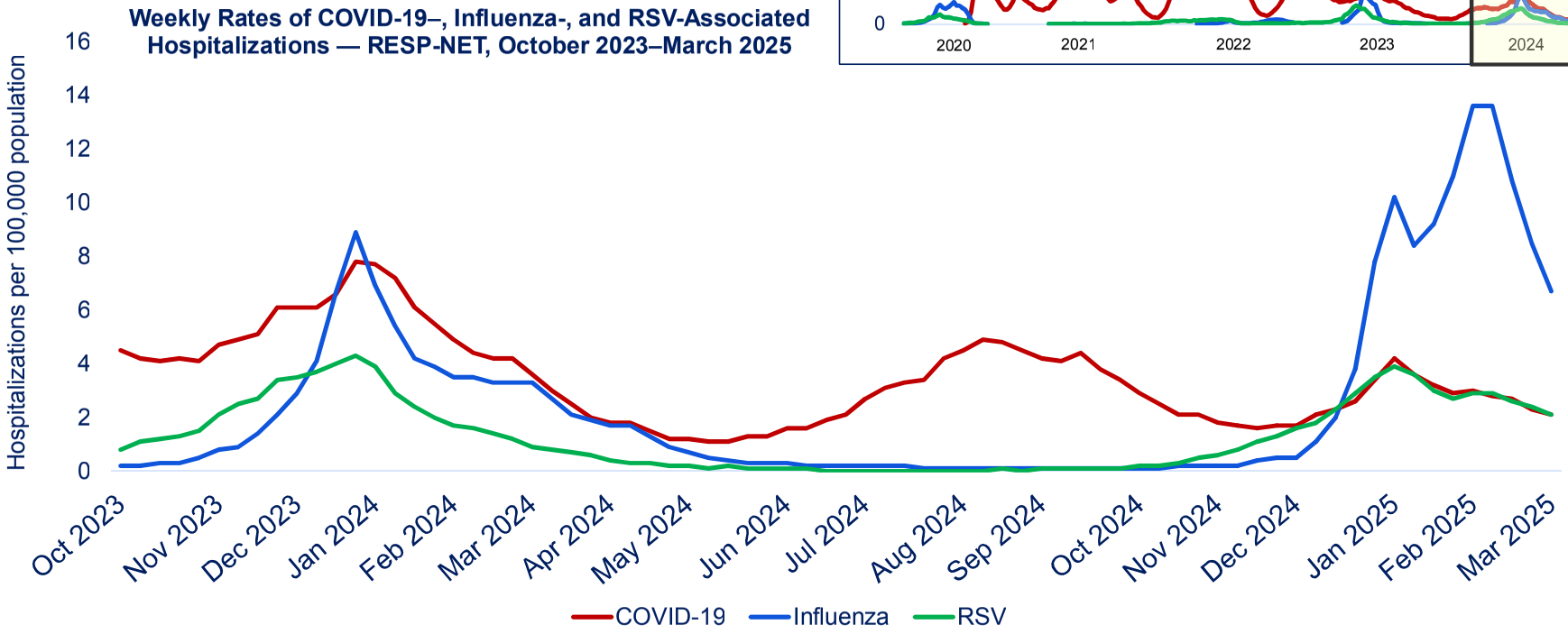
- RESP-NET: COVID-NET, RSV-NET, FluSurv-NET
- >300 acute-care hospitals
- 98 counties in 13 states
- ~10% of the U.S. population
- Positive SARS-CoV-2 test ≤14 days before admission or during hospitalization
- Screening or clinician-driven testing
- Clinical data: age- and site-stratified random sample



COVID-NET: https://www.cdc.gov/covid/php/covid-net/index.html Some slides display data from 90 counties in 12 states due to incomplete data.

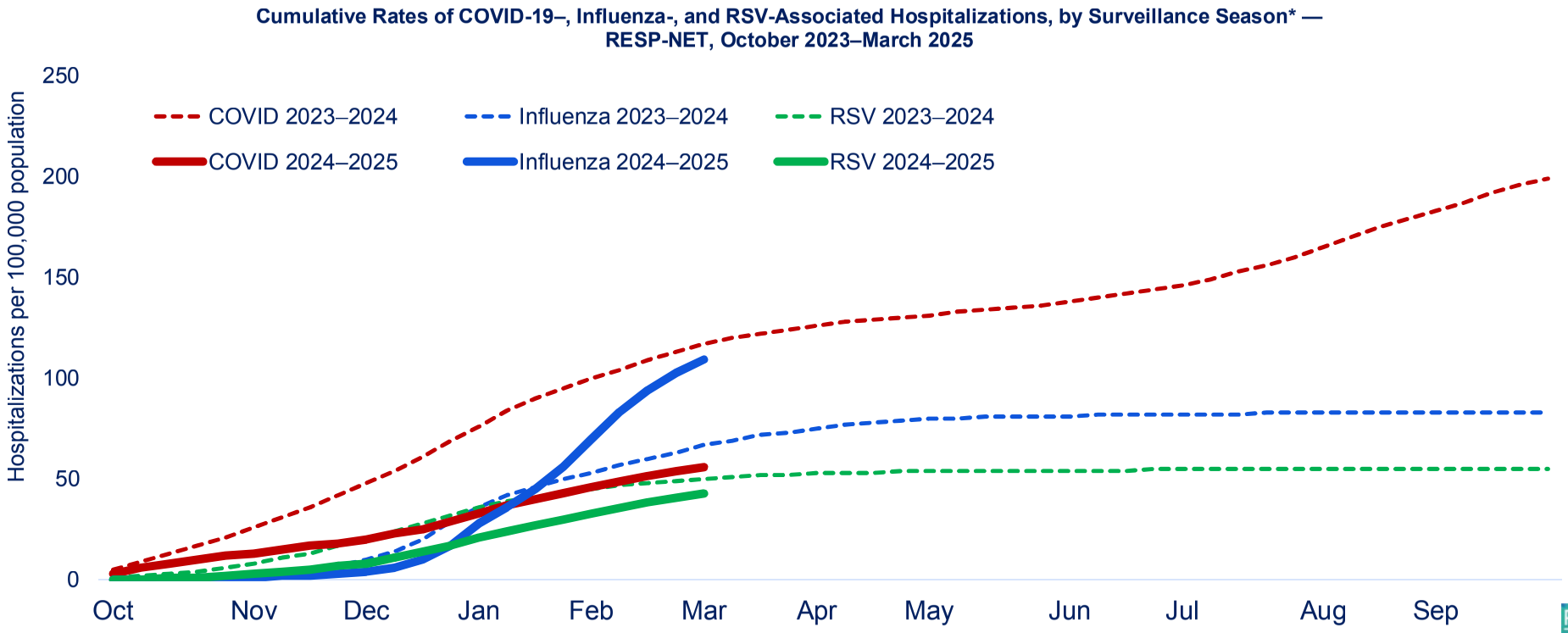
COVID-19 hospitalization rates have had both winter and summer peaks.





Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed. Data source: https://www.cdc.gov/resp-net/dashboard/
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

Rates of COVID-19 hospitalizations for the 2024–2025 season are lower compared to last season.

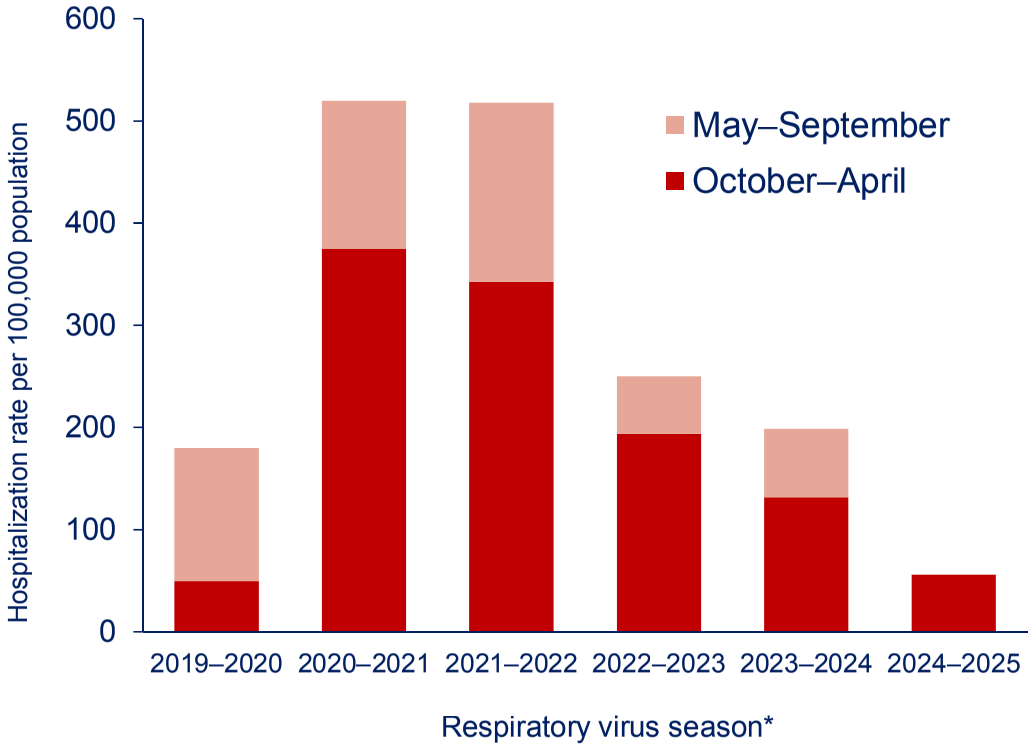


* Seasons are defined as October through September. The 2024–2025 season shows data from October 2024–March 2025 and is ongoing.

Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed. Data source: https://www.cdc.gov/resp-net/dashboard/

Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

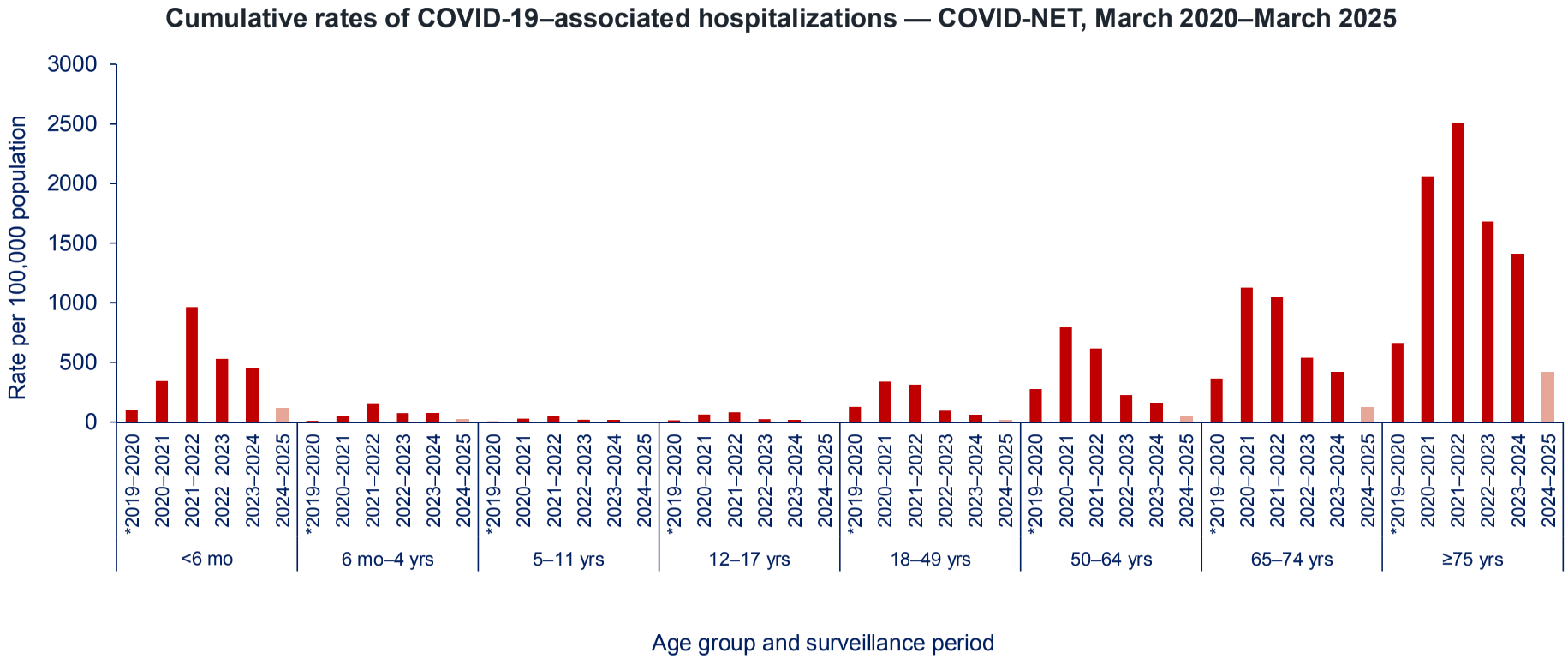
Cumulative COVID-19–associated hospitalization rates by surveillance season — COVID-NET, March 2020–March 2025



Many COVID-19-associated hospitalizations occur outside of the typical respiratory virus season.

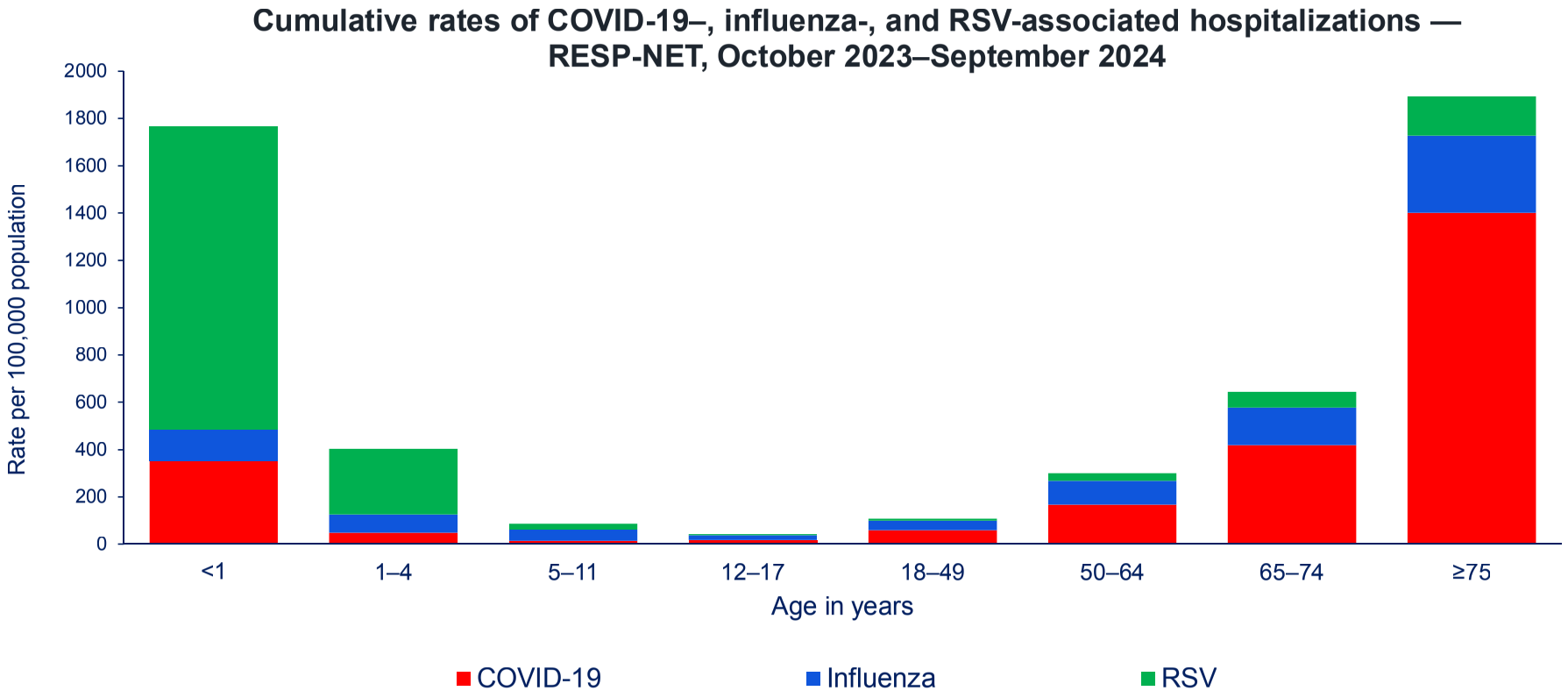
* The 2019–2020 surveillance period includes March–September 2020; other seasons are defined as October through September. The 2024–2025 season shows data from October 2024–March 2025 and is ongoing.

Among all age groups, rates of COVID-19–associated hospitalizations have declined since the 2021–2022 season



* The 2019–2020 surveillance period includes March–September 2020; other seasons are defined as October through September. The 2024–2025 season shows data from October 2024–March 2025 and is ongoing.

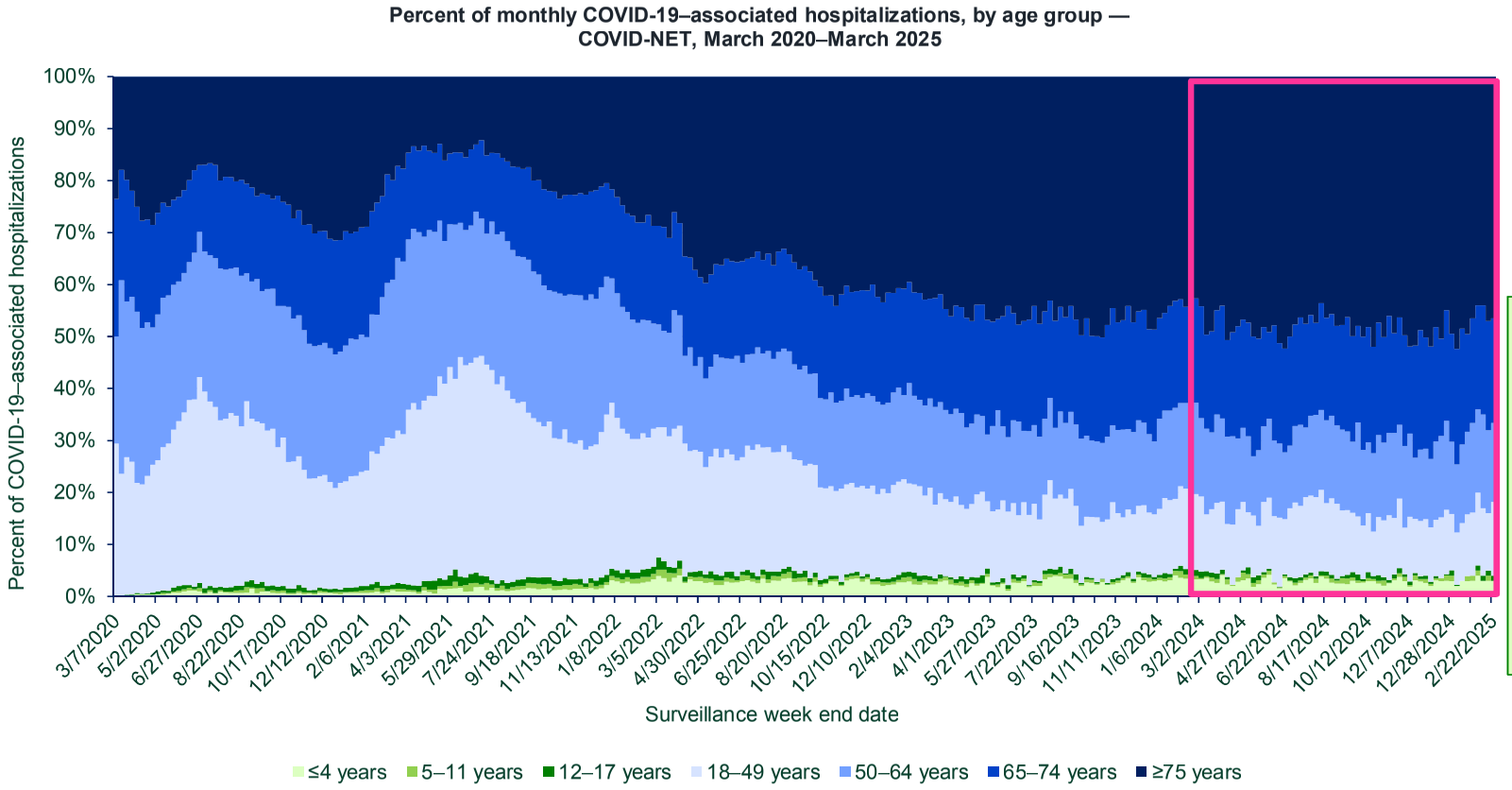
Rates of respiratory virus-associated hospitalizations vary by age group and pathogen.



Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed. Data source: https://www.cdc.gov/resp-net/dashboard/
Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

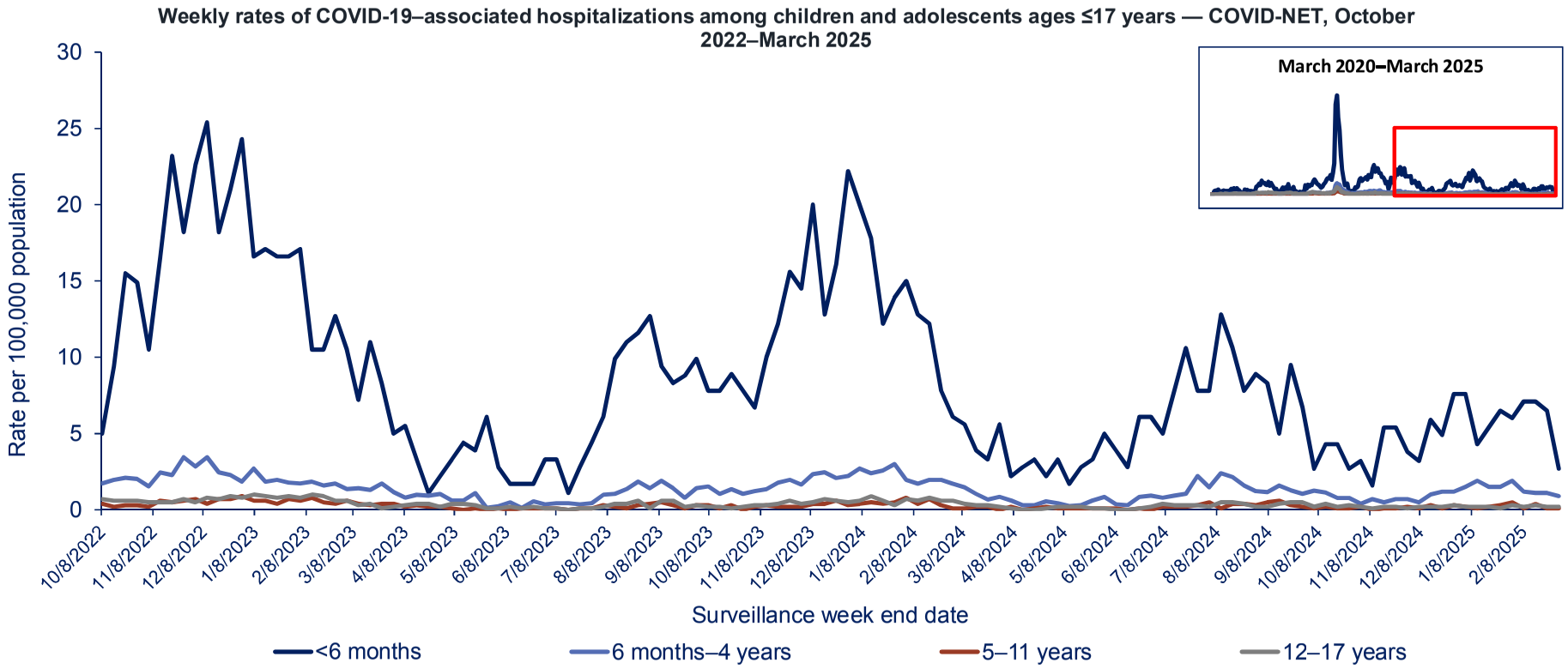
Pediatric COVID-19–Associated Hospitalizations

During 2024–2025, children and adolescents comprised about 4% of COVID-19–associated hospitalizations.

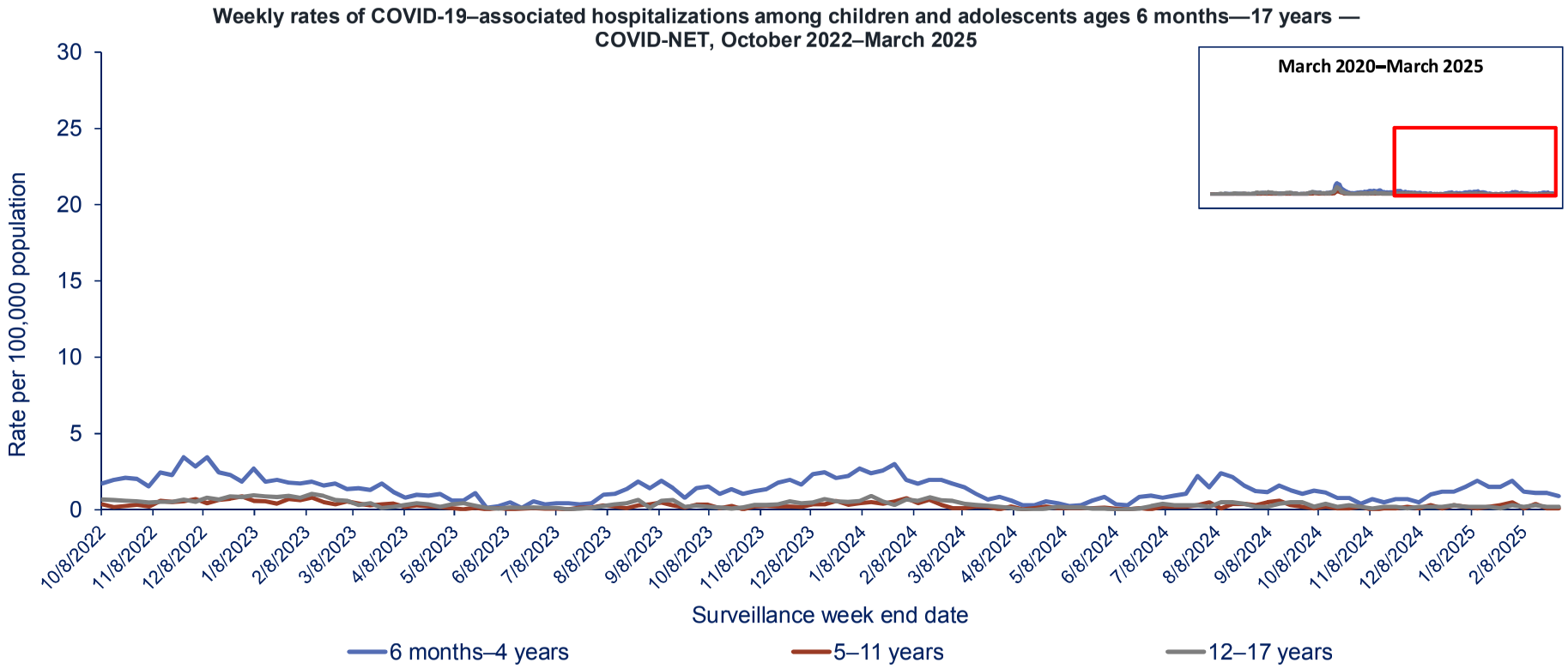


- ≤17 years = 4.3% of COVID-19–associated hospitalizations during October 2024–March 2025
- ≤4 years = 2.9%
- 5–11 years = 0.6%
- 12–17 years = 0.6%

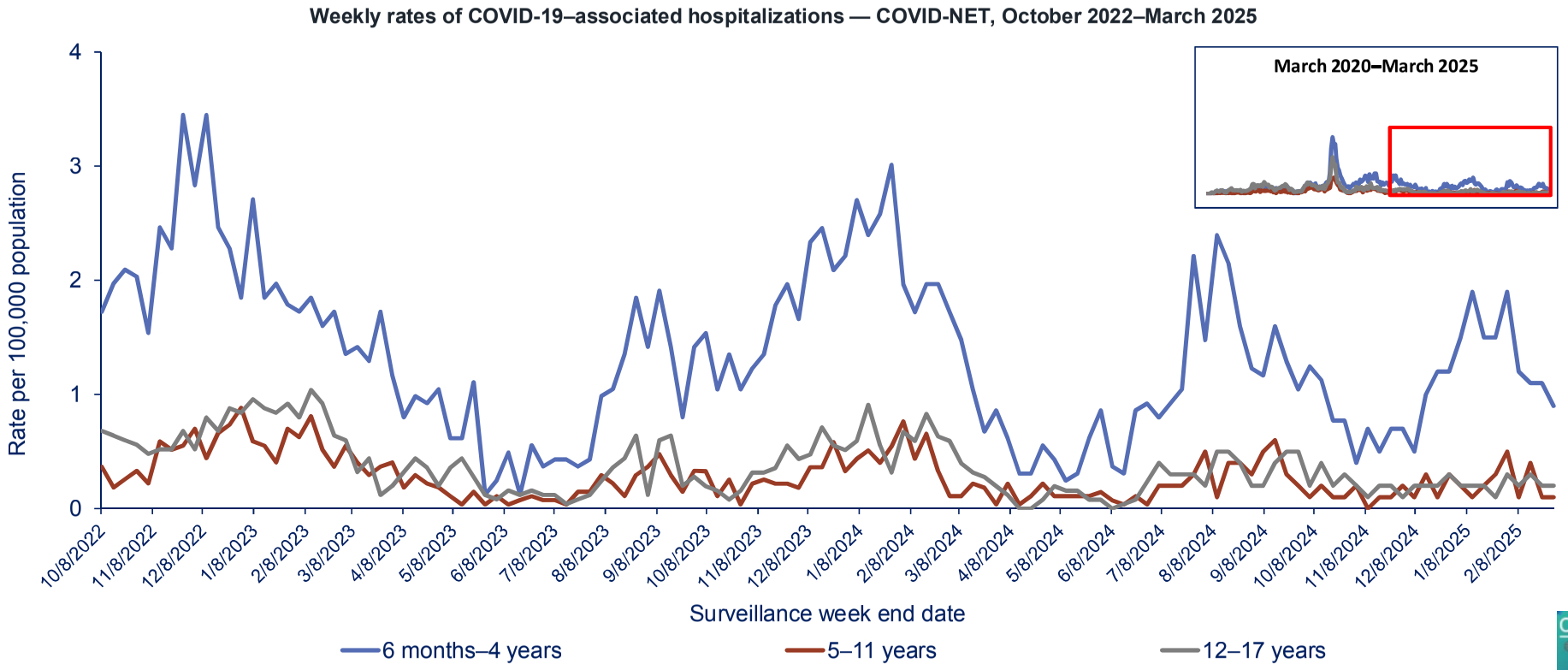
Among all children and adolescents, rates of COVID-19–associated hospitalizations are highest among infants ages <6 months.

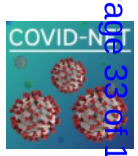


Among all children and adolescents, rates of COVID-19 hospitalizations are highest among infants ages <6 months.

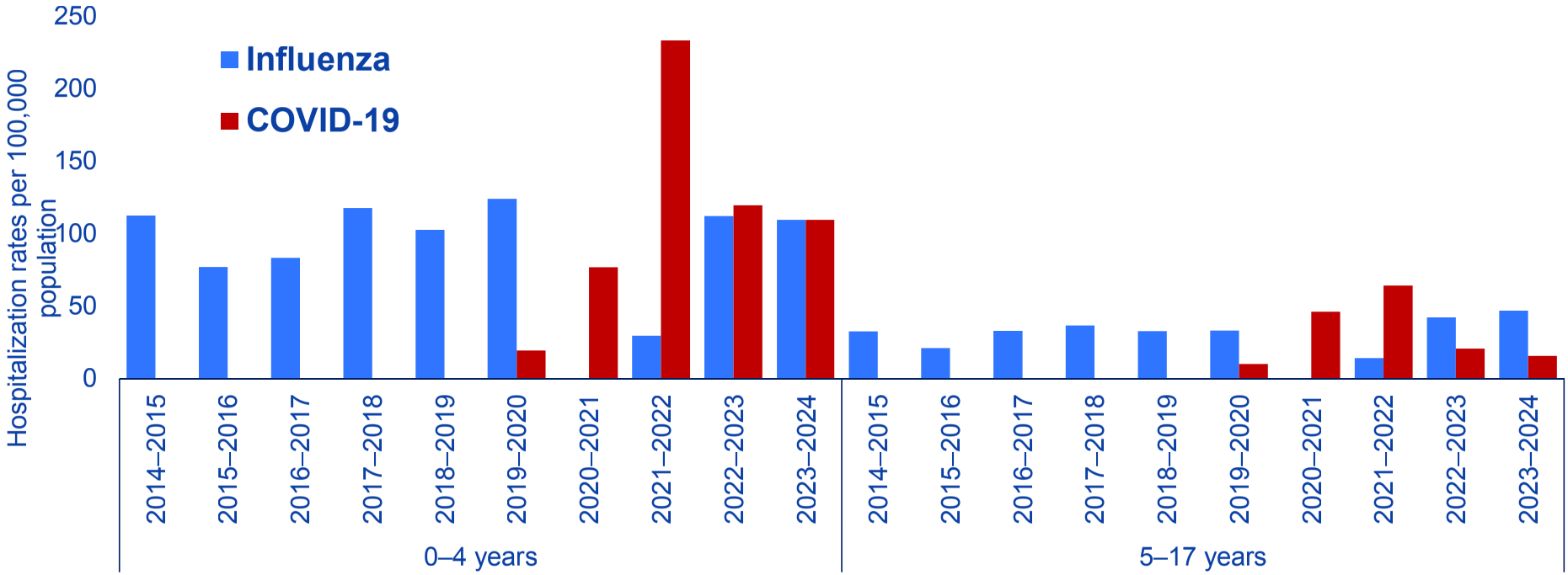


Among children and adolescents eligible for COVID-19 vaccines, cumulative rates of COVID-19–associated hospitalizations remain the highest among children ages 6 months–4 years.





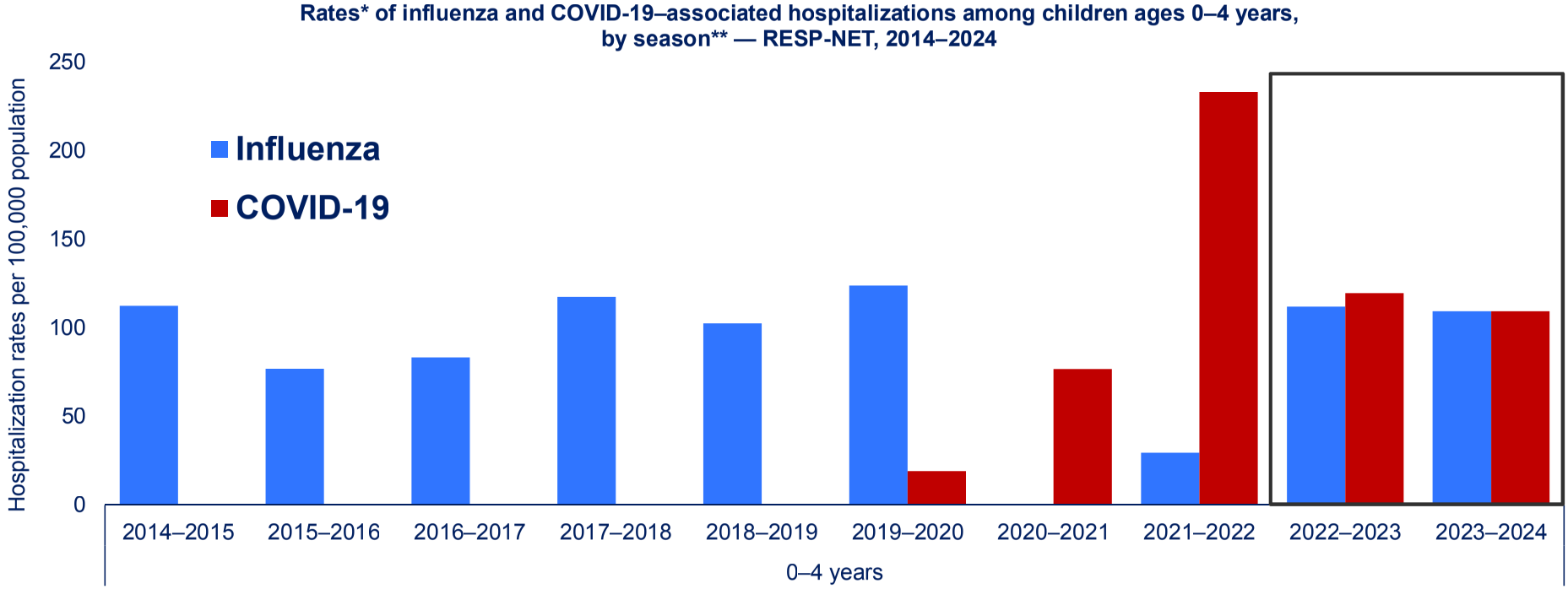
Rates* of influenza and COVID-19–associated hospitalizations among children ages ≤17 years** — RESP-NET, 2014–2024



** Note that rates of influenza hospitalizations are adjusted for undertesting and under-detection. Rates of COVID-19 hospitalizations are not adjusted for undertesting or under-detection. Rates of COVID-19 hospitalization might be higher when adjusted for these factors.*

*** Monitoring for influenza hospitalizations typically occurs during October through April; for COVID-19 hospitalizations, monitoring for a given respiratory season begins in October and continues through the following September. For the 2019–2020 period, monitoring for COVID-19 hospitalizations began in March 2020. Historical flu data from https://www.cdc.gov/flu-burden/php/data-vis/past-seasons.html. Historical flu data are not available for the 2020–2021 period.*

Among children ages ≤4 years, COVID-19–associated hospitalization rates during the 22–23 and 23–24 seasons were similar to those due to influenza.



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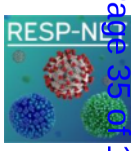
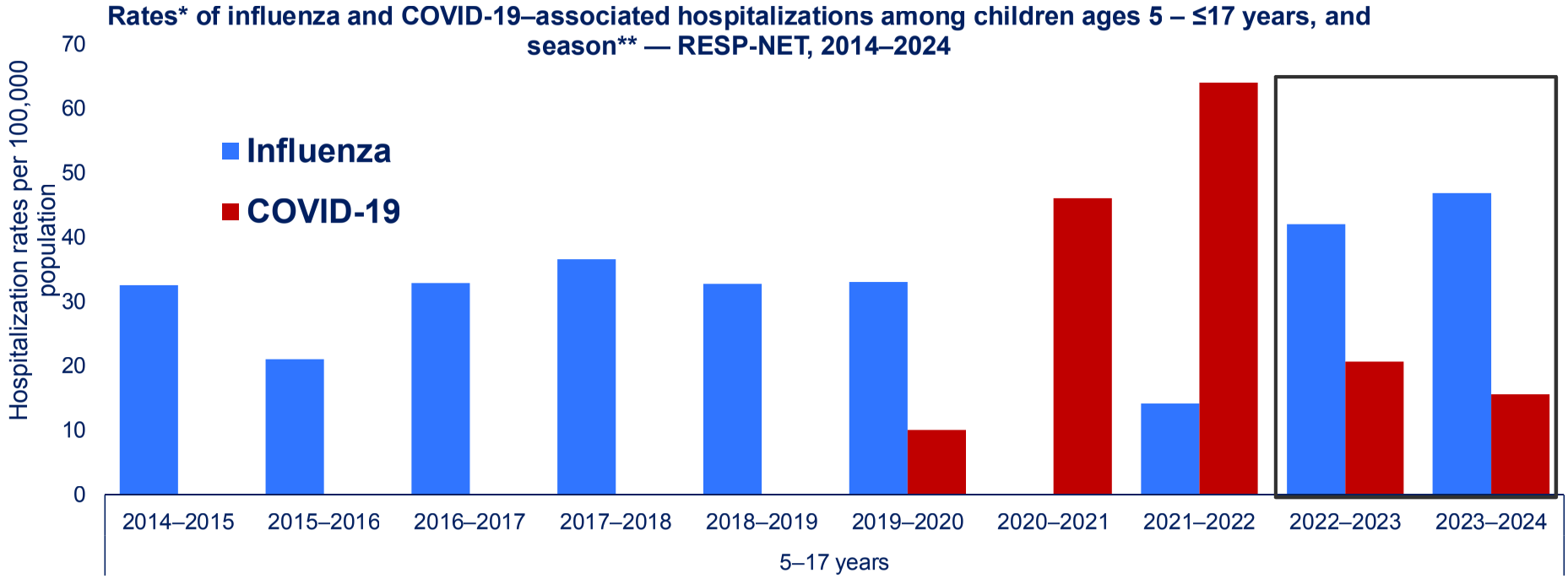
*** Monitoring for influenza hospitalizations typically occurs during October through April; for COVID-19 hospitalizations, monitoring for a given respiratory season begins in October and continues through the following September. For the 2019–2020 period, monitoring for COVID-19 hospitalizations began in March 2020.*

Historical flu data from https://www.cdc.gov/flu-burden/php/data-vis/past-seasons.html. Historical flu data are not available for the 2020–2021 period.



Among children aged 5–17 years, COVID-19–associated hospitalization rates during the 22–23 and 23–24 seasons were lower than those due to influenza.

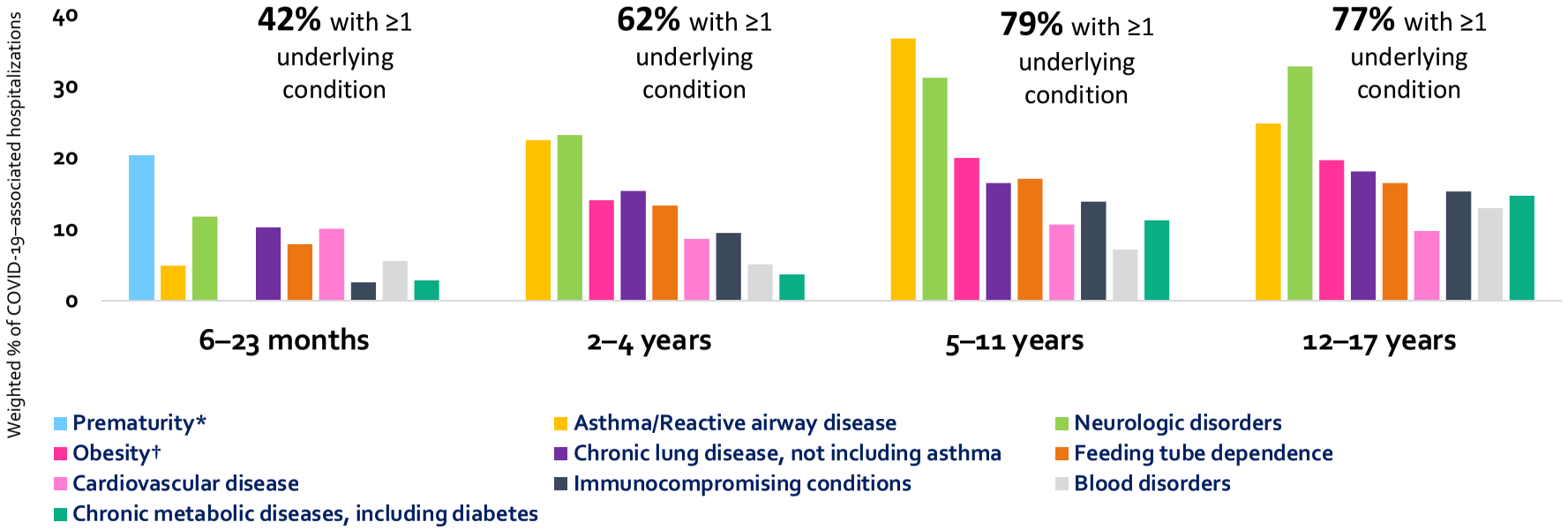


** Note that rates of influenza hospitalizations are adjusted for undertesting and under-detection. Rates of COVID-19 hospitalizations are not adjusted for undertesting or under-detection. Rates of COVID-19 hospitalization might be higher when adjusted for these factors.*

*** Monitoring for influenza hospitalizations typically occurs during October through April; for COVID-19 hospitalizations, monitoring begins in October and is conducted year-round. For the 2019–2020 period, monitoring for COVID-19 hospitalizations began in March 2020.*

Historical flu data from https://www.cdc.gov/flu-burden/php/data-vis/past-seasons.html. Historical flu data are not available for the 2020–2021 period.

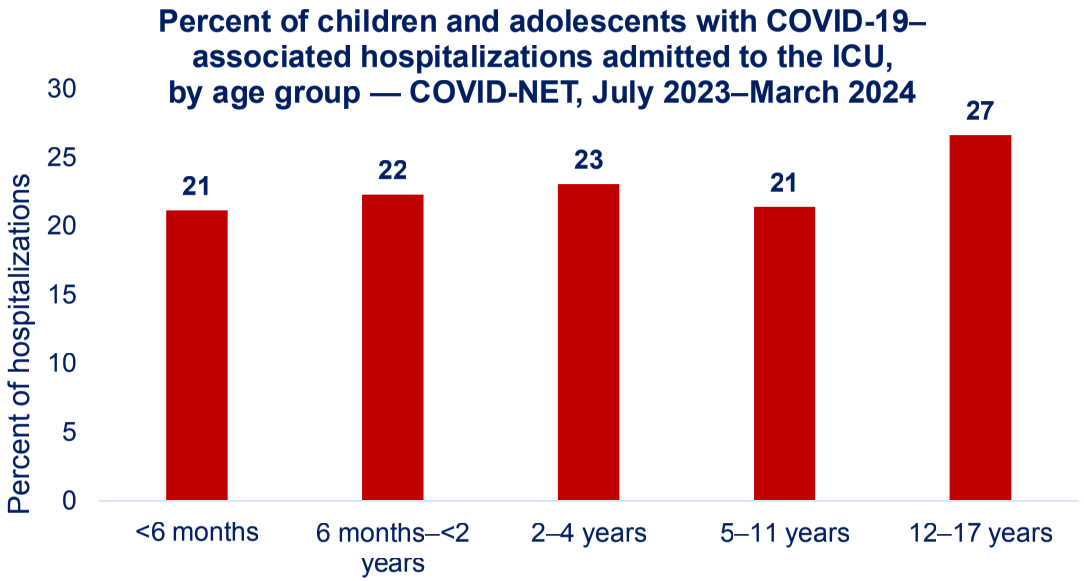
During October 2022–April 2024, more older children hospitalized with COVID-19 had underlying medical conditions compared with younger age groups.



Among children and adolescents ages 6 months–17 years hospitalized with COVID-19, 59% had ≥1 underlying condition.

* Prematurity is only assessed for children aged <2 years. †Obesity is not calculated for children aged <2 years. Data are limited to hospitalizations with COVID-19 as the likely reason for admission. Source: Pre-publication analysis from Rebecca Free and presented at IDWeek 2024. Data reflect the period of October 1, 2022–April 30, 2024.

~1 in 5 children and adolescents with COVID-19–associated hospitalization are admitted to the intensive care unit (ICU)



Age category	Among those admitted to ICU, % with no underlying conditions
<6 months	56%
6–23 months	52%
2–4 years	30%
5–11 years	6%
12–17 years	24%

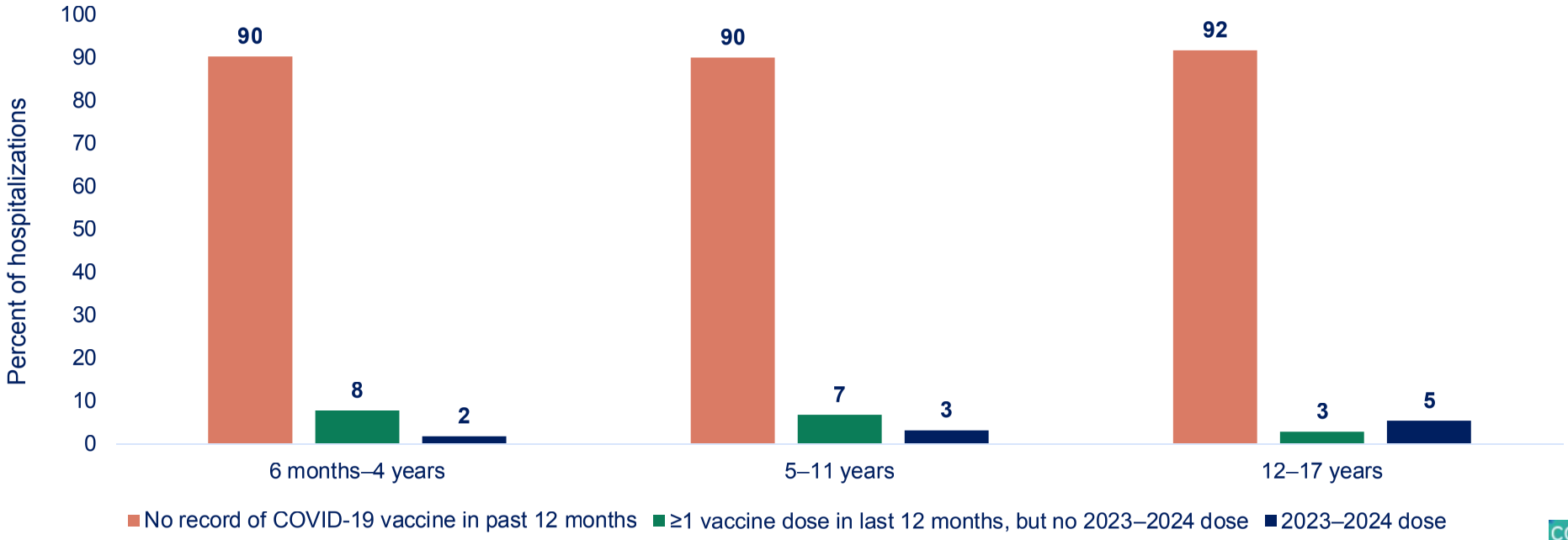
During this period, 7 children with COVID-19–associated hospitalization died in-hospital in the COVID-NET catchment area.

41% of children admitted to the ICU had no underlying conditions, but this varied by age group

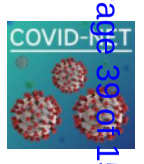
Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission.

Fewer than 5% of children and adolescents eligible to received COVID-19 vaccinations and hospitalized with COVID-19 received the most recently recommended COVID-19 vaccination.

Vaccination status among children and adolescents with COVID-19–associated hospitalizations, by age group — COVID-NET, October 2023–September 2024



No record of COVID-19 dose in past 12 months*: No recorded doses of any COVID-19 vaccine dose in the 12 months preceding hospitalization.* ***≥1 vaccine dose in last 12 months, but no 2023–2024 dose:*** *Received at least one COVID-19 bivalent booster vaccination in the 12 months preceding hospitalizations, but no record of receiving 2023-2024 vaccine dose.* ***2023–2024 vaccine dose:*** *Received 2023-2024 vaccine dose. Persons with unknown vaccination status are excluded. Hospitalizations are limited to those with COVID-19 as the presenting complaint upon admission.*

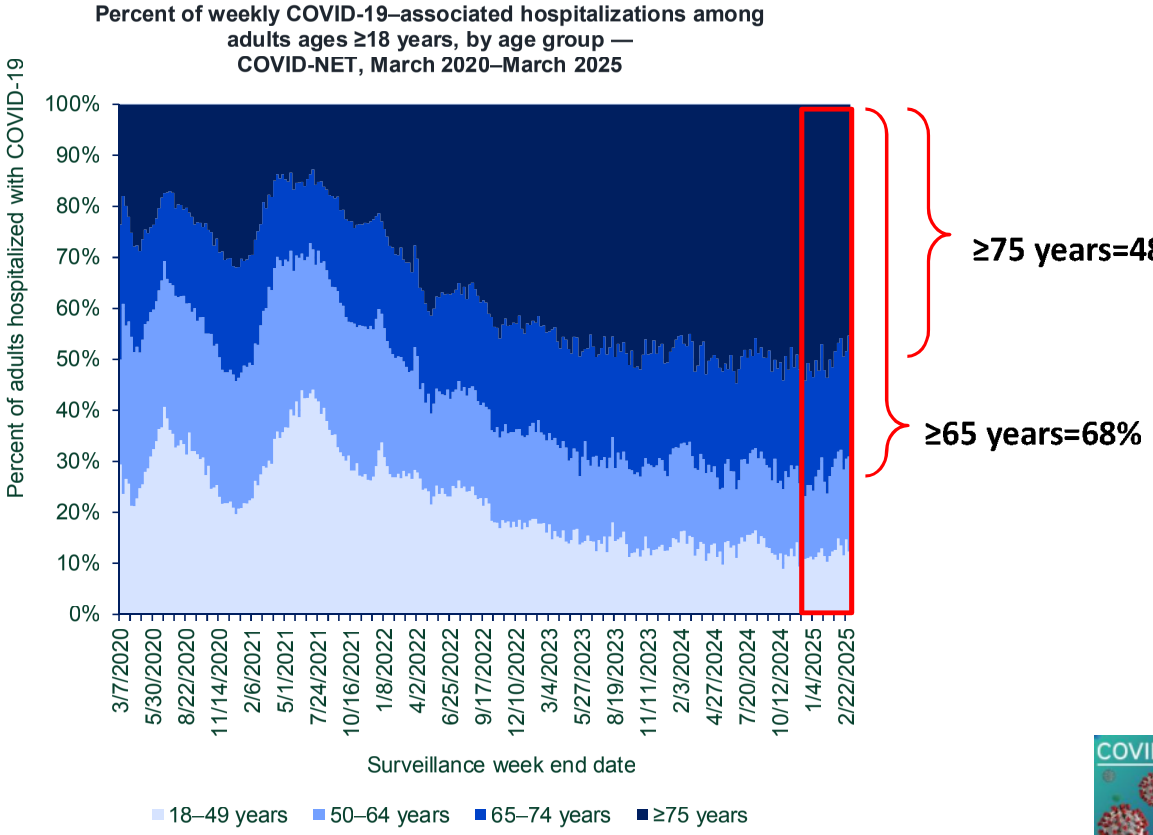


Summary (Children and Adolescents)

- Rates of COVID-19–associated hospitalizations are highest among youngest age groups.
- Among children and adolescents ages 5–17 years, rates of hospitalization are higher for influenza than COVID-19.
- More than half (59%) of children and adolescents hospitalized with COVID-19 had ≥1 underlying medical condition.
  - Proportion of children with ≥1 underlying condition increased with age.
- Most common underlying conditions among children and adolescents hospitalized with COVID-19 varied by age group.
- Fewer than 5% of children and adolescents hospitalized with COVID-19 had received the most recently recommended COVID-19 vaccination during the 23-24 season.

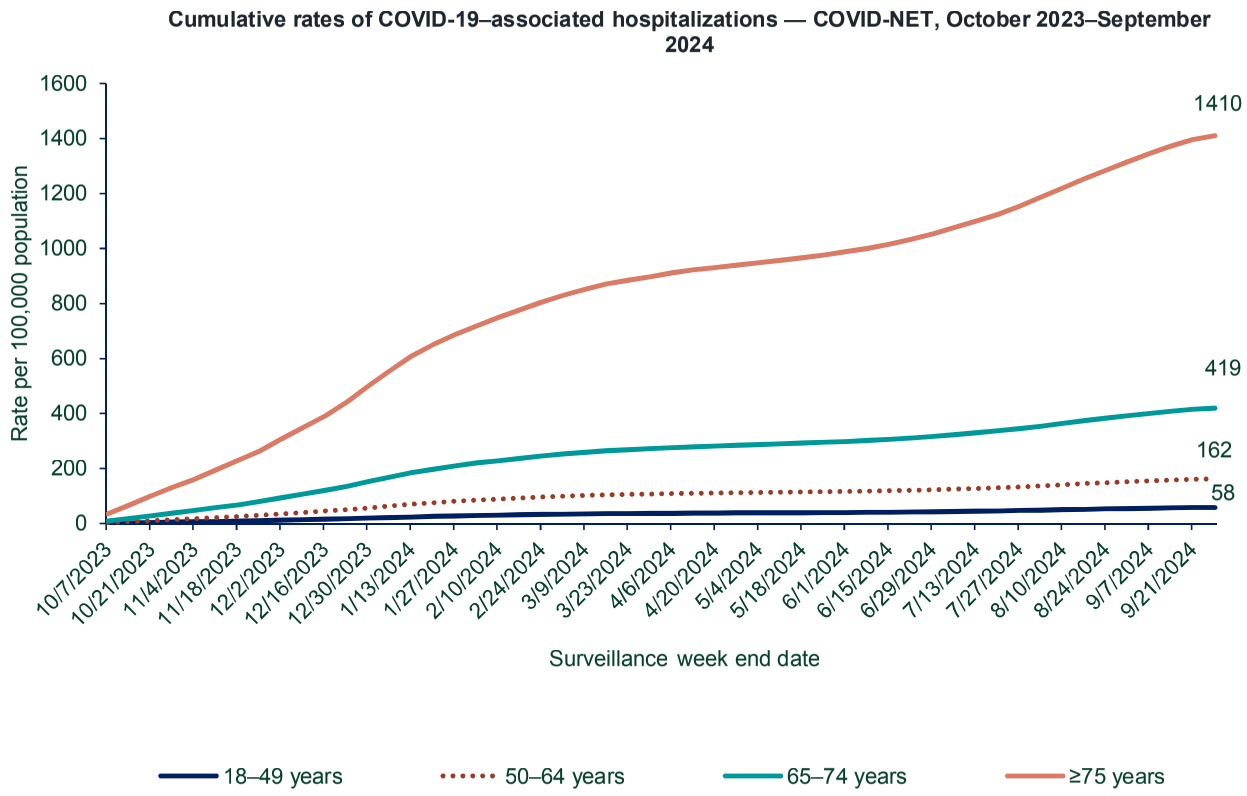
COVID-19–Associated Hospitalizations Among Adults Ages ≥18 Years

Adults ages ≥65 years comprise more than 2/3 of all COVID-19–associated hospitalizations among adults.



During this same period of January 2024 through March 2025, children and adolescents ages 17 years and younger comprised 4% of all COVID-19-associated hospitalizations.

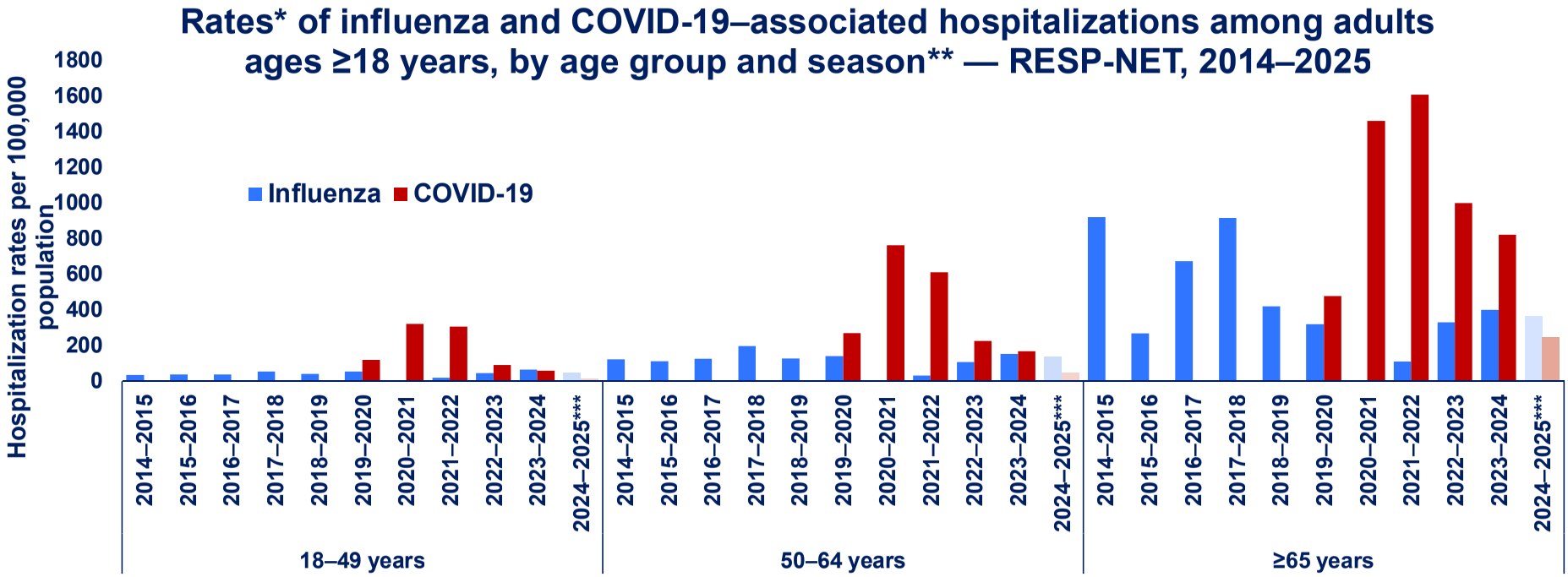
Among adults, rates of COVID-19–associated hospitalizations increase with age.



Age group	Rate ratio of ≥75 years relative to adult age groups
18–49	24.4
50–64	8.7
65–74	3.4

Rates among adults ages ≥75 years are many times higher compared to younger adults.

Among adults ages ≥65 years, rates of COVID-19–associated hospitalization during recent years remained higher than rates of influenza–associated hospitalization.



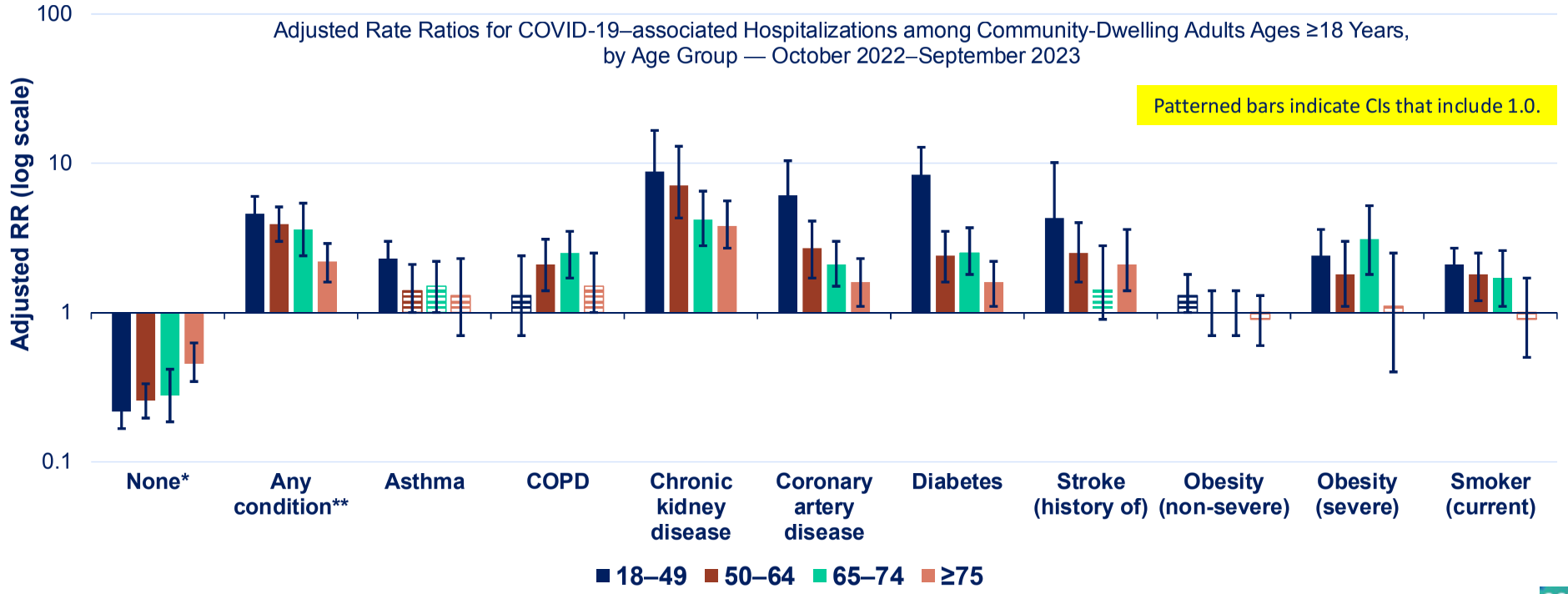
** Note that rates of influenza hospitalization for 2014–2015 through 2023–2024 are adjusted for undertesting and under-detection. Rates of influenza hospitalizations for 2024–2025 (shown in lighter colors) and all COVID-19 hospitalizations are not adjusted for undertesting or under-detection. Rates of hospitalization might be higher when adjusted for these factors.*

*** Monitoring for influenza hospitalizations typically occurs during October through April; for COVID-19 hospitalizations, monitoring begins in October and is conducted year-round. For the 2019–2020 period, monitoring for COVID-19 hospitalizations began in March 2020.*

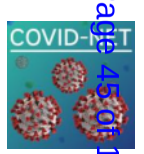
**** Data for 2024-2025 show data for October 2024 – March 2025 only as the season is ongoing.*

Historical flu data from https://www.cdc.gov/flu-burden/php/data-vis/past-seasons.html. Historical flu data are not available for the 2020–2021 period.

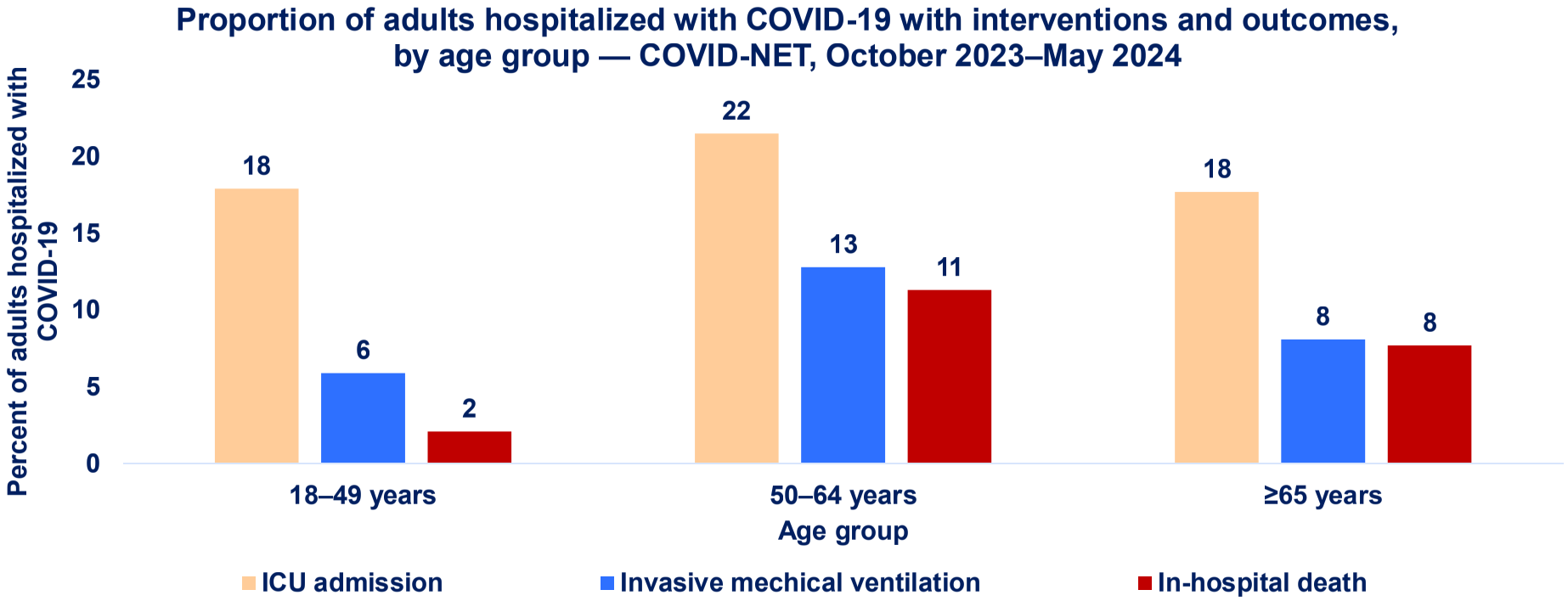
Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



Abbreviations: RR, rate ratio; CI, confidence interval; COPD, chronic obstructive pulmonary disease.
* "None" refers to having none of the conditions examined in this analysis (asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking).
** "Any condition" refers to having at least 1 of these conditions. Notes: Non-severe obesity is defined as BMI 30–39kg/m². Severe obesity is defined as BMI ≥40kg/m². "Any condition" includes asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking. Rate ratios were estimated using multivariable Poisson models adjusted for sex, and race/ethnicity. "Smoker (current)" Includes people who quit smoking within the past 12 months. Data are limited to hospitalizations where COVID-19 is the likely reason for admission.



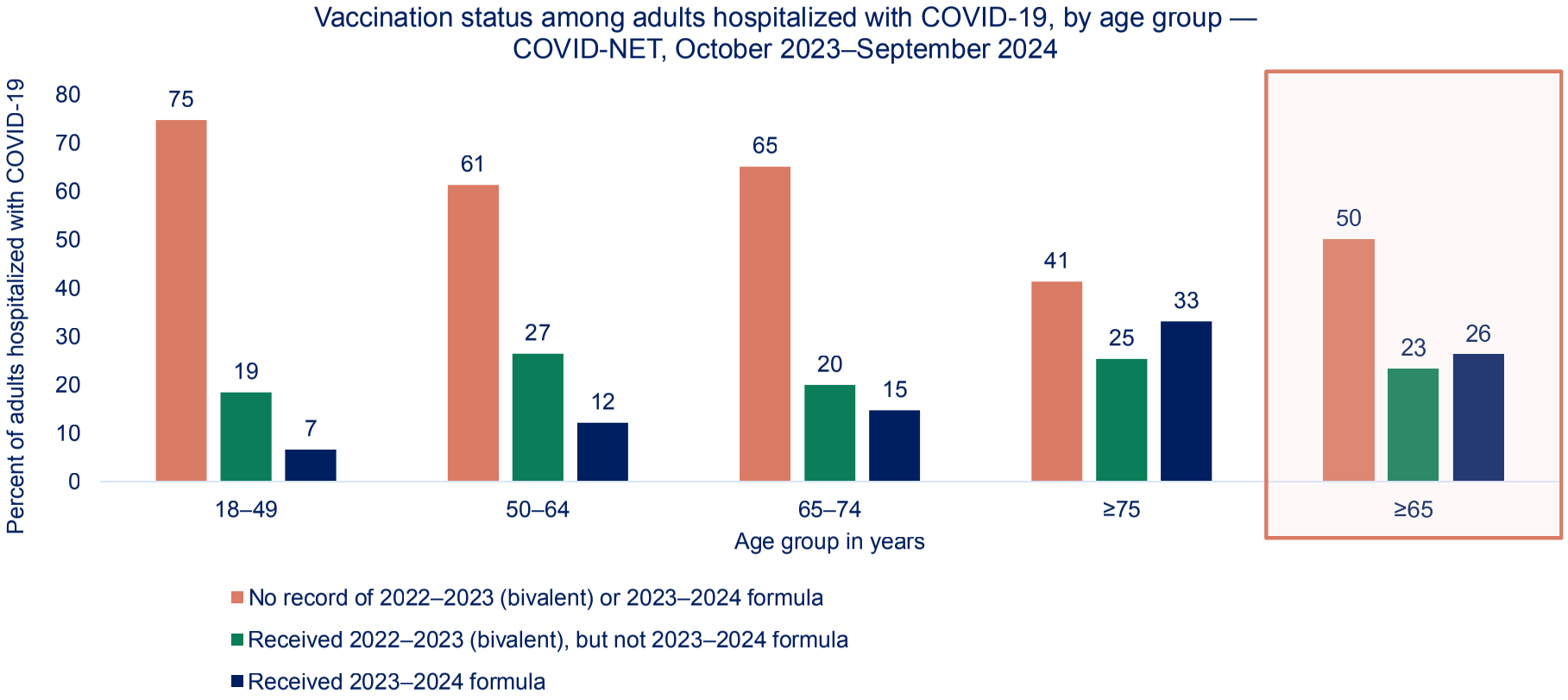
~1 in 5 adults hospitalized due to COVID-19 were admitted to the intensive care unit (ICU)



During this period, 80% of all adults hospitalized with COVID-19 who died in-hospital were ages ≥65 years.

Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission. Deaths do not include other COVID-19-related deaths that might occur after a patient is discharged to hospice or other deaths that occur soon after hospital discharge that could be attributable to COVID-19-related illness.

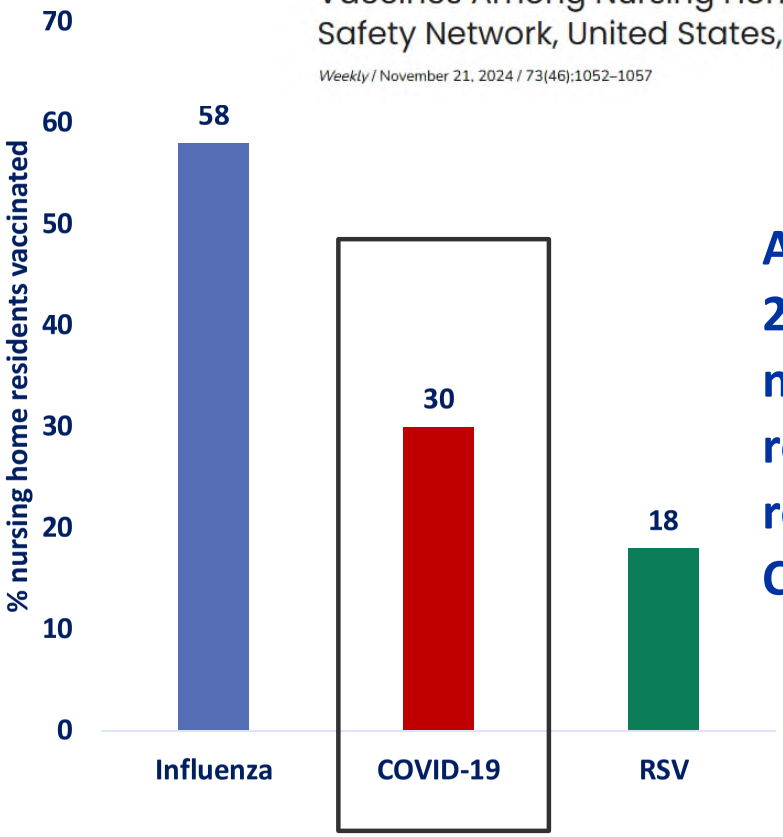
Most adults hospitalized with COVID-19 had received no COVID-19 vaccine since September 2022.



Data are limited to hospitalizations where COVID-19 is a likely primary reason for admission.

Coverage with Influenza, Respiratory Syncytial Virus, and COVID-19 Vaccines Among Nursing Home Residents — National Healthcare Safety Network, United States, November 2024

Weekly / November 21, 2024 / 73(46);1052–1057



As of November 30, 2024, only 30% of nursing home residents had received a 2024–2025 COVID-19 vaccine.

* As of December 10, 2024. Reses et al. "Coverage with Influenza, Respiratory Syncytial Virus, and Updated COVID-19 Vaccines Among Nursing Home Residents - National Healthcare Safety Network, United States, November 2024". *MMWR*, November 21, 2024.

Summary (Adults) (slide 1 of 2)

- Rates of COVID-19–associated hospitalizations are highest among oldest adult age groups.
- Adults aged ≥65 years comprise 68% of adult COVID-19–associated hospitalizations
  - Aged ≥75 years: 48% of adult hospitalizations
- COVID-19-associated hospitalization rates decreased over time, but cumulative rates among adults aged ≥75 years for the 2023-2024 season remained higher than those experienced by any other adult age group for any previous season.
- Risk of hospitalization with COVID-19 remains during summer months (May–Sept).
- 26% of adults ages ≥65 years hospitalized with COVID-19 received the recommended 2023-24 COVID-19 vaccine prior to hospitalization.

Summary (Adults) (slide 2 of 2)

- Some underlying medical conditions increase the risk for COVID-19 hospitalization among adults
  - CKD, diabetes, and CAD increased risk in all adult age groups
- Having none of the underlying medical conditions examined decreased the risk for COVID-19–associated hospitalization across all adult age groups.
- In general, the relative risk of COVID-19 hospitalization among adults with vs. without select conditions declined with age for most, but not all, conditions examined.

Abbreviations: CKD: chronic kidney disease; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease.

EXHIBIT D

ACIP COVID-19 Vaccines Work Group

Robert Schechter, MD, MSc
COVID-19 ACIP Work Group Chair

Advisory Committee on Immunization Practices Meeting

April 15, 2025

2024–2025 COVID-19 vaccines

- In August 2024, the Food and Drug Administration authorized and approved:
  - Moderna COVID-19 vaccine* in persons ≥6 months
  - Novavax COVID-19 vaccine** in persons ≥12 years
  - Pfizer-BioNTech COVID-19 vaccine* in persons ≥6 months

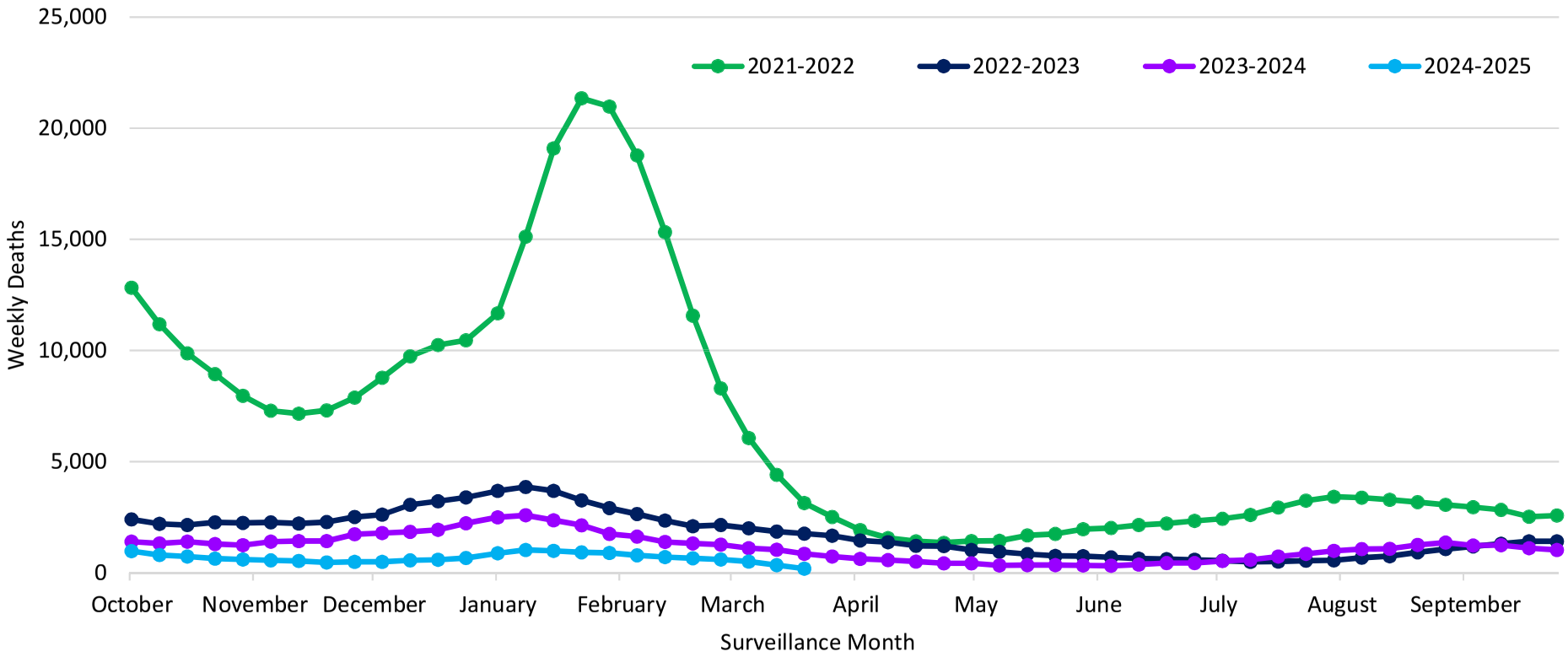
*Omicron JN.1 lineage, KP.2 strain
**Omicron JN.1 lineage, JN.1 strain

2024–2025 COVID-19 vaccine recommendations

- Everyone aged ≥6 months should receive 2024–2025 COVID-19 vaccination
  - Children aged 6 months–4 years need multiple doses of COVID-19 vaccines to be up to date, including at least 1 dose of 2024–2025 COVID-19 vaccine
  - People aged 5-64 years should get 1 dose[1] of 2024-2025 COVID-19 vaccine
  - People who are ≥65 years[2] and people ≥6 months of age with moderate or severe immunocompromise[3] should receive a second dose of 2024–2025 COVID-19 vaccine 6 months after their first 2024–2025 dose (minimum interval of 2 months)
  - People with moderate or severe immunocompromise may receive additional doses of 2024–2025 COVID-19 vaccines under shared clinical decision-making (minimum interval of 2 months)

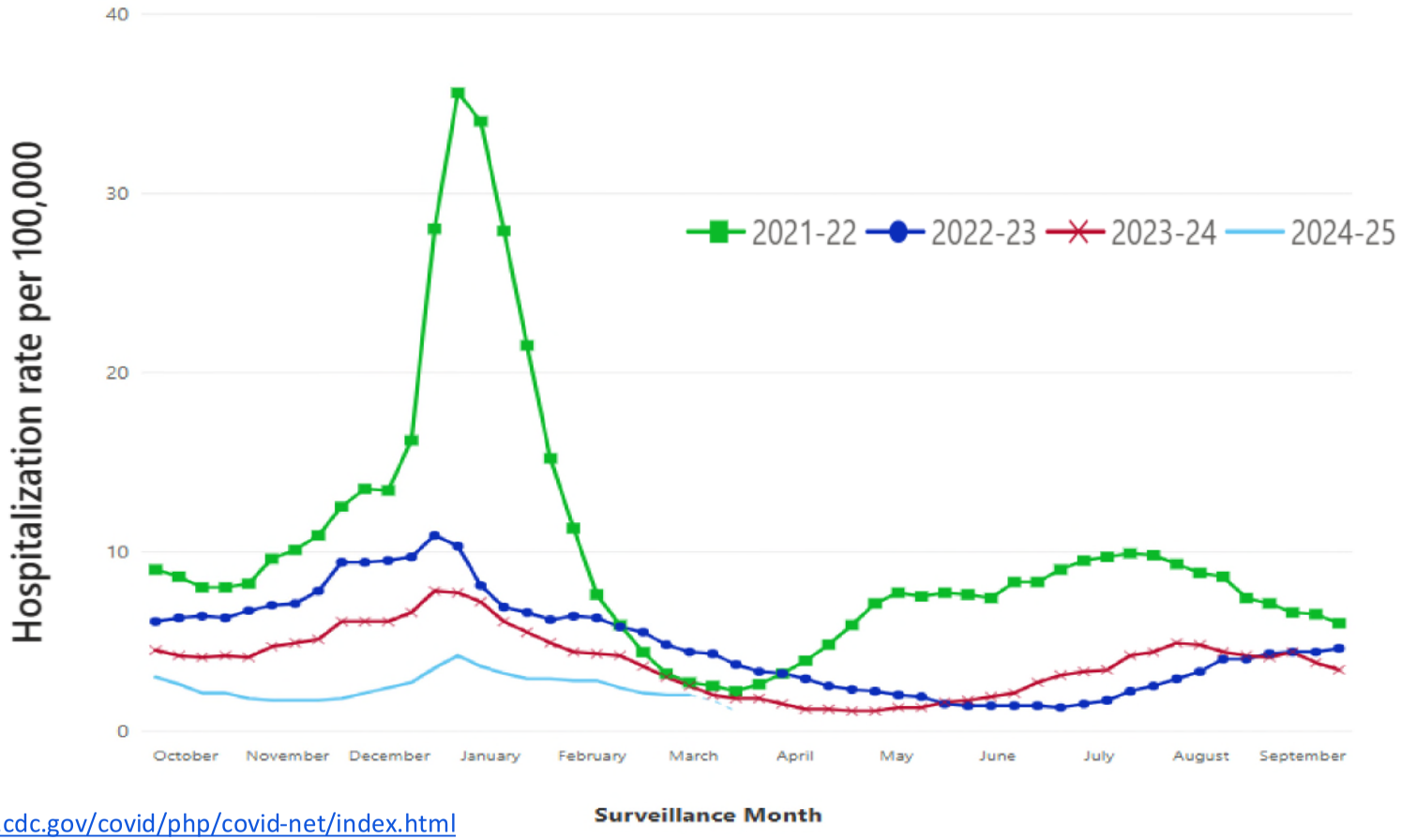
1. People who are unvaccinated and receive Novavax COVID-19 vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine
2. People who are unvaccinated and receive Novavax COVID-19 vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months (minimum interval 2 months) after the second dose.
3. If previously unvaccinated or receiving initial vaccination series, at least 2 doses of 2024–2025 vaccine are recommended, and depending on vaccination history more may be needed. This additional 2024–2025 vaccine dose is recommended 6 months (minimum interval 2 months) after completion of initial vaccination series.

Provisional Weekly COVID-19 Deaths in the United States Reported to CDC, by Week October 2021–March 2025



https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00
Accessed April 4, 2025

Weekly rates of COVID-19 associated hospitalizations by season – COVID-NET



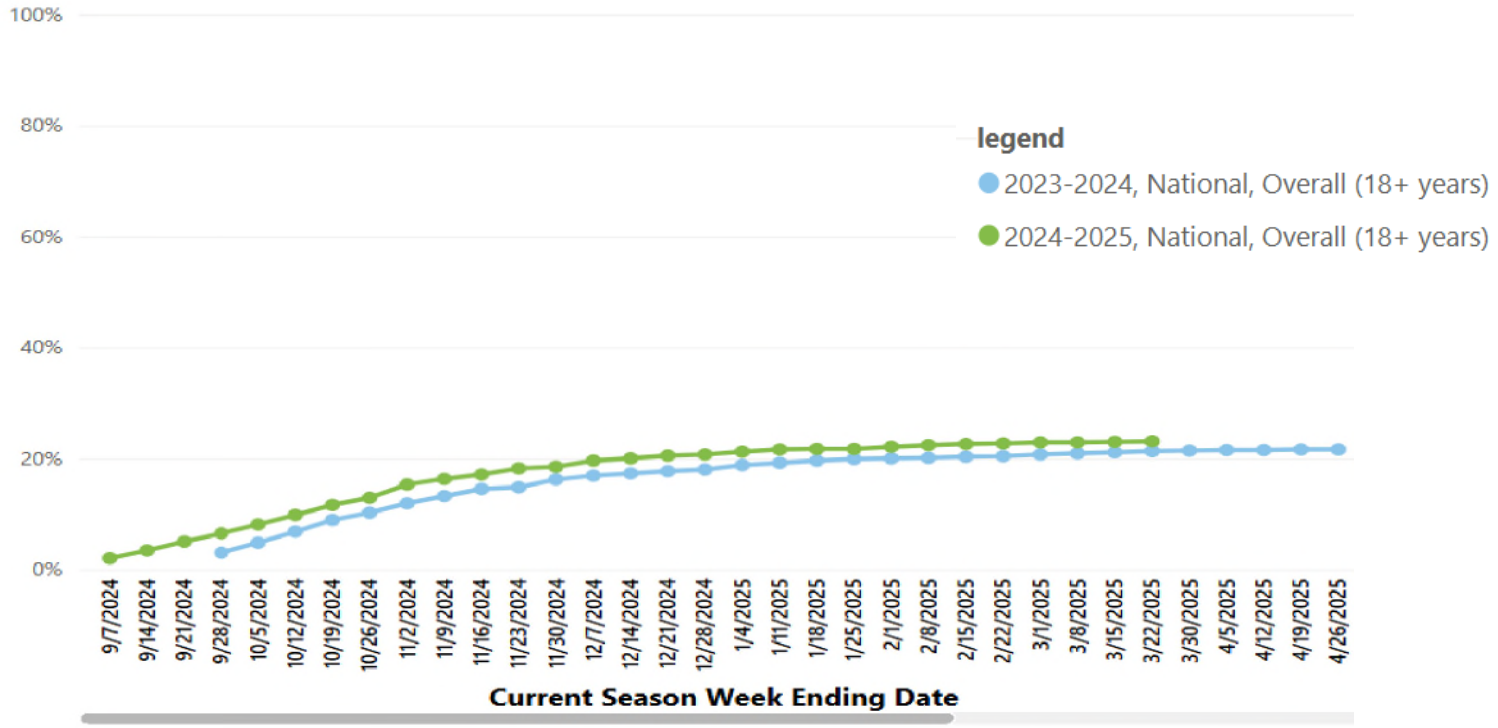
https://www.cdc.gov/covid/php/covid-net/index.html
Accessed April 4, 2025

Preliminary Estimates of Disease Burden, October 1, 2024 through March 22, 2025

Disease	Illnesses	Outpatient Visits	Hospitalizations	Deaths
COVID-19[1]	7.7 – 13.5 Million	1.9 – 3.2 Million	220,000 – 370,000	26,000 – 43,000
Influenza[2]	44 – 76 Million	20 – 34 Million	580,000 – 1.2 Million	25,000 – 120,000

1 https://www.cdc.gov/covid/php/surveillance/burden-estimates.html
2 https://www.cdc.gov/flu-burden/php/data-vis/2024-2025.html
Accessed April 4, 2025

COVID-19 vaccination coverage among adults 18 years and older, 2023–2024 through 2024–2025



Current season week ending date refers to the 2024-2025 season only. For the 2023-2024 season, the corresponding week is represented.
2024-2025 vaccines were available starting August 22, 2024. 2023-2024 vaccines were available starting September 12, 2023.
https://www.cdc.gov/covidvaxview/weekly-dashboard/adult-vaccination-coverage.html
Accessed April 4, 2025

ACIP COVID-19 Work Group Meeting Review November 2024 – April 2025

- **Considerations for a risk-based and universal vaccine recommendation for the 2025–2026 COVID-19 vaccines**

- COVID-NET data for those with and without risk factors
- COVID-19 mortality
- COVID-19 vaccine hesitancy and uptake
- COVID-19 vaccine safety and effectiveness
- Moderna mRNA-1283 COVID-19 vaccine candidate
- Seroprevalence of SARS-CoV-2
- Post-COVID conditions (Long COVID)
- Multisystem Inflammatory Syndrome in Children (MIS-C)
- Feedback from liaison organizations

Agenda: April 15, 2025

Introduction	**Dr. Robert Schechter (ACIP, WG Chair)**
Moderna mRNA-1283 COVID-19 vaccine candidate	**Dr. Bishoy Rizkalla**
Epidemiology and risk factors for COVID-19 hospitalizations	**Dr. Fiona Havers**
Vaccine effectiveness update	**Dr. Ruth Link-Gelles**
Work Group Considerations for use of 2025–2026 COVID-19 vaccines	**Dr. Lakshmi Panagiotakopoulos**

Preliminary Timeline, 2025–2026 COVID-19 Vaccines

- **Today's meeting:** Update on ongoing review of considerations for use of 2025–2026 COVID-19 vaccines
- **Spring**: Anticipated FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to discuss and make recommendations on strain selection for 2025–2026 COVID-19 vaccines
- **June ACIP meeting**: Discussion and vote on recommended use of the 2025–2026 vaccine
- **Late summer/early fall**: Anticipated 2025–2026 COVID-19 vaccine availability

Work Group members

ACIP members

- Robert Schechter (chair)
- Noel Brewer
- Oliver Brooks
- George Kuchel
- Keipp Talbot

Ex-officio/government members

- BARDA: Christine Oshansky
- CDC: Alan Lam
- FDA: Adam Spanier, Rachel Zhang
- IHS: Uzo Chukwuma
- NIH: Chris Roberts

CDC co-Leads

- Lakshmi Panagiotakopoulos
- Lauren Roper

Liaisons

- AAFP: Jonathan Temte
- AAP: Sean O'Leary
- ACOG: Naima Joseph, Laura Riley (alternate)
- ACP: Jason Goldman
- AGS: Ken Schmader
- AIM: Heather Roth
- AMA: Sandra Fryhofer
- ANA: Ruth Francis
- APhA: Richard Dang
- ASTHO: Marcus Plescia
- CSTE: Paul Cieslak, Christine Hahn
- IDSA: James McAuley
- NACCHO: Matt Zahn

Liaisons, cont'd

- NACI: Eva Wong, Matthew Tunis (alternate)
- NFID: Robert Hopkins, Bill Schaffner (alternate)
- SHEA: Preeti Mehrotra, Marci Drees (alternate)

Consultants

- Ed Belongia
- Hank Bernstein
- Matthew Daley
- Lisa Jackson
- Jennifer Nelson
- Stanley Perlman
- Peter Szilagyi

CDC participants

- Amadea Britton
- Mary Chamberland
- Fatimah Dawood
- Nicole Dowling
- Jonathan Duffy
- Kristen Folsom
- Molly Gaines-McCollom
- Julianne Gee
- Monica Godfrey
- Susan Goldstein
- Lisa Grohskopf
- Demorah Hayes
- Suzanne Heitfeld
- Michele Hlavsa
- Jefferson Jones
- Ruth Link-Gelles
- Jessica MacNeil
- Josephine Mak
- Seth Abram Meador
- Michael Melgar
- Sarah Meyer
- Noelle-Angelique Molinari
- Danielle Moulia
- Ismael Ortega-Sanchez
- Manisha Patel
- Pragna Patel
- Amanda Payne
- Jamison Pike
- Hannah Rosenblum
- Sierra Scarbrough
- John Su
- Diya Surie
- Natalie Thornburg
- Melinda Wharton
- Trang Wisard
- JoEllen Wolicki

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

EXHIBIT E

Interim Estimates of 2024-2025 COVID-19 Vaccine Effectiveness

Ruth Link-Gelles, PhD, MPH

CDR, US Public Health Service

Coronavirus and Other Respiratory Viruses Division

Centers for Disease Control and Prevention

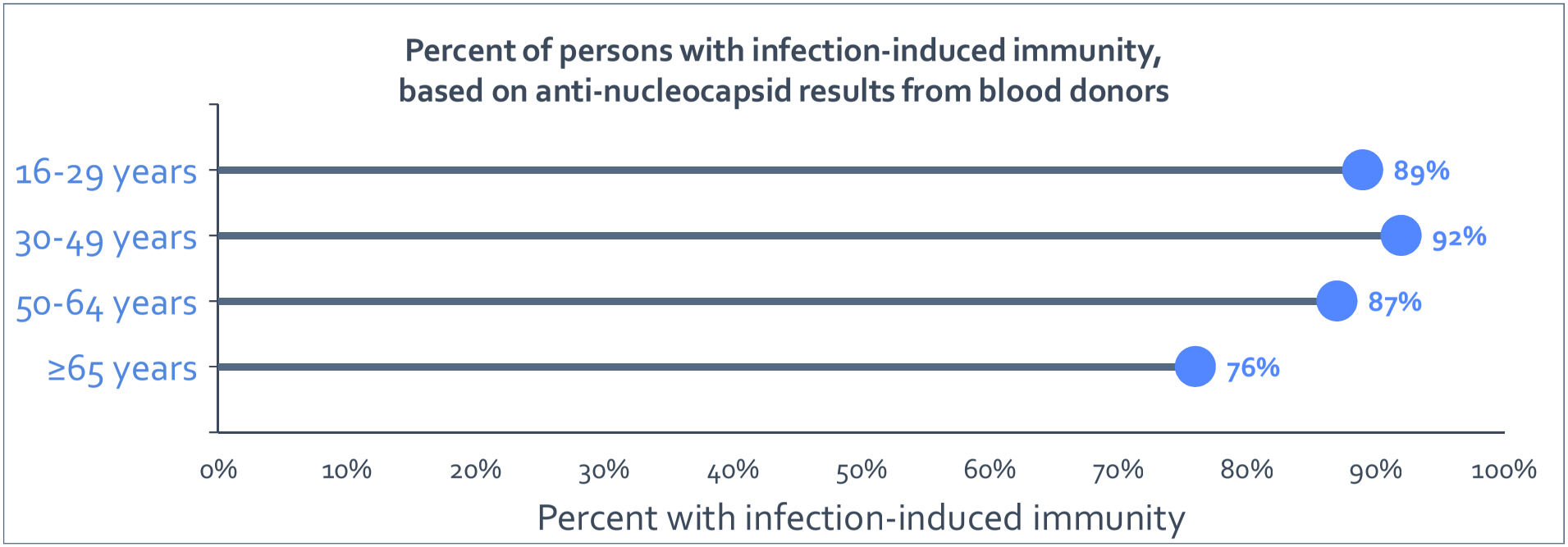
April 15, 2025

Agenda – COVID-19 vaccine effectiveness (VE)

- Context for interpretation of VE
- 2024-2025 COVID-19 vaccine coverage
- Vaccine effectiveness methods
- Interim 2024-2025 COVID-19 vaccine effectiveness

Context for interpreting COVID-19 VE across age groups: high infection-induced seroprevalence by end of 2023

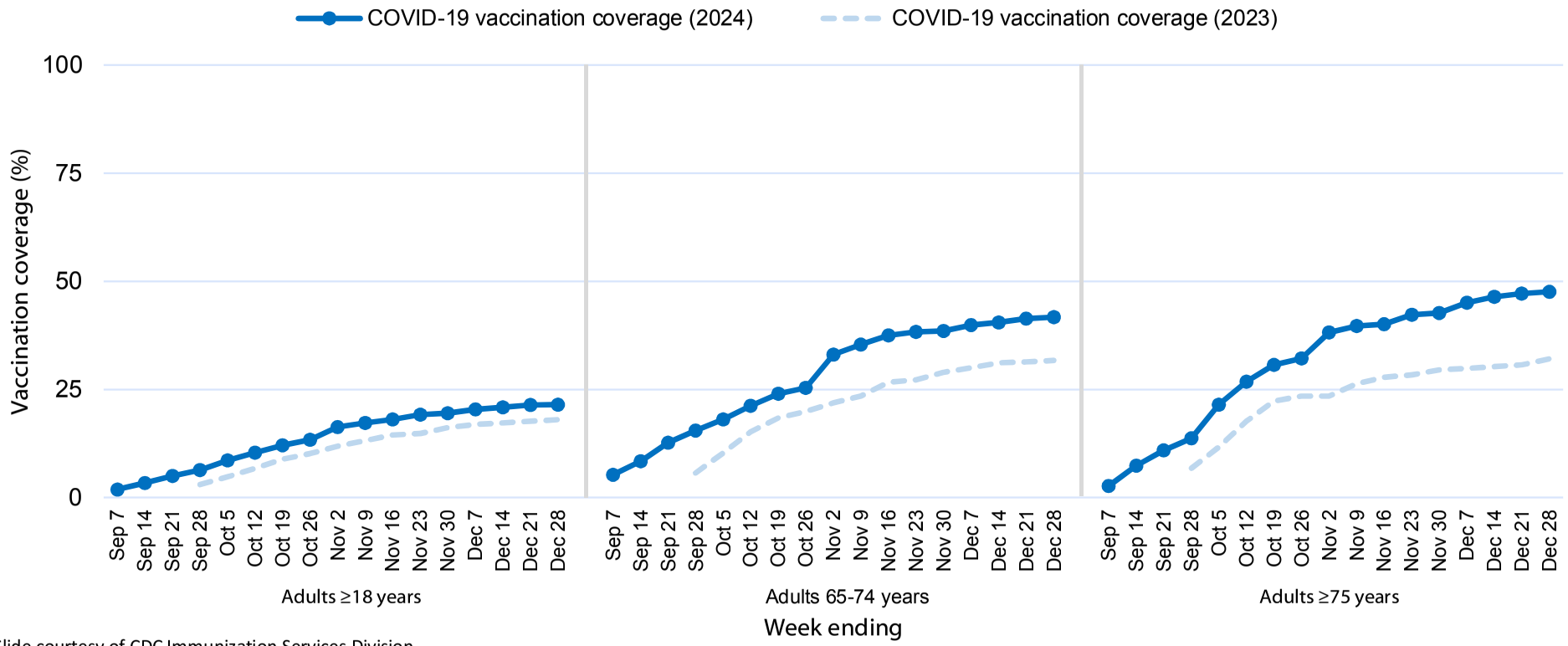
- High rates of SARS-CoV-2 infection-induced immunity by October – December 2023.*



VE findings should be interpreted as the added benefit provided by COVID-19 vaccination in a population with a high prevalence of vaccine- and infection-induced immunity.

* Data on persons aged ≥16 years from a longitudinal, national cohort of ~35,000 blood donors.
Methods and data available at: https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022

COVID-19 Vaccination Coverage Among Adults ≥18 Years, 65-74 Years, and ≥75 Years, 2023 and 2024, NIS-ACM



Slide courtesy of CDC Immunization Services Division.

National Immunization Survey-Adult COVID Module: Data from adults age ≥18 years are collected by telephone interview using a random-digit-dialed sample of cell telephone numbers stratified by state, the District of Columbia, five local jurisdictions (Bexar County TX, Chicago IL, Houston TX, New York City NY, and Philadelphia County PA), and Puerto Rico and the U.S. Virgin Islands. Data are weighted to represent the non-institutionalized U.S. population and mitigate possible bias that can result from an incomplete sample frame (exclusion of households with no phone service or only landline telephones) or non-response. All responses are self-reported. For more information about the survey, see https://www.cdc.gov/nis/about/index.html.

Methods

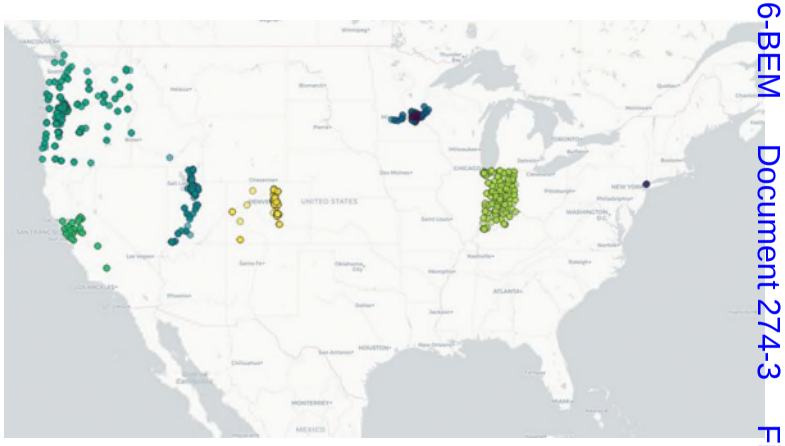
Measuring COVID-19 vaccine effectiveness

Measure	Definition	Example vaccinated group	Example comparison group
Absolute VE	Compares frequency of health outcomes in vaccinated and unvaccinated people	Received **original monovalent COVID-19 vaccine**	Received no COVID-19 vaccines ever
Relative VE	Compares frequency of health outcomes in people who received one type of vaccine to people who received a different vaccine	Received **bivalent COVID-19 vaccine**	Eligible for, but did not receive, bivalent COVID-19 vaccine, but received **original monovalent COVID-19 vaccine**
VE of 2024-2025 COVID-19 vaccines*	Compares people who received **2024-2025** COVID-19 vaccine to people who did not, regardless of past vaccination	Received **2024-25 dose**	Eligible for, but did not receive, an **2024-25 dose**, regardless of past vaccination history

*Vaccine effectiveness was also measured this way for 2023-2024 COVID-19 vaccines

VISION Multi-Site Network of Electronic Health Records

>300 emergency departments and urgent cares and >200 hospitals



- **Design:** Test-negative design
- **Population:** Adults ≥18 years visiting a participating emergency department or urgent care (ED/UC) or hospitalized with COVID-19-like illness (CLI) with a SARS-CoV-2 NAAT test result within 10 days before or 72 hours after encounter
  - **Cases**: CLI with *positive* NAAT or antigen for SARS-CoV-2 and no positive NAAT for RSV or influenza
  - **Controls**: CLI with *negative* NAAT for SARS-CoV-2 and no positive NAAT for influenza (≥18 years) or RSV (≥60 years)
- **Vaccination data:** Documented by electronic health records and state and city registries

CLI = COVID-19-like illness; ED/UC = emergency department/urgent care; RSV = respiratory syncytial virus; NAAT = nucleic acid amplification test
CLI is defined based on the presence of specific discharge diagnosis codes. Link-Gelles, et al. In press, MMWR.

IVY Network — 26 hospitals, 20 U.S. States

- **Design**: Test-negative, case-control design
- **Population**: Adults aged ≥65 years hospitalized with COVID-like illness (CLI)* and SARS-CoV-2 test results within 10 days of illness onset and 3 days of admission
  - **Cases:** CLI and test *positive* for SARS-CoV-2 by NAAT or antigen
  - **Controls**: CLI and test *negative* for SARS-CoV-2, influenza and RSV by RT-PCR
- **Vaccination data:** Electronic medical records (EMR), state and city registries, and plausible self-report
- **Specimens:** Nasal swabs obtained on all patients for central RT-PCR testing and whole genome sequencing

IVY

INVESTIGATING RESPIRATORY VIRUSES IN THE ACUTELY ILL

*CLI is defined as presence of any one of the following: fever, cough, shortness of breath, chest imaging consistent with pneumonia, or hypoxemia
NAAT = nucleic acid amplification test

Interim Estimates of 2024-2025 COVID-19 Vaccine Effectiveness

Characteristics of emergency department and urgent care encounters and hospitalizations among adults aged ≥18 years with COVID-19-like illness, by COVID-19 case status and CDC vaccine effectiveness network — VISION and IVY Networks

September 2024–January 2025

Characteristic	Vaccine effectiveness network and setting, no. (column %)								
	VISION ED/UC encounters, all adults aged ≥18 years			VISION hospitalizations, all adults aged ≥65 years			IVY hospitalizations, immunocompetent adults aged ≥65 years		
	Total	COVID-19 case-patients	COVID-19 control-patients	Total	COVID-19 case-patients	COVID-19 control-patients	Total	COVID-19 case-patients	COVID-19 control-patients
Total	**137,543**	**10,459**	**127,084**	**34,411**	**2,846**	**31,565**	**1,929**	**683**	**1,246**
Median age	53 [34, 72]	58 [37, 74]	53 [34, 71]	78 [72, 84]	79 [73, 86]	78 [71, 84]	77 [71, 84]	78 [72, 85]	76 [70, 83]
Age group									
18-64 years	88,858 (65)	6,113 (58)	82,745 (65)	--	--	--	--	--	
≥65 years	48,685 (35)	4,346 (42)	44,339 (35)	34,411 (100)	2,846 (100)	31,565 (100)	1,929 (100)	683 (100)	1,246 (100)
Immunocompromised*	--	--	--	8,192 (24)	598 (21)	7,594 (24)	--	--	

Link-Gelles, et al. MMWR: https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm

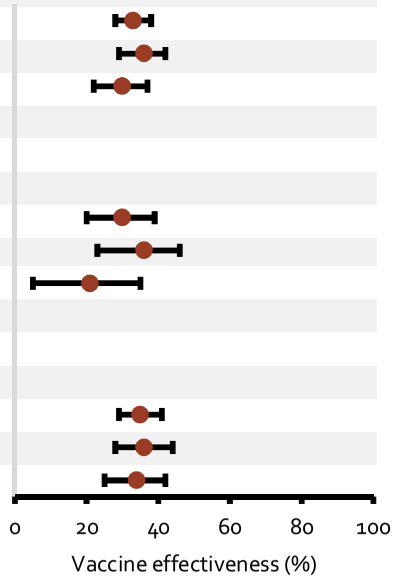
ED/UC = emergency department/urgent care

* Immunocompromised status is not evaluated for ED/UC encounters due to a higher likelihood of incomplete discharge diagnosis codes in this setting.

Effectiveness of 2024–2025 COVID-19 vaccination against COVID-19–associated emergency department/urgent care encounters by age group — VISION Network

September 2024 – January 2025

Age group/2024-2025 COVID-19 vaccination status/days since dose	COVID-19 case-patients N (Col %)	COVID-19 control-patients N (Col %)	Median interval since last dose among vaccinated*, days (IQR)	Adjusted vaccine effectiveness (95% CI)
≥18 years				
No **2024-2025 COVID-19 dose** (Ref)	9,545 (91)	108,972 (86)	998 (539-1,142)	**Ref**
Received **2024-2025 COVID-19 dose** 7–119 days earlier	914 (9)	18,112 (14)	55 (32-80)	**33 (28-38)**
2024-2025 COVID-19 dose, 7–59 days earlier	480 (5)	9,789 (8)	33 (20-46)	**36 (29-42)**
2024-2025 COVID-19 dose, 60–119 days earlier	434 (4)	8,323 (7)	82 (71-97)	**30 (22-37)**
18-64 years				
No **2024-2025 COVID-19 dose** (Ref)	5,860 (96)	76,792 (93)	1,042 (751-1,180)	**Ref**
Received **2024-2025 COVID-19 dose** 7–119 days earlier	253 (4)	5,953 (7)	53 (29-77)	**30 (20-39)**
2024-2025 COVID-19 dose, 7–59 days earlier	134 (2)	3,379 (4)	32 (20-45)	**36 (23-46)**
2024-2025 COVID-19 dose, 60–119 days earlier	119 (2)	2,574 (3)	81 (70-95)	**21 (5-35)**
≥65 years				
No **2024-2025 COVID-19 dose** (Ref)	3,685 (85)	32,180 (73)	750 (346-1,076)	**Ref**
Received **2024-2025 COVID-19 dose** 7–119 days earlier	661 (15)	12,159 (27)	57 (33-82)	**35 (29-41)**
2024-2025 COVID-19 dose, 7–59 days earlier	346 (8)	6,410 (14)	34 (21-47)	**36 (28-44)**
2024-2025 COVID-19 dose, 60–119 days earlier	315 (7)	5,749 (13)	83 (71-97)	**34 (25-42)**



Link-Gelles, et al. MMWR: https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm

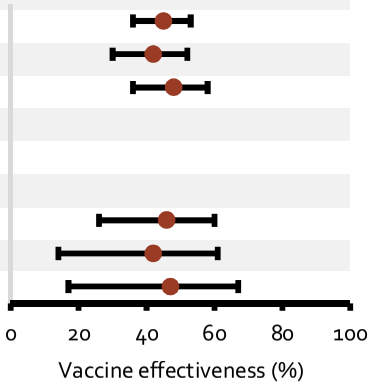
Vaccine effectiveness was calculated by comparing the odds of 2024–2025 COVID-19 vaccination in case-patients and control-patients using the equation: (1 – adjusted odds ratio) x 100%. Odds ratios were estimated by multivariable logistic regression. The odds ratio was adjusted for age, sex, race and ethnicity, calendar day, and geographic region. The "no 2024–2025 dose" group included all eligible persons who did not receive a 2024–2025 COVID-19 vaccine dose, regardless of number of previous COVID-19 vaccine doses (if any) received.

* Time since vaccination is for most recent dose, which could have been an original monovalent, bivalent, 2023-2024, or 2024-2025 COVID-19 vaccine.

Effectiveness of 2024–2025 COVID-19 vaccination against COVID-19–associated hospitalization among immunocompetent adults aged ≥65 years — VISION and IVY Networks

September 2024 – January 2025

Age group/2024-2025 COVID-19 vaccination status/days since dose	COVID-19 case-patients N (Col %)	COVID-19 control-patients N (Col %)	Median interval since last dose among vaccinated*, days (IQR)	Adjusted vaccine effectiveness (95% CI)
VISION				
No 2024-2025 COVID-19 dose (Ref)	2,016 (90)	19,198 (80)	775 (357-1,084)	**Ref**
Received 2024-2025 COVID-19 dose 7–119 days earlier	232 (10)	4,773 (20)	53 (30-77)	**45 (36-53)**
2024-2025 COVID-19 dose, 7–59 days earlier	129 (6)	2,759 (12)	33 (20-46)	**42 (30-52)**
2024-2025 COVID-19 dose, 60–119 days earlier	103 (5)	2,014 (8)	81 (70-94)	**48 (36-58)**
IVY				
No 2024-2025 COVID-19 dose (Ref)	614 (90)	1,021 (82)	Not available	**Ref**
Received 2024-2025 COVID-19 dose 7–119 days earlier	69 (10)	225 (18)	60 (31–85)	**46 (26-60)**
2024-2025 COVID-19 dose, 7–59 days earlier	41 (6)	105 (9)	31 (20–45)	**42 (14-61)**
2024-2025 COVID-19 dose, 60–119 days earlier	28 (4)	120 (11)	85 (72–98)	**47 (17-67)**



Link-Gelles, et al. MMWR: https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm

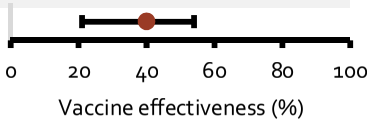
Vaccine effectiveness was calculated by comparing the odds of 2024–2025 COVID-19 vaccination in case-patients and control-patients using the equation: (1 – adjusted odds ratio) x 100%. Odds ratios were estimated by multivariable logistic regression. For VISION, the odds ratio was adjusted for age, sex, race and ethnicity, calendar day, and geographic region. For IVY, the odds ratio was adjusted for age, sex, race and ethnicity, geographic region (U.S. Department of Health and Human Services Region) and calendar time (biweekly intervals). The "no 2024–2025 dose" group included all eligible persons who did not receive a 2024–2025 COVID-19 vaccine dose, regardless of number of previous COVID-19 vaccine doses.

*Time since vaccination is for most recent dose, which could have been an original monovalent, bivalent, 2023-2024, or 2024-2025 COVID-19 vaccine.

Effectiveness of 2024–2025 COVID-19 vaccination against COVID-19–associated hospitalization among immunocompromised adults aged ≥65 years — VISION

September 2024 – January 2025

2024-2025 COVID-19 vaccination status/days since dose	COVID-19 case-patients N (Col %)	COVID-19 control-patients N (Col %)	Median interval since last dose among vaccinated, days (IQR)	Adjusted VE (95% CI)
VISION				
No 2024-2025 COVID-19 dose (Ref)	524 (88)	5,885 (78)	720 (343-1,064)	Ref
Received 2024-2025 COVID-19 dose 7–119 days earlier	74 (12)	1,709 (22)	53 (31-78)	40 (21-54)



Link-Gelles, et al. MMWR: https://www.cdc.gov/mmwr/volumes/74/wr/mm7406a1.htm

Vaccine effectiveness was calculated by comparing the odds of 2024–2025 COVID-19 vaccination in case-patients and control-patients using the equation: (1 – adjusted odds ratio) x 100%. Odds ratios were estimated by multivariable logistic regression. For VISION, the odds ratio was adjusted for age, sex, race and ethnicity, calendar day, and geographic region. The "no 2024–2025 dose" group included all eligible persons who did not receive a 2024–2025 COVID-19 vaccine dose, regardless of number of previous COVID-19 vaccine doses (if any) received.

* Time since vaccination is for most recent dose, which could have been an original monovalent, bivalent, 2023-2024, or 2024-2025 COVID-19 vaccine.

Conclusions: effectiveness of 2024-2025 COVID-19 vaccines

- **2024-2025 COVID-19 vaccination provided additional protection against COVID-19-associated emergency department and urgent care visits and hospitalizations compared to no 2024-2025 vaccine dose.**
- **2024-2025 COVID-19 vaccination also provided additional protection against COVID-19-associated hospitalizations among adults aged ≥65 years with immunocompromising conditions.**
- **VE should be interpreted as the added benefit of 2024–2025 COVID-19 vaccination in a population with high levels of infection-induced immunity, vaccine-induced immunity, or both.**
  - Prior SARS-CoV-2 infection contributes protection against future disease, though protection wanes over time.
  - An increase in SARS-CoV-2 circulation in the United States during late summer 2024, just before the 2024–2025 COVID-19 vaccines were approved and authorized, may have resulted in higher population-level immunity against JN.1-lineage strains, which could have resulted in lower measured VE than in a population with less recent infection.

Acknowledgements

CDC
Amanda B. Payne
Lakshmi Panagiotakopoulos
Lauren Roper
Diya Surie

Amadea Britton
Allison Ciesla
Fatimah Dawood
Jennifer DeCuir
Shikha Garg
Amber Kautz
Nathaniel M. Lewis
Josephine Mak
Morgan Najdowski
Caitlin Ray
Emily Reeves
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Intermountain Health
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Kaiser Permanente Center for Health Research
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Kaiser Permanente Northern California
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Regenstrief
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Kevin W. Gibbs
David N. Hager
Matthew E. Prekker
Amira Mohamed
Nicholas Johnson
Jay S. Steingrub
Akram Khan
Jamie R. Felzer
Abhijit Duggal
Jennifer G. Wilson
Nida Qadir
Christopher Mallow
Jennie H. Kwon
Cristie Columbus
Ivana A. Vaughn
Basmah Safdar

Jarrod M. Mosier
Estelle S. Harris
James D. Chappell
Natasha Halasa
Cassandra Johnson

+ many more!

EXHIBIT F

Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations

Lakshmi Panagiotakopoulos, MD, MPH

Advisory Committee on Immunization Practices

April 15, 2025

Overview

- Current recommendations for 2024–2025 COVID-19 vaccines
- Policy options for 2025–2026 COVID-19 vaccine recommendations
- Supporting data and Work Group interpretations
- Discussion questions for committee

COVID-19 vaccine: ACIP Meeting Schedule

October 2024

- Additional dose of 2024-2025 COVID-19 vaccines in adults ages ≥65 years
- Additional dose(s) of 2024-2025 COVID-19 vaccines in moderately to severely immunocompromised persons ages ≥6 months

April 2025

- **Moderna mRNA-1283 COVID-19 vaccine**
- **Epidemiology and risk factors for COVID-19 hospitalizations**
- **Vaccine effectiveness update**
- **Work Group Considerations**
- **No vote scheduled**

June 2025 (proposed)

- **Vote on 2025–2026 COVID-19 vaccine recommendations (including additional dose recommendations)**

Review of 2024–2025 COVID-19 vaccine policy

Overview of the current COVID-19 vaccination schedule: *Routine vaccination*

- **Children ages 6 months–4 years**
  - Unvaccinated: Should receive a multidose initial series with a 2024–2025 mRNA vaccine
  - Previously completed an initial series: Should receive 1 dose of a 2024–2025 mRNA vaccine from the same manufacturer as the initial series
- **People ages 5–64 years:**
  - Should receive 1 dose of an age-appropriate 2024–2025 COVID-19 vaccine*
- **People ages 65 years and older:**
  - Should receive 2 doses of any 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)**

*People ages 12–64 years who are unvaccinated and receive the 2024–2025 Novavax COVID-19 vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine.
**People ages 65 years and older who are unvaccinated and receive Novavax COVID-19 Vaccine for initial vaccination should receive 2 doses of 2024–2025 Novavax COVID-19 vaccine followed by a third dose of any 2024–2025 COVID-19 vaccine dose 6 months after the second dose (minimum interval 2 months).
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#routine-vaccination-guidance

Overview of the current COVID-19 vaccination schedule: *Moderate or severe immunocompromise*

- **Unvaccinated:**
  - Should receive a multidose initial vaccination series with an age-appropriate 2024–2025 vaccine and receive 1 dose of 2024–2025 6 months after completing the initial series (minimum interval 2 months)
- **Previously completed an initial series:**
  - Should receive 2 doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced 6 months apart (minimum interval 2 months)
- **May receive additional age-appropriate 2024–2025 COVID-19 vaccine doses under shared clinical decision-making** (minimum interval 2 months)

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

Policy considerations for use of the 2025–2026 COVID-19 vaccine

Policy Options for 2025–2026 COVID-19 vaccines: Multi-dose initial series

- **Currently a multi-dose initial series is recommended for people ages 6 months–4 years and people with immunocompromise**

  - **Option 1:** Maintain a universal vaccine policy for everyone ages ≥6 months that includes the multi-dose initial series

  - **Option 2:** Narrow current vaccine recommendations and only maintain this series for certain populations within these groups who we determine should be vaccinated

Policy Options for 2025–2026 COVID-19 vaccines: Annual COVID-19 vaccine doses

- **Currently annual vaccines are recommended for everyone ages ≥6 months**
  - **Option 1:** Maintain a universal vaccine policy for everyone ages ≥6 months
  - **Option 2:** Risk-based recommendation only for groups at increased risk of severe COVID-19
  - **Option 3:** Combination of risk-based and universal vaccine recommendations (e.g., risked-based recommendation for ages 6 months-64 years and universal recommendations for ages ≥65 years.

Policy Options for 2025–2026 COVID-19 vaccines:
Semi-annual COVID-19 vaccine doses

- **Persons ages ≥65 years**
  - 2 doses per year for most; may be more if previously unvaccinated and receiving Novavax or immunocompromised
- **Persons ages ≥6 months who are moderately or severely immunocompromised**
  - Initial series if unvaccinated or post-immune ablative therapy
  - Initial series is followed by 2 doses per year
  - Additional doses can be administered under shared clinical decision-making

How to define who is at increased risk?

- **How much increased risk is needed to be included in a risk-based recommendation?**
- **Increased risk of severe outcomes**
  - Age
  - Underlying conditions
  - Pregnancy (also protects infants <6 months of age)
- **Risk of exposure**
  - Healthcare workers
  - People living in long-term care facilities and other congregate settings
  - Other groups at risk of increased exposure or transmission?

Higher Risk of Severe Illness of COVID-19 (conclusive)

- Asthma
- Cancer
  - Hematologic Malignancies
- Cerebrovascular disease
- Chronic kidney disease*
  - People receiving dialysis^
- Chronic lung diseases limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - Pulmonary hypertension
- Chronic liver diseases limited to:
  - Cirrhosis
  - Non-alcoholic fatty liver disease
  - Alcoholic liver disease
  - Autoimmune hepatitis
- Cystic fibrosis
- Diabetes mellitus, type 1
- Diabetes mellitus, type 2*
- Disabilities‡,**, including Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)
- HIV (Human immunodeficiency virus)
- Mental health conditions limited to:
  - Mood disorders, including depression
  - Schizophrenia spectrum disorders
- Neurologic conditions limited to dementia‡ and Parkinson's Disease
- Obesity (BMI $\geq$30 kg/m^2 or $\geq$95th percentile in children)
- Physical inactivity
- Pregnancy and recent pregnancy
- Primary immunodeficiencies
- Smoking, current and former
- Solid organ or blood stem cell transplantation
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

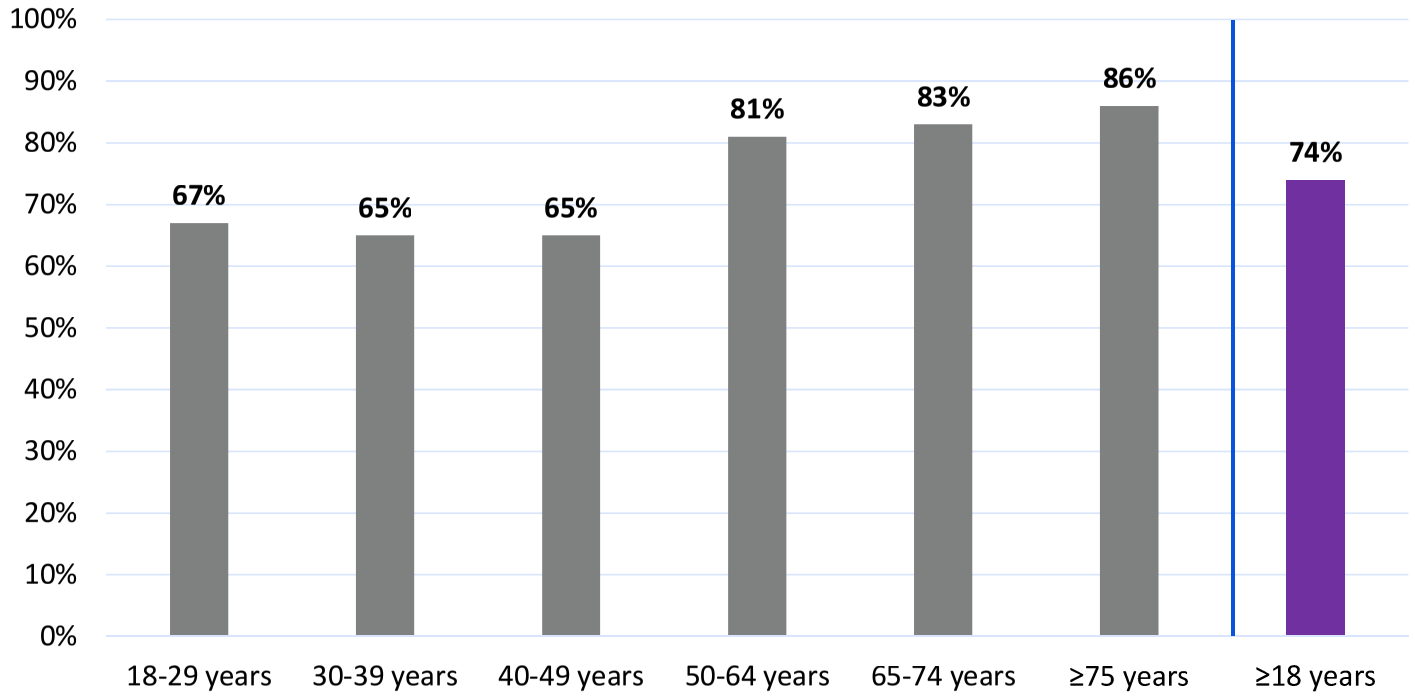
* Indicates presence of evidence for pregnant and non-pregnant women
‡ Underlying conditions for which there is evidence in pediatric patients
^ Risk may be further increased for people receiving dialysis
** Attention-deficit/hyperactivity disorder (ADHD), Autism, Cerebral palsy, Charcot foot, Chromosomal disorders, Chromosome 17 and 19 deletion, Chromosome 18q deletion, Cognitive impairment, Congenital hydrocephalus, Congenital malformations, Deafness/hearing loss, Disability indicated by Barthel Index, Down syndrome, Fahr's syndrome, Fragile X syndrome, Gaucher disease, Hand and foot disorders, Learning disabilities, Leber's hereditary optic neuropathy (LHON) or Autosomal dominant optic atrophy (ADOA), Leigh syndrome, Limitations with self-care or activities of daily living, Maternal inherited diabetes and deafness (MIDD), Mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) and risk markers, Mobility disability, Movement disorders, Multiple disability (referred to in research papers as "bedridden disability"), Multisystem disease, Myoclonic epilepsy with ragged red fibers (MERRF), Myotonic dystrophy, Neurodevelopmental disorders, Neuromuscular disorders, Neuromyelitis optica spectrum disorder (NMOSD), Neuropathy, ataxia, and retinitis pigmentosa (NARP), Perinatal spastic hemiparesis, Primary mitochondrial myopathy (PMM), Progressive supranuclear palsy, Senior-Loken syndrome, Severe and complex disability (referred to in research papers as "polyhandicap disability"), Spina bifida and other nervous system anomalies, Spinal cord injury, Tourette syndrome, Traumatic brain injury, Visual impairment/blindness, Wheelchair use
https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

Higher Risk of Severe Illness of COVID-19 (conclusive)

- **Asthma**
- **Cancer**
  - Hematologic Malignancies
- **Cerebrovascular disease**
- **Chronic kidney disease***
  - People receiving dialysis^
- **Chronic lung diseases** limited to:
  - Bronchiectasis
  - COPD (Chronic obstructive pulmonary disease)
  - Interstitial lung disease
  - Pulmonary embolism
  - Pulmonary hypertension
- **Chronic liver diseases** limited to:
  - Cirrhosis
  - Non-alcoholic fatty liver disease
  - Alcoholic liver disease
  - Autoimmune hepatitis
- **Cystic fibrosis**
- **Diabetes mellitus, type 1**
- **Diabetes mellitus, type 2***
- **Disabilities**‡,**, including Down syndrome
- **Heart conditions** (such as heart failure, coronary artery disease, or cardiomyopathies)
- **HIV (Human immunodeficiency virus)**
- **Mental health conditions** limited to:
  - **Mood disorders,** including **depression**
  - **Schizophrenia** spectrum disorders
- **Neurologic conditions limited to dementia**‡ and Parkinson's Disease
- **Obesity** (BMI ≥30 kg/m^2 or ≥95th percentile in children)
- Physical inactivity
- **Pregnancy** and recent pregnancy
- **Primary immunodeficiencies**
- **Smoking, current and former**
- **Solid organ or blood stem cell transplantation**
- **Tuberculosis**
- Use of corticosteroids or other immunosuppressive medications

* Indicates presence of evidence for pregnant and non-pregnant women
‡ Underlying conditions for which there is evidence in pediatric patients
^ Risk may be further increased for people receiving dialysis
** Attention-deficit/hyperactivity disorder (ADHD), Autism, Cerebral palsy, Charcot foot, Chromosomal disorders, Chromosome 17 and 19 deletion, Chromosome 18q deletion, Cognitive impairment, Congenital hydrocephalus, Congenital malformations, Deafness/hearing loss, Disability indicated by Barthel Index, Down syndrome, Fahr's syndrome, Fragile X syndrome, Gaucher disease, Hand and foot disorders, Learning disabilities, Leber's hereditary optic neuropathy (LHON) or Autosomal dominant optic atrophy (ADOA), Leigh syndrome, Limitations with self-care or activities of daily living, Maternal inherited diabetes and deafness (MIDD), Mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) and risk markers, Mobility disability, Movement disorders, Multiple disability (referred to in research papers as "bedridden disability"), Multisystem disease, Myoclonic epilepsy with ragged red fibers (MERRF), Myotonic dystrophy, Neurodevelopmental disorders, Neuromuscular disorders, Neuromyelitis optica spectrum disorder (NMOSD), Neuropathy, ataxia, and retinitis pigmentosa (NARP), Perinatal spastic hemiparesis, Primary mitochondrial myopathy (PMM), Progressive supranuclear palsy, Senior-Loken syndrome, Severe and complex disability (referred to in research papers as "polyhandicap disability"), Spina bifida and other nervous system anomalies, Spinal cord injury, Tourette syndrome, Traumatic brain injury, Visual impairment/blindness, Wheelchair use
Bolded conditions were included in analysis on prevalence of risk conditions by the Center for Forecasting Analytics (unpublished data); those highlighted by the red boxes were not included
https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html

Estimates of adults in the United States with at least 1 condition that puts them at higher risk of severe illness from COVID-19, by age group, October 2022–September 2023



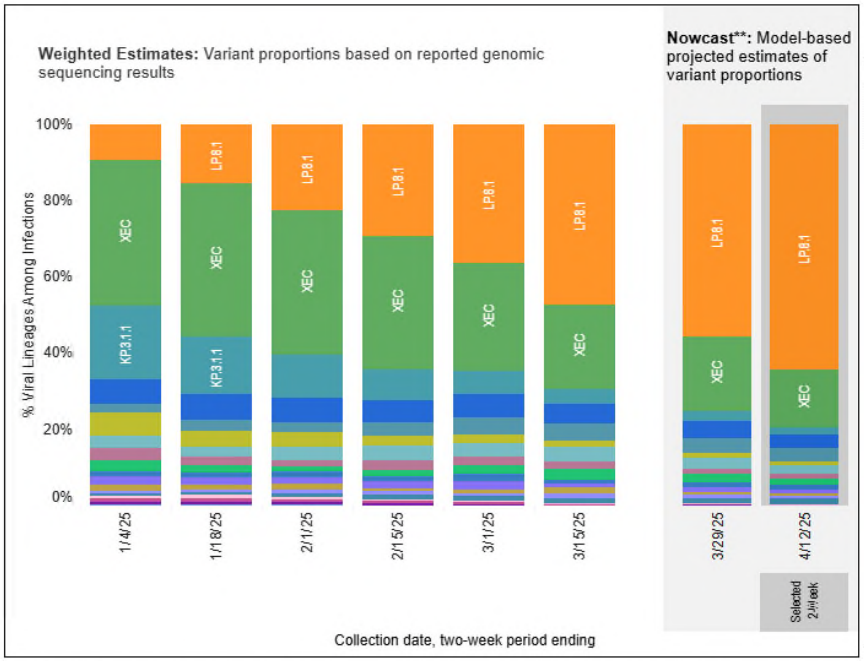
Unpublished results from September 2024 analysis of medical claims data, consumer data, Behavioral Risk Factors Surveillance System, and/or National Health Interview Survey to enumerate the US population with conditions that put them at increased risk of severe illness from COVID-19 using multilevel regression modeling, CDC Center for Forecasting and Outbreak Analytics

Summary of supporting evidence

COVID-19 Epidemiology

Weighted and Nowcast SARS-CoV-2 estimates in the United States for 2-week periods, December 2, 2024–April 12, 2025

Weighted and Nowcast Estimates in United States for 2-Week Periods in 12/22/2024 – 4/12/2025



Nowcast Estimates in United States for 3/16/2025 – 3/29/2025

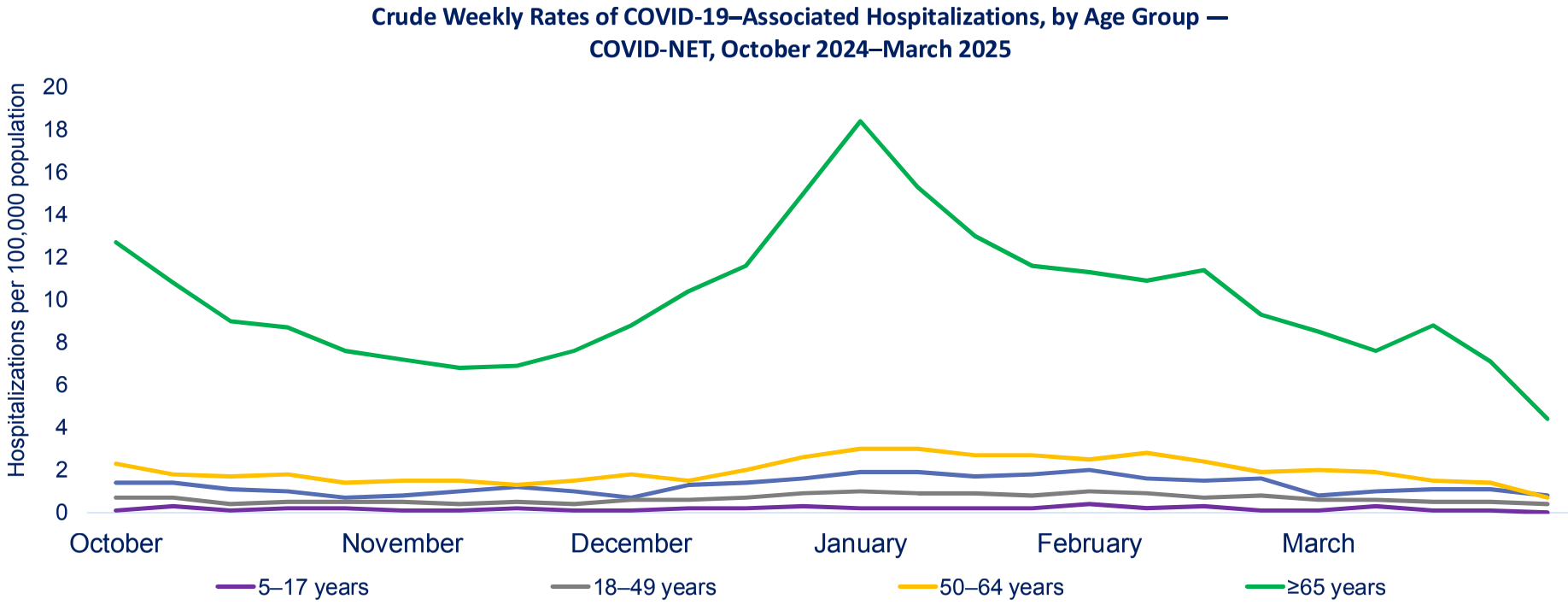
USA

WHO label	Lineage #	%Total	95%PI
Omicron	LP.8.1	64%	59–70%
	XEC	15%	12–18%
	MC.10.1	4%	1–9%
	LF.7	4%	2–7%
	LB.1.3.1	2%	1–4%
	KP.3.1.1	2%	1–3%
	XEC.4	2%	1–3%
	MC.28.1	1%	1–3%
	MC.19	1%	1–2%
	KP.3	1%	1–2%
	XEQ	1%	0–2%
	MC.1	1%	1–1%
	LF.7.2.1	1%	0–2%
	XEK	1%	0–1%
	JN.1.16	0%	0–1%
	JN.1	0%	NA

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates
# Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one 2-week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all 2-week periods displayed. While all lineages are tracke by CDC, those named lineages not enumerated in this graphic are aggregated with their parent lineages, based on Pango lineage definitions, described in more detail here: https://web.archive.org/web/20240116214031/https://www.pango.network/the-pango-nomenclature-system/statement-of-nomenclature-rules.

These data include Nowcast estimates, which are modeled predictions that may differ from weighted estimates generated at later dates
https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed April 14, 2025

Weekly rates of COVID-19–associated hospitalizations in the United States by age group, October 2024–March 2025

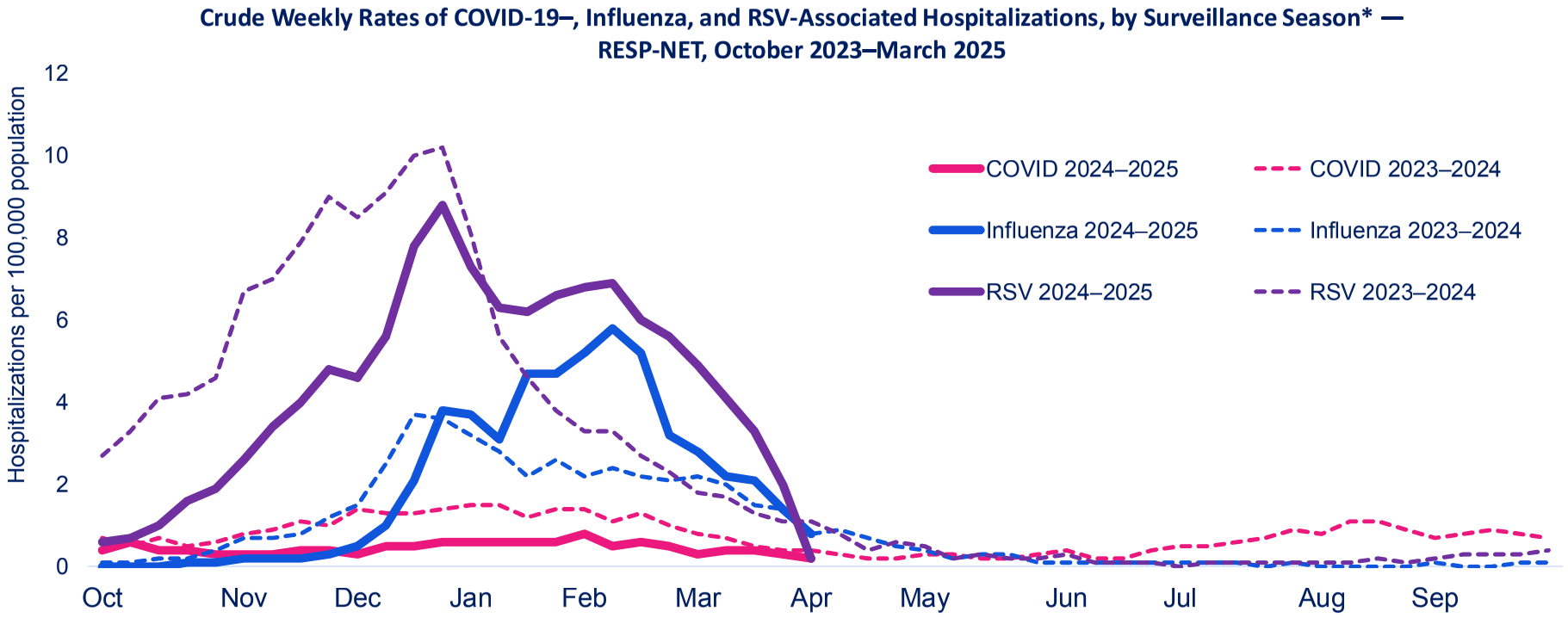


Rates for SARS-CoV-2 are laboratory-confirmed.

Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

Data source: https://www.cdc.gov/resp-net/dashboard/ Accessed April 7, 2025

Weekly rates of respiratory virus-associated hospitalizations in the United States among children ages 0–17 years, 2023–2025

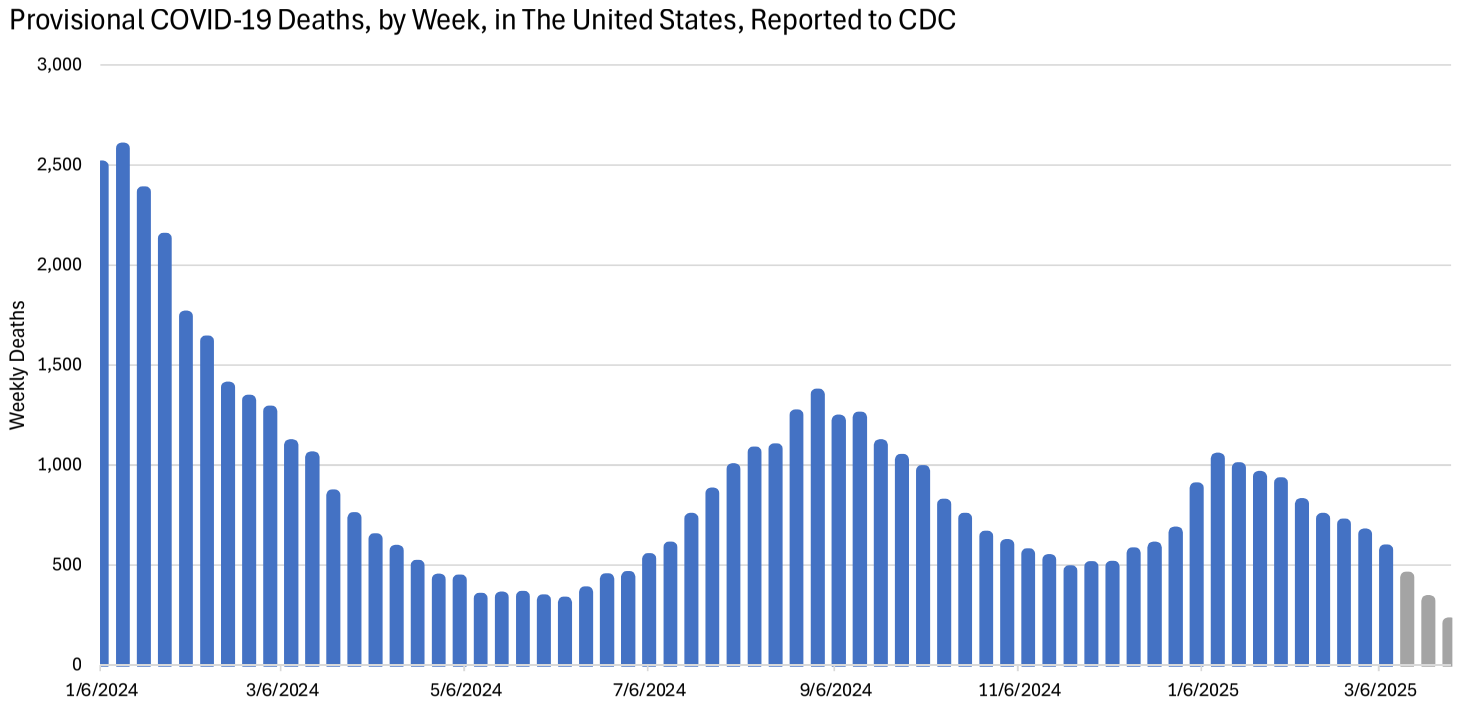


Rates for all three pathogens (COVID-19, influenza, and respiratory syncytial virus [RSV]) are laboratory-confirmed.

Note that rates are not adjusted for testing or limited to admissions where the respiratory infection is the likely primary reason for admission.

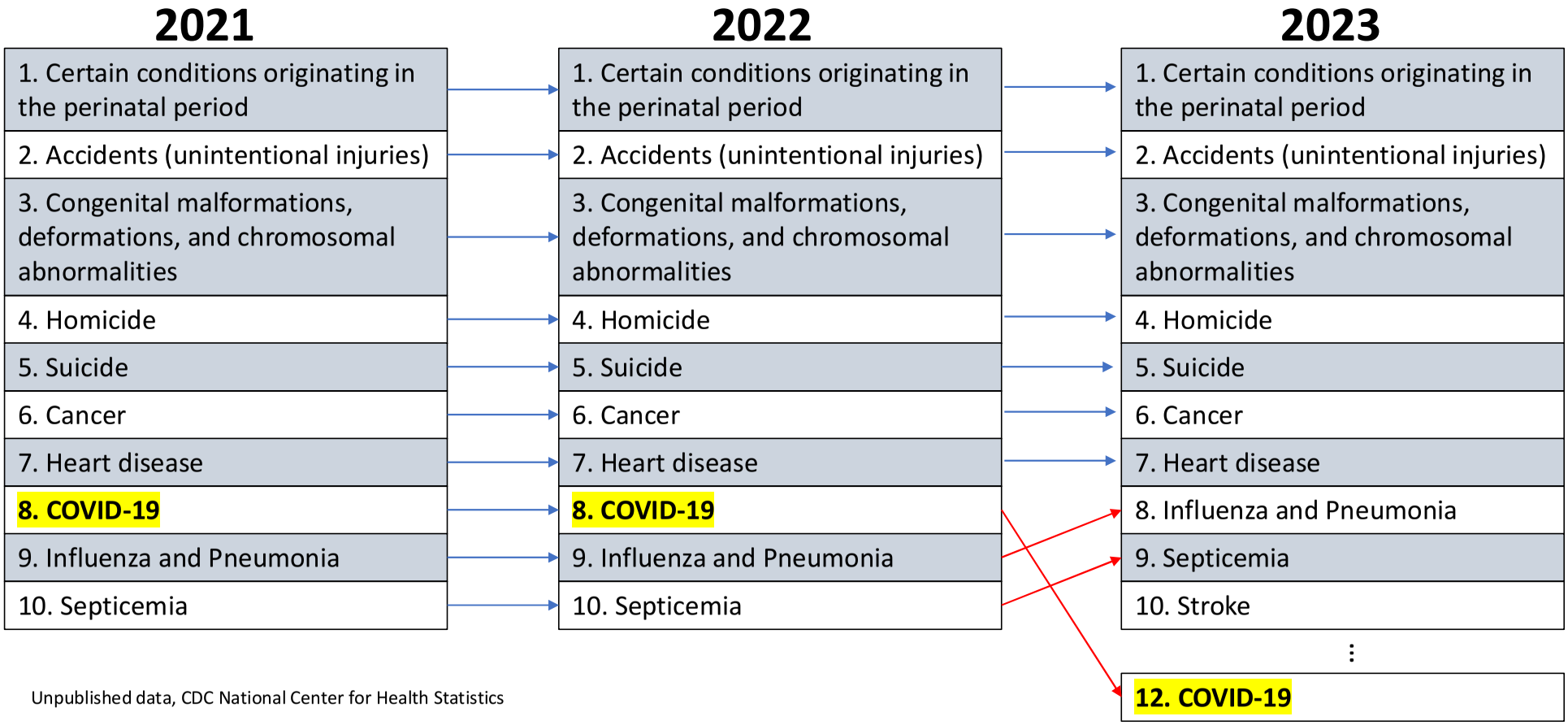
Data source: https://www.cdc.gov/resp-net/dashboard/ accessed April 7, 2025

Weekly number of COVID-19 deaths reported to CDC, United States, January 1, 2024 – March 29, 2025



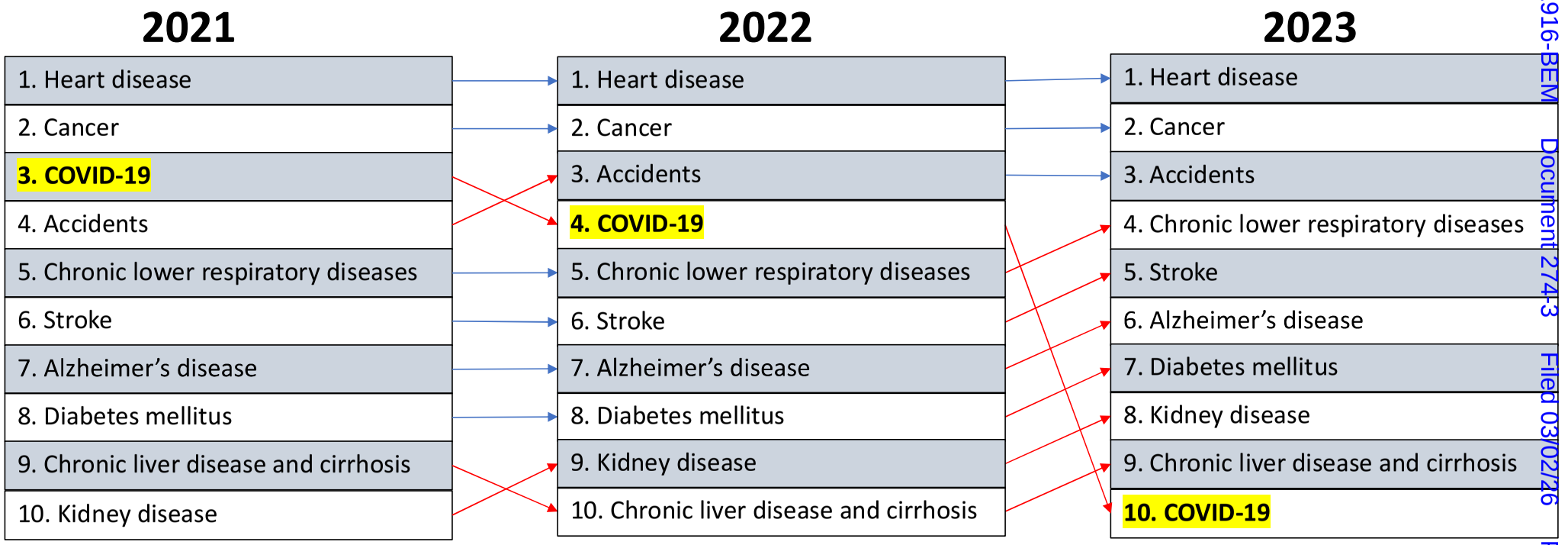
The most recent 3 weeks of mortality counts are shaded grey because NVSS reporting is <95% during this period.
Provisional data are non-final counts of deaths based on reported mortality data in NVSS. Deaths include those with COVID-19, coded as ICD–10 code U07.1, on the death certificate. Death data are displayed by date of death (event). Data include underlying and contributing causes of death.
CDC COVID Data Tracker. National Center for Health Statistics (NCHS) National Vital Statistics System (NVSS). https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 . Accessed April 7, 2025

Top 10 leading causes of death in the United States, children and adolescents 0–17 years



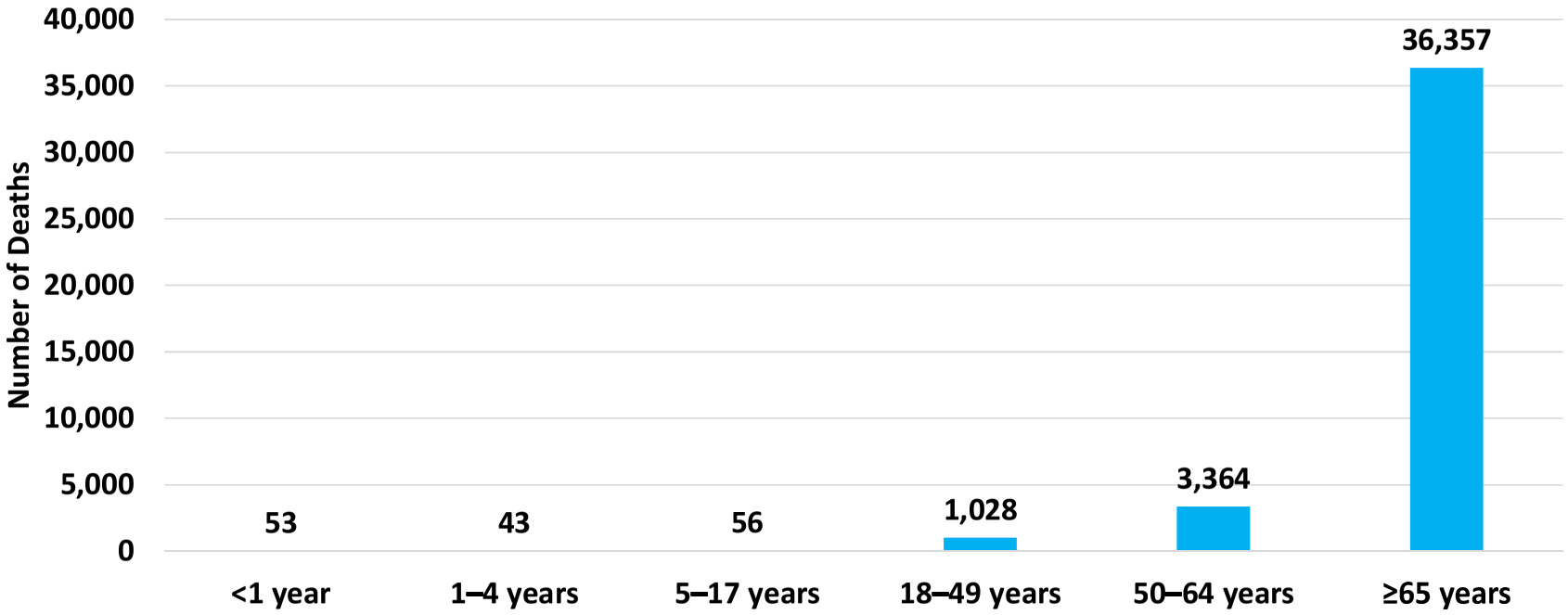
Unpublished data, CDC National Center for Health Statistics

Top 10 leading causes of death in the United States, adults ages ≥18 years



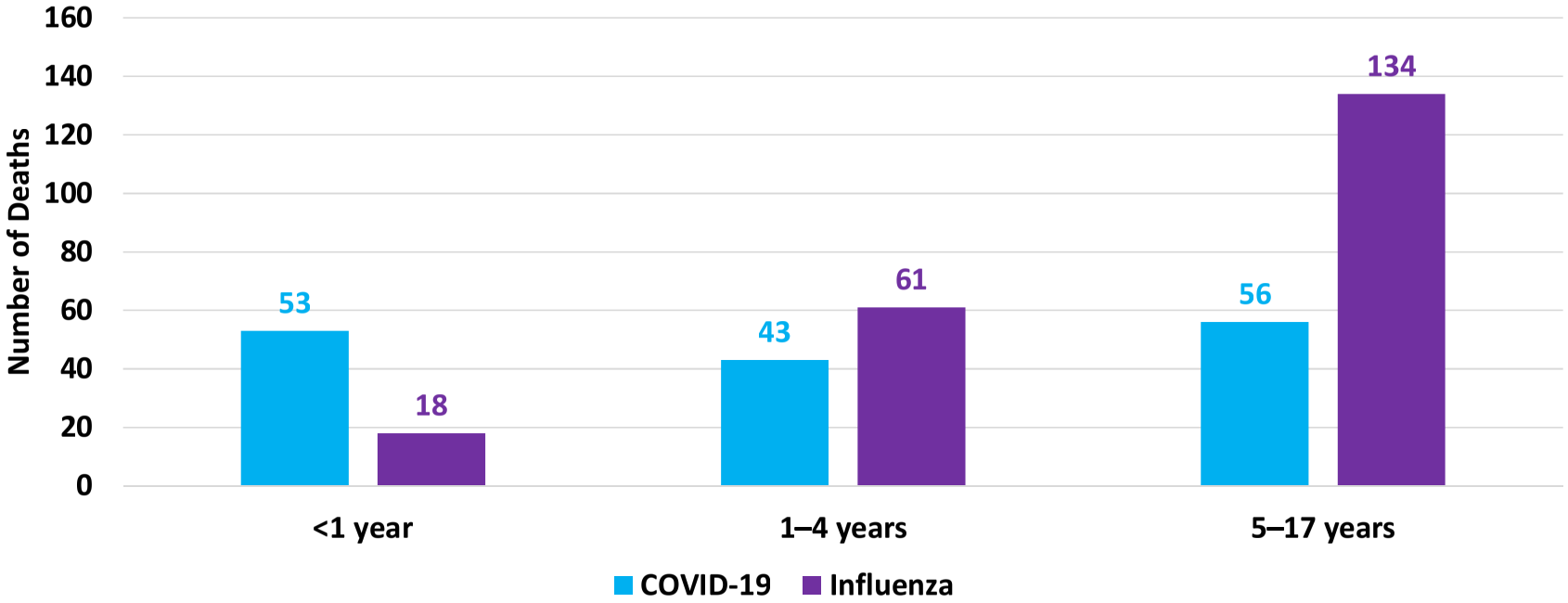
Influenza and pneumonia was ranked 9th pre-pandemic in 2019; ranked 13th in 2023
Unpublished data, CDC National Center for Health Statistics

Total number of COVID-19 deaths,[1,2] September 2023–August 2024, by age group, United States



1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Underlying Cause of Death Files, 2018-2023, and from provisional data for 2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes COVID-19 code (U07.1) as the underlying cause of death. http://wonder.cdc.gov/mcd-icd10-provisional.html, accessed January 16, 2025

Total number of COVID-19 and Influenza deaths[1,2], among ages 0–17 years, September 2023–August 2024, United States



1. Provisional data
2. Underlying cause of death Source: Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database Data are from the final Underlying Cause of Death Files, 2018-2023, and from provisional data for 2024, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Number of deaths includes influenza codes (J09-J11) or COVID-19 code (U07.1) as the underlying cause of death. http://wonder.cdc.gov/mcd-icd10-provisional.html, accessed January 16, 2025

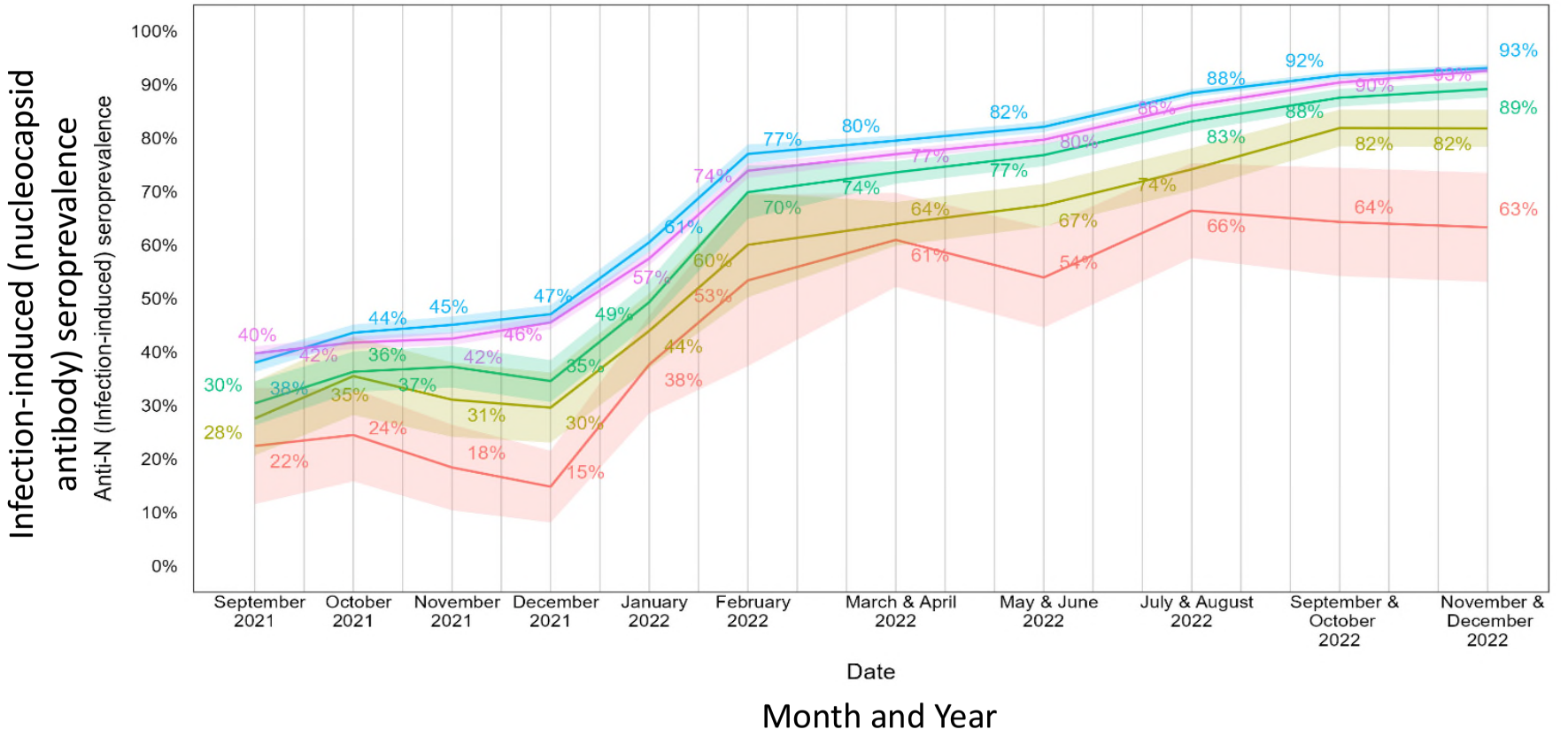
Note: Estimates of pediatric influenza deaths reported to CDC can be found here: https://www.cdc.gov/flu/weekly/index.htm. Estimates will vary due to differences in reporting methods and timeframes used.

COVID-19—associated changes from 2023–2024 to 2024–2025

	2023–2024	2024–2025	Difference
Routine vaccine recommendation	6 months and older 65 and older: 2 doses	6 months and older 65 and older: 2 doses	No change
Vaccine coverage <18 years[1]	13.8% (13.4–14.3) (3/23/2024)	12.8% (12.2–13.4) (3/22/2025)	Similar
Vaccine coverage ≥18 years[2]	21.3% (21.0–21.5) (3/23/2024)	23.1% (22.5–23.7) (3/22/2025)	Similar
Vaccine coverage ≥65 years[2]	37.5% (36.7–38.3) (3/23/2024)	44.0% (42.5–45.4) (3/22/2025)	***Increase***
Vaccine effectiveness against hospitalization, immunocompetent adults ≥65 years	VISION: 42% (37–47)[3] IVY: 35% (20–47)[3]	VISION: 45% (36–53)[4] IVY: 46% (26–60)[4]	Similar
Cumulative hospitalization rates (week 13)[5]	125.6/100,000	62.9/100,000	***Decrease***

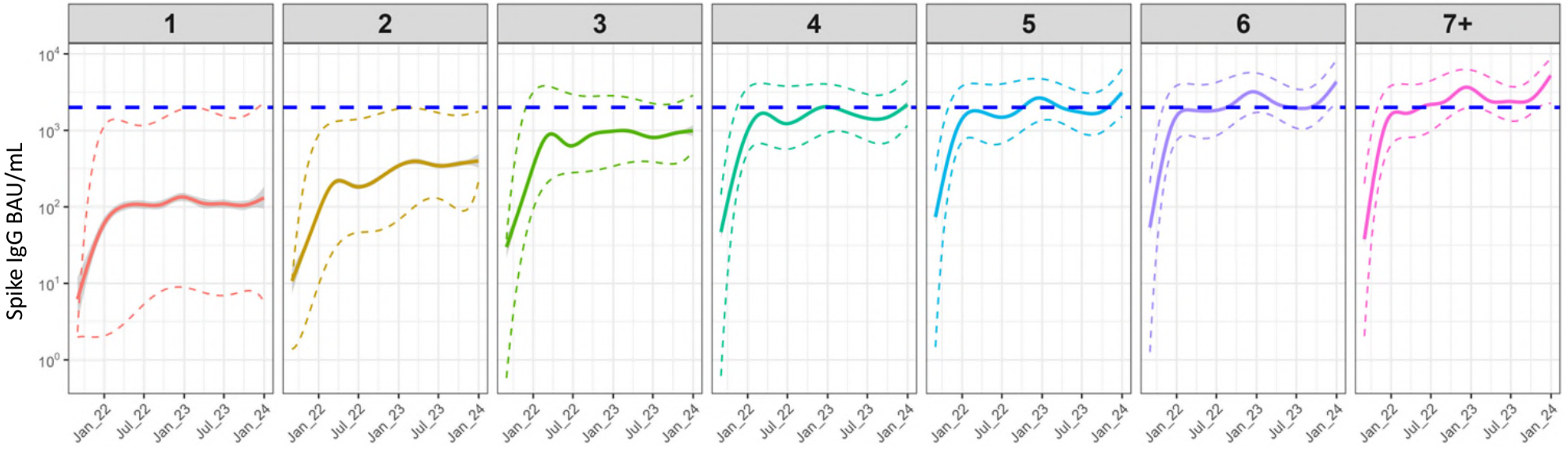
1 https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html, accessed April 7, 2025
2 https://www.cdc.gov/covidvaxview/weekly-dashboard/adult-vaccination-coverage.html, accessed April 7, 2025
3 https://www.cdc.gov/acip/downloads/slides-2024-06-26-28/03-COVID-Link-Gelles-508.pdf; median (IQR) days since dose: VISION: 84 (46–127) IVY: 81 (43–121)
4 Link-Gelles R, Chickery S, Webber A, et al. Interim Estimates of 2024–2025 COVID-19 Vaccine Effectiveness Among Adults Aged ≥18 Years — VISION and IVY Networks, September 2024–January 2025. MMWR Morb Mortal Wkly Rep 2025;74:73–82. Median (IQR) days since dose– VISION: 53 (30–77) IVY: 60 (31–85)
5 https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network, accessed April 7, 2025

Infection-induced SARS-CoV-2 seroprevalence among U.S. children — September 2021 – December 2022



Shaded ranges depict 95% confidence intervals for the estimated seroprevalence shown by the dark line in the corresponding color.
Source: https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence
Accessed: March 20, 2025

Population SARS-CoV-2 spike antibody over time by the cumulative number of combined infections and vaccinations - U.S. blood donors ages ≥16 years, September 2021-December 2023



Solid lines represent mean anti-spike IgG levels; dotted lines represent model based 25th-75th% percentiles

Higher number of cumulative SARS-CoV-2 infections and COVID-19 vaccinations leads to higher antibody levels, but with smaller incremental increases in antibodies with each exposure

Source: https://covid.cdc.gov/covid-data-tracker/#nationwide-blood-donor-seroprevalence-2022, CDC unpublished data

Long COVID is a significant public health threat

National surveys in 2023 estimated approximately 9.2 million adults and 0.3 million children in the U.S. had Long COVID.

Among adults aged ≥18 years, **3.6% reported Long COVID symptoms,** and **8.4% reported ever having Long COVID**[1]

Among children aged 0-17 years, **0.4% reported Long COVID symptoms,** and **1.4% reported ever having Long COVID**[2]

More than 3 in 5 adults with Long COVID report activity limitations[1]

Almost 4 in 5 children with Long COVID report activity limitations[2]

1. Vahratian A, Saydah S, Bertolli J, Unger ER, Gregory CO. Prevalence of Post–COVID-19 Condition and Activity-Limiting Post–COVID-19 Condition Among Adults. *JAMA Netw Open.* 2024;7(12):e2451151.
2. Ford ND, Vahratian A, Pratt CQ, Yousaf AR, Gregory CO, Saydah S. Long COVID Prevalence and Associated Activity Limitation in US Children. *JAMA Pediatr.* Published online February 03, 2025.

COVID-19 mRNA vaccination associated with reduced occurrence of Long COVID following COVID-19: June 2021-September 2022

Among children aged 5 – 17 years:

Completion of the primary vaccine series prior to infection associated with **reduced likelihood** of Long COVID symptoms[1]

- **57% for 1 or more symptoms**
- **73% for 2 or more symptoms**
- **72% for respiratory symptoms**

Among adults:

3 doses of original monovalent vaccine prior to infection associated with **reduced likelihood** of Long COVID symptoms[2]

- **63% for gastrointestinal symptoms**
- **44% for neurological symptoms**
- **52% for other non-specific symptoms**

1. Yousaf AR, Mak J, Gwynn L, et al. COVID-19 Vaccination and Odds of Post–COVID-19 Condition Symptoms in Children Aged 5 to 17 Years. *JAMA Netw Open.* 2025;8(2):e2459672.
2. Mak J, Khan S, Britton A et al. Association of Messenger RNA Coronavirus Disease 2019 (COVID-19) Vaccination and Reductions in Post COVID Conditions Following Severe Acute Respiratory Syndrome Coronavirus 2 Infection in a US Prospective Cohort of Essential Workers, The Journal of Infectious Diseases, Volume 231, Issue 3, 15 March 2025, Pages 665–676

Multisystem Inflammatory Syndrome in Children (MIS-C) U.S. Incidence Over Time

- US incidence of MIS-C by SARS-CoV-2 variant-predominant periods was previously published[1], updated data shown below
  - Defined using surveillance data and allowing for 2 weeks to MIS-C onset from when a variant exceeded 50% circulating lineages

Variant predominant period	Dates	Number of MIS-C cases	Incidence per 1,000,000 (95% CI) person-years	Median age (IQR), years
Pre-Delta	Oct 15, 2020–Apr 5, 2021	3,287	6.80 (6.57–7.03)	9.2 (5.4–13.1)
Delta	Jul 10–Dec 24, 2021	2,305	4.91 (4.71–5.11)	9.1 (5.5–12.3)
Omicron BA.1/BA 1.1	Jan 1–Apr 8, 2022	1,148	4.21 (3.97–4.46)	7.5 (4.1–11.5)
Omicron BA.2/BA.4/BA.5	Apr 9–Dec 31, 2022	428	0.57 (0.52–0.63)	5.4 (2.9–9.7)
Omicron XBB.1.5	Jan 1–Dec 31, 2023	141	0.14 (0.12–0.16)	6.9 (3.7–11.5)
Omicron JN.1/others	Jan 1-Dec 31, 2024	79	0.08 (0.06 - 0.10)	9.1 (4.7-14.3)

- Similarly decreased incidence was observed in other countries[2-4]

1. Yousaf AR, et al, *MMWR* 2023
2. Shingleton J et al, *Journal of Infection*, 2022.
3. Cohen JM, et al. *Clin Infect Dis*. 2023
4. Whittaker R et al. *Pediatrics.* 2022

COVID-19 Vaccination Status of 2023 and 2024 U.S. Multisystem Inflammatory Syndrome in Children (MIS-C) Cases

	2023 Illness Onset N=141 (%)	2024 Illness Onset N=79 (%)
Vaccine age-eligible[1] at time of MIS-C onset	134 (95)	78 (99)
No vaccination	108/134 (81)	58/78 (74)
Vaccinated (at least one dose received)	26/134 (19)	20/78 (26)
Last vaccine dose >12 months before MIS-C onset	17/26 (65)	20/20 (100)

[1]10 months of age at onset considered the minimum age by which a child could plausibly have completed an mRNA primary vaccination series, with 6 months being the earliest possible age at first dose and ≥12 weeks from first dose required to complete a 3-dose primary series, and 4 weeks between time since last dose and hospitalization

- **Although 95% of children with MIS-C in 2023 and 99% in 2024 were eligible to receive a COVID-19 vaccine ≥16 weeks before their MIS-C illness, only 19% in 2023 and 26% in 2024 of eligible children received any vaccine dose**
- **Of the 25 vaccinated children in 2023 with information on timing, 65% in 2023 received their last vaccine dose more than 12 months prior to MIS-C onset**
- **All vaccinated children in 2024 received their last vaccine dose > 12 months prior to MIS-C onset**

Yousaf AR et al, MMWR 2023 and unpublished data

COVID-19 Vaccine and Myocarditis

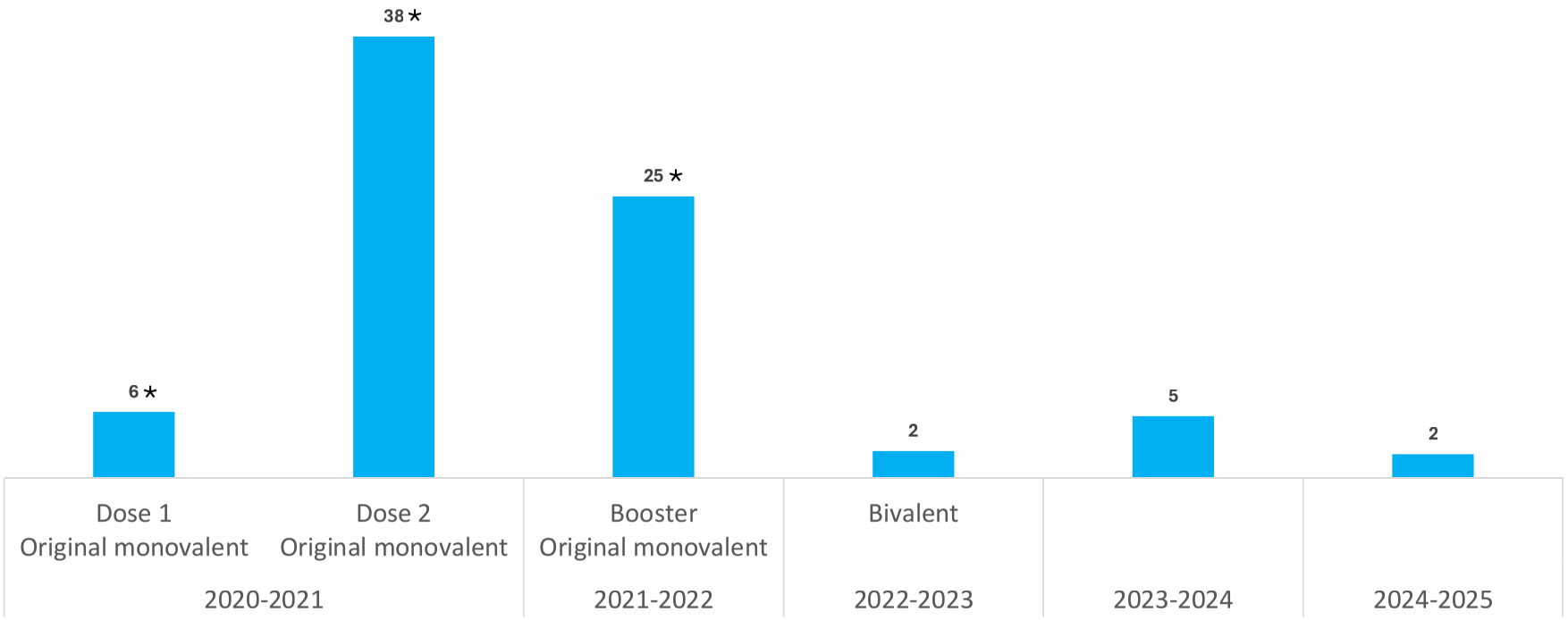
COVID-19 vaccine prescribing information or fact sheet warnings and precautions about myocarditis and pericarditis

Manufacturer	Precaution
Pfizer	Post marketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For COMIRNATY, the observed risk is highest in males 12 through 17 years of age.
Moderna	Post marketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For SPIKEVAX, the observed risk is highest in males 18 years through 24 years of age.
Novavax	Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted.

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines-2024-2025

Myocarditis following mRNA COVID-19 vaccination among people ages 12–39 years in the Vaccine Safety Datalink

Incidence of myocarditis within 7 days of vaccination per million mRNA vaccine doses administered



*Statistically significant increased rate ratio in vaccinated concurrent comparator analysis
Source: CDC Immunization Safety Office, unpublished data

Myocarditis/pericarditis concurrent comparator analysis in Vaccine Safety Datalink (VSD) after COVID-19 vaccine doses among people ages 12-39 years, 2024-2025

Vaccine	Doses	Cases in Risk Interval (Days 1-21)	Cases in Comparison Interval (Days 22-42)	Adjusted Rate Ratio[1] (95% Confidence Interval)
Pfizer	530,095	5	5	0.61 (0.11 – 2.88)
Moderna	35,194	0	0	n/a
Novavax	1,576	0	0	n/a

- **The VSD has not detected a statistical signal for myocarditis/pericarditis following the 2024-2025 COVID-19 vaccine to date**

[1] Adjusted for outcome calendar date, age group, sex, race/ethnicity, VSD site
Source: CDC Immunization Safety Office, unpublished data through March 22, 2025

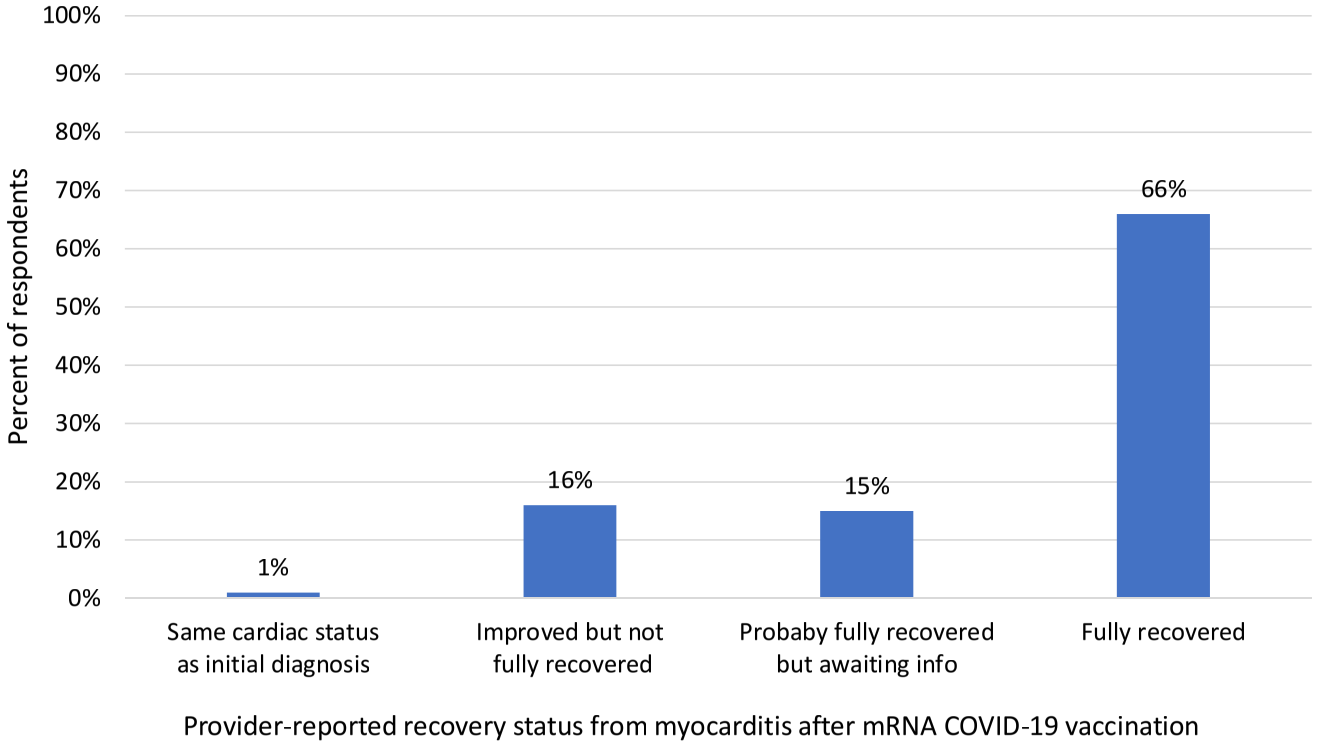
Vaccine Adverse Event Reporting System (VAERS) reports of myocarditis within 7 days of COVID-19 vaccination among people ages 12-39 years, 2024-2025

Age group (years)	Verified cases	Reporting rate per million doses
12-17	3	0.74
18-29	0	0
30-39	1	0.14

- **The reporting rates are similar to the expected background rates of <2 cases per million doses**

Source: CDC Immunization Safety Office, unpublished data through March 22, 2025

MOVING Study: Outcomes after myocarditis following COVID-19 vaccine: Cardiologist/healthcare provider assessment of recovery in persons ages 12–29 years at least 90 days since onset of myocarditis after COVID-19 vaccination, 2021-2022



- **81% (320/393) of patients were considered fully or probably recovered by their cardiologist or other healthcare provider**

Kracalik I, Oster ME, Broder KR et al. Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child & Adolescent Health,* 2022.

MOVING: Myocarditis Outcomes after COVID-19 Vaccine INvestiGation

MOVING* study: Outcomes after myocarditis following COVID-19 vaccine: Patient-reported assessment of recovery in persons ages 12–29 years at least 90 days since onset of myocarditis after COVID-19 vaccination, 2021-2022

	Patients fully or probably fully recovered (n=320)	Patients not recovered (n=65)	All patients (n=519)	p value
Patient-reported symptoms in the patient survey	n=195§	n=28§	n=357	..
At least one symptom	94 (48%)	18 (64%)	178 (50%)	0·16
Chest pain or discomfort	55 (28%)	13 (46%)	113 (32%)	0·082
Chest pain or discomfort while resting	45 (23%)	11 (39%)	92 (26%)	0·011
Fatigue	40 (21%)	12 (43%)	89 (25%)	0·018
Fatigue while resting	28 (14%)	10 (36%)	63 (18%)	0·012
Shortness of breath	38 (19%)	9 (32%)	80 (22%)	0·28
Shortness of breath while resting	15 (8%)	4 (14%)	38 (11%)	0·42
Heart palpitations	36 (18%)	6 (21%)	77 (22%)	0·71
Heart palpitations while resting	28 (14%)	5 (18%)	59 (17%)	0·84

- **50% (178/357) of patients self-report at least 1 lingering symptom at 3 months**

*MOVING: Myocarditis Outcomes after COVID-19 Vaccine INvestiGation

Kracalik I, Oster ME, Broder KR et al. Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study. *Lancet Child & Adolescent Health,* 2022.

Comparison of myocarditis attributed to COVID-19 mRNA vaccination, SARS-CoV-2 infection or conventional etiologies, 2020-2022

Table 3. Associations Between Clinical Outcomes and Myocarditis Groups Over 18 Months

Outcome	Postvaccine myocarditis (n = 558)		Post-COVID-19 myocarditis (n = 298)		Conventional myocarditis (n = 3779)	
	No. of events (%)	Weighted hazard ratio[a]	No. of events (%)	Weighted hazard ratio[a]	No. of events (%)	Weighted hazard ratio[a]
Rehospitalization for myopericarditis	18 (3.2)	0.75 (0.40-1.42)	12 (4.0)	1.07 (0.53-2.13)	220 (5.8)	1
Cardiovascular event (excluding myopericarditis)	15 (2.7)	0.54 (0.27-1.05)	22 (7.4)	1.01 (0.62-1.64)	277 (7.3)	1
Heart failure, heart rhythm and conduction disorders, cardiomyopathy[b]	6 (1.1)	0.53 (0.07-4.28)	11 (3.7)	1.23 (0.58-2.63)	132 (3.5)	1
Hospitalization for any cause	68 (12.2)	0.69 (0.50-0.94)	63 (21.1)	1.04 (0.73-1.48)	739 (19.6)	1
Death from any cause	1 (0.2)		4 (1.3)		49 (1.3)	1
Composite outcome 1[c]	32 (5.7)	0.55 (0.36-0.86)	36 (12.1)	1.04 (0.70-1.52)	497 (13.2)	1
Composite outcome 2[c]	75 (13.4)	0.64 (0.48-0.85)	76 (25.5)	1.03 (0.75-1.40)	874 (23.1)	1

Composite outcome 1: rehospitalization for myopericarditis, cardiovascular event, or death from any cause.

Composite outcome 2: rehospitalization for myopericarditis, cardiovascular event, hospitalization for any cause (>1 night stay), or death from any cause.

Semenzato L, Le Vu S, Botton J et al. Long-term prognosis of patients with myocarditis attributed to COVID-19 mRNA vaccination, SARS-CoV-2 infection, or conventional etiologies. *JAMA*. 2024. https://jamanetwork.com/journals/jama/fullarticle/2822933

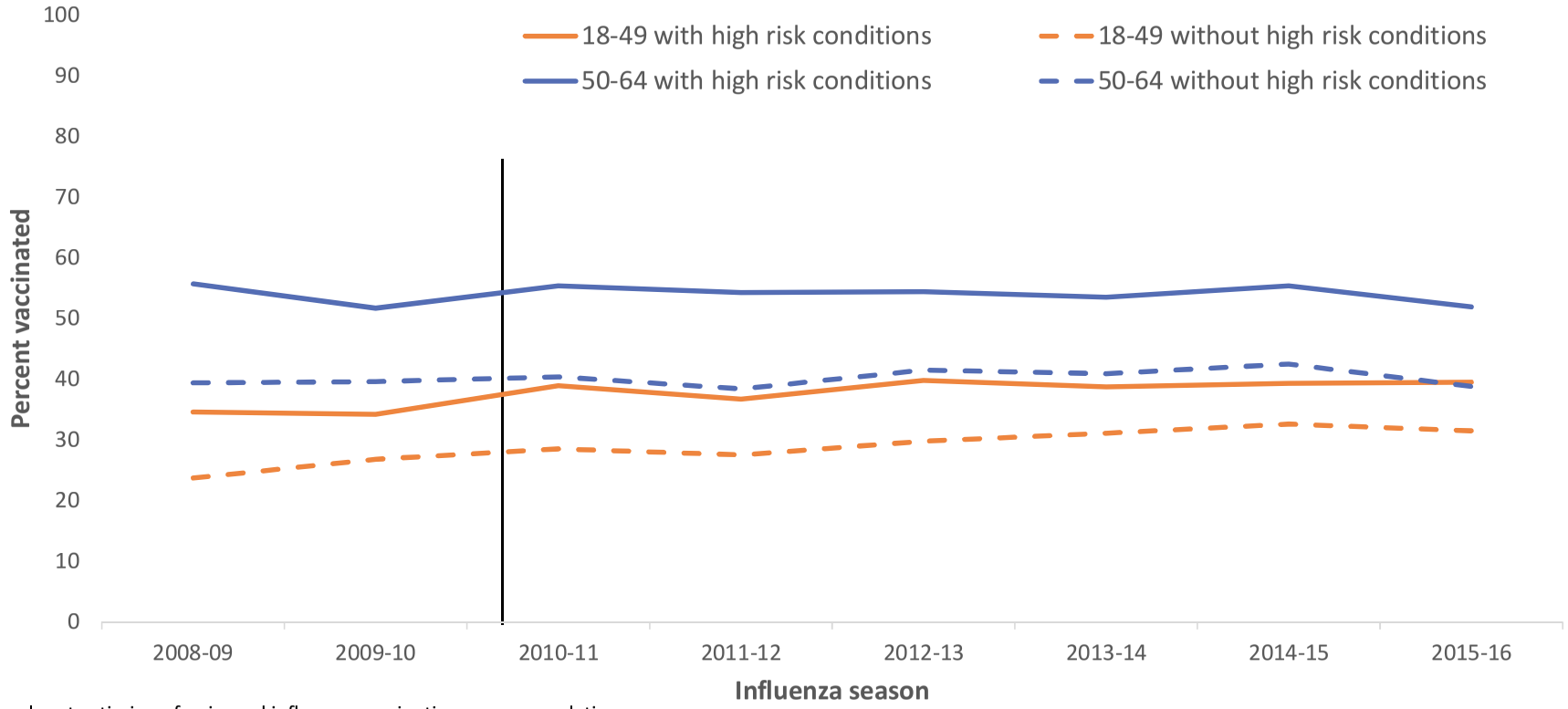
Summary: myocarditis after COVID-19 vaccine

- An increased risk of myocarditis following COVID-19 vaccines was observed during 2020-2022 following the primary series and first booster doses
- No increased risk was observed in VSD and VAERS with the 2022-2023 and 2023-2024 vaccines or the 2024-25 vaccine to date
- Acute clinical picture following myocarditis after COVID-19 vaccine tends to resolve quickly
- Post-COVID-19 vaccine myocarditis associated with less severe cardiovascular events than post-COVID-19 myocarditis and conventional myocarditis

VSD: Vaccine Safety Datalink | VAERS: Vaccine Adverse Event Reporting System

Risk-based v. universal vaccine recommendations and vaccine coverage

Influenza vaccination coverage among adults 18-64 years with and without high-risk medical conditions, 2008–09 through 2015–16 influenza seasons, Behavioral Risk Factor Surveillance System



Vertical line denotes timing of universal influenza vaccination recommendation

Selected high risk conditions include asthma, diabetes or heart disease (before the 2013-14 season) or asthma, diabetes, heart disease, chronic obstructive pulmonary disease or cancers other than skin cancer (2013-14 season through present)

Source: CDC Immunization Services Division, unpublished

Vaccination coverage: risk-based vs. universal recommendations

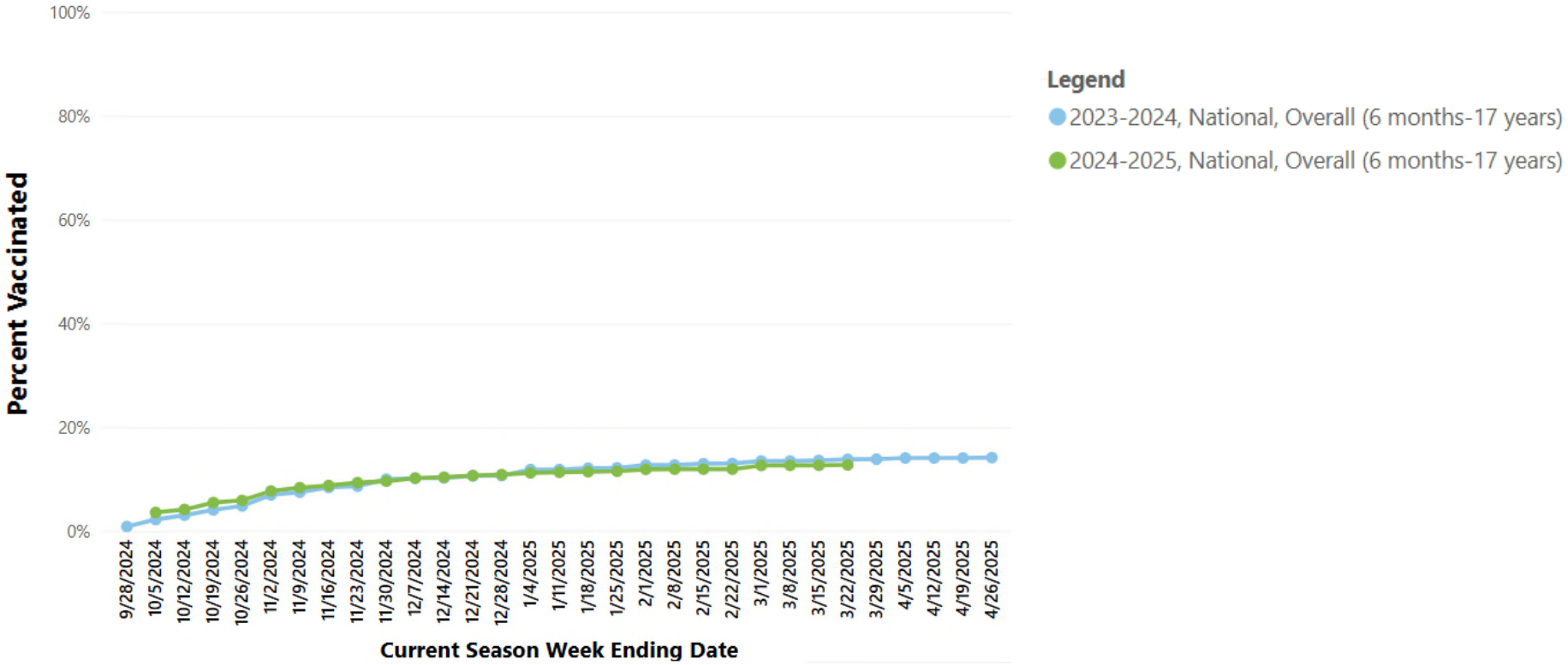
- Influenza vaccination coverage among adults with high-risk conditions increased slightly after the universal recommendation in the 2010-11 season, but it was already trending upward and plateaued shortly after the change in recommendation.
- Hepatitis B vaccination coverage among adults with risk factors remained below pre-pandemic coverage after the universal recommendation in 2022.
- Coverage among adults universally recommended for zoster vaccination was approaching pneumococcal vaccination coverage among high-risk adults by 2023, despite longstanding pneumococcal vaccination recommendations for high-risk adults.
- It is unclear how a change from a universal to risk-based recommendations may impact COVID-19 vaccine coverage

Source: CDC Immunization Services Division, unpublished data

Parental vaccine confidence

COVID-19 vaccination coverage among children 6 months–17 years, United States, 2023-2024 through 2024-2025

- As of March 22, 2025, 12.8% of children 6 months-17 years reported having received the 2024–25 COVID-19 vaccine.

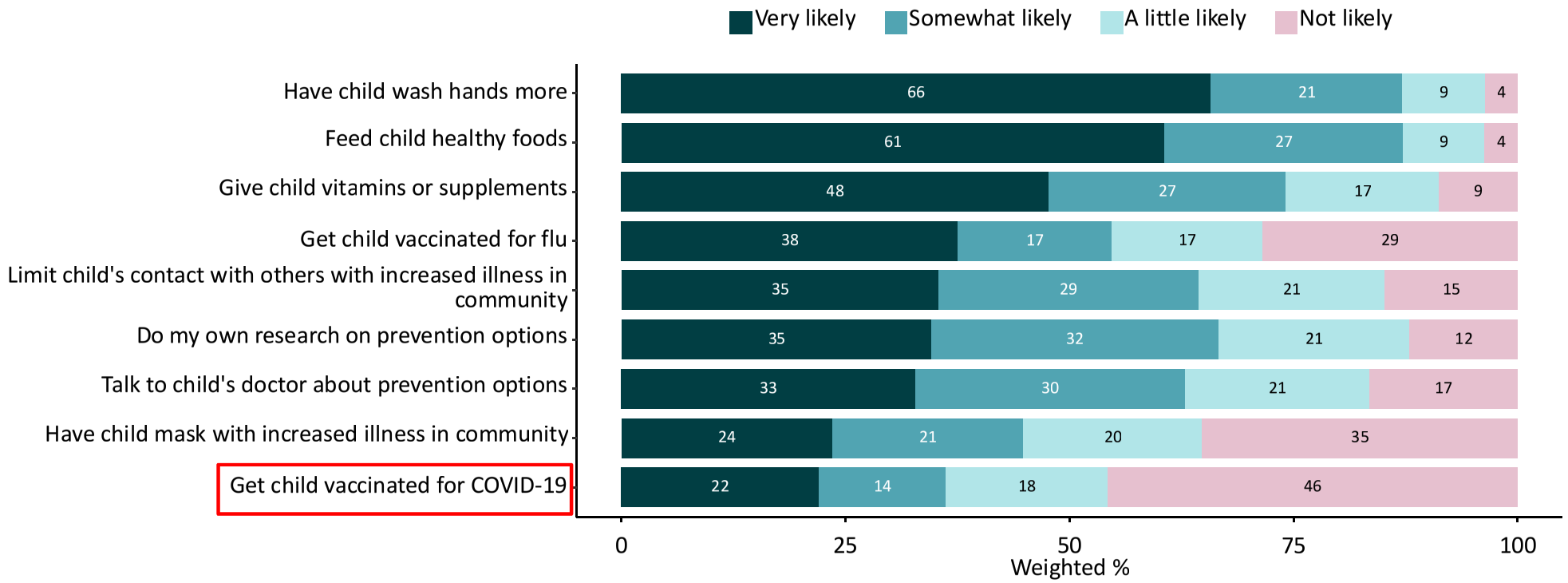


Current season week ending date refers to the 2024-2025 season only. For the 2023-2024 season, the corresponding week is represented

Data source: National immunization survey – Flu https://www.cdc.gov/covidvaxview/weekly-dashboard/child-coverage-vaccination.html

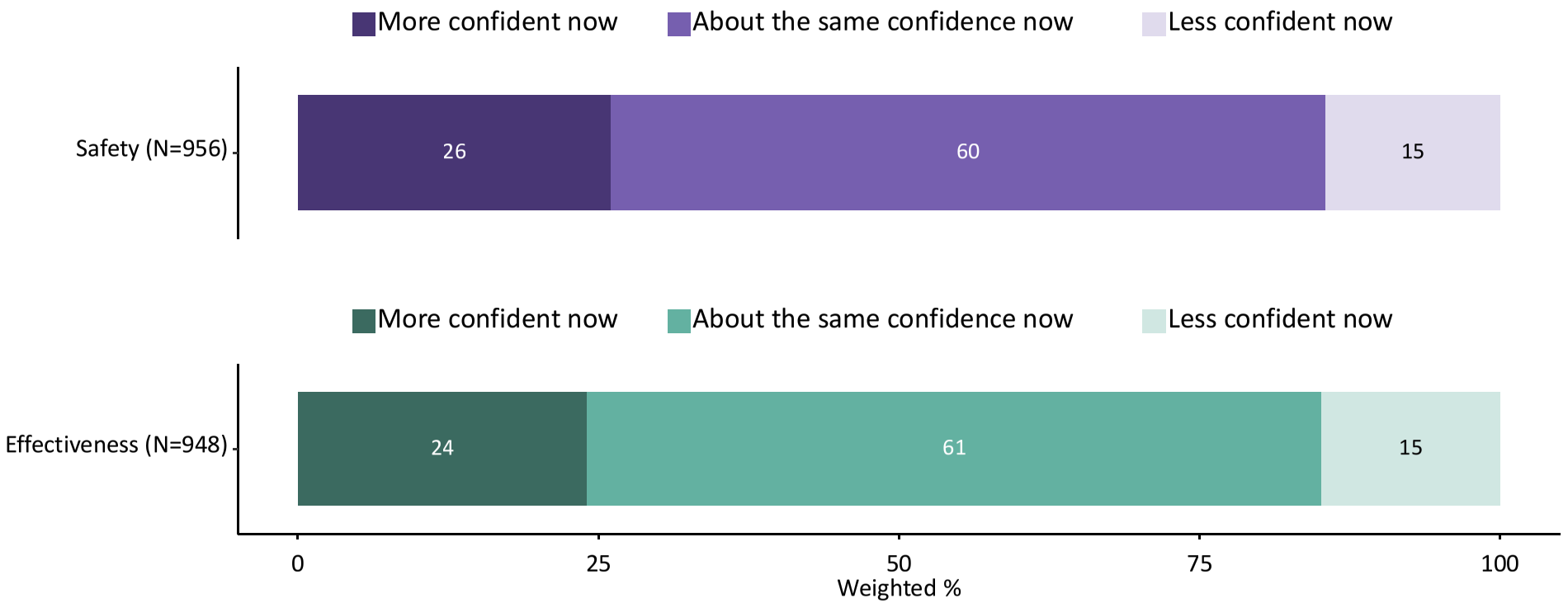
Accessed April 7, 2025

"How likely are you to take the following actions to help prevent your child from getting sick from a respiratory illness?" Results Among Parents of Child Ages 0–17 Years, Omnibus Surveys, November 7–29, 2024 (N=1,141)



Omnibus Surveys: Data for this analysis were collected through the Ipsos KnowledgePanel and NORC AmeriSpeak Omnibus Surveys, which use probability-based panels to survey a nationally representative sample of U.S. adults ages 18 years and older. CDC fields questions about vaccination status, intent, knowledge, attitudes, beliefs, and behaviors on each survey for 2 waves each month, for a combined sample size of ~4,000 respondents. These slides present results from November (N=4,240). Data were weighted to represent the non-institutionalized U.S. population and mitigate possible non-response bias. All responses are self-reported.

"Are you more or less confident in the safety/effectiveness of COVID-19 vaccines for children *now* compared to when they first came out?" Results Among Parents of Child Ages 0–17 Years Who Received at Least 1 Dose of a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024–January 27, 2025



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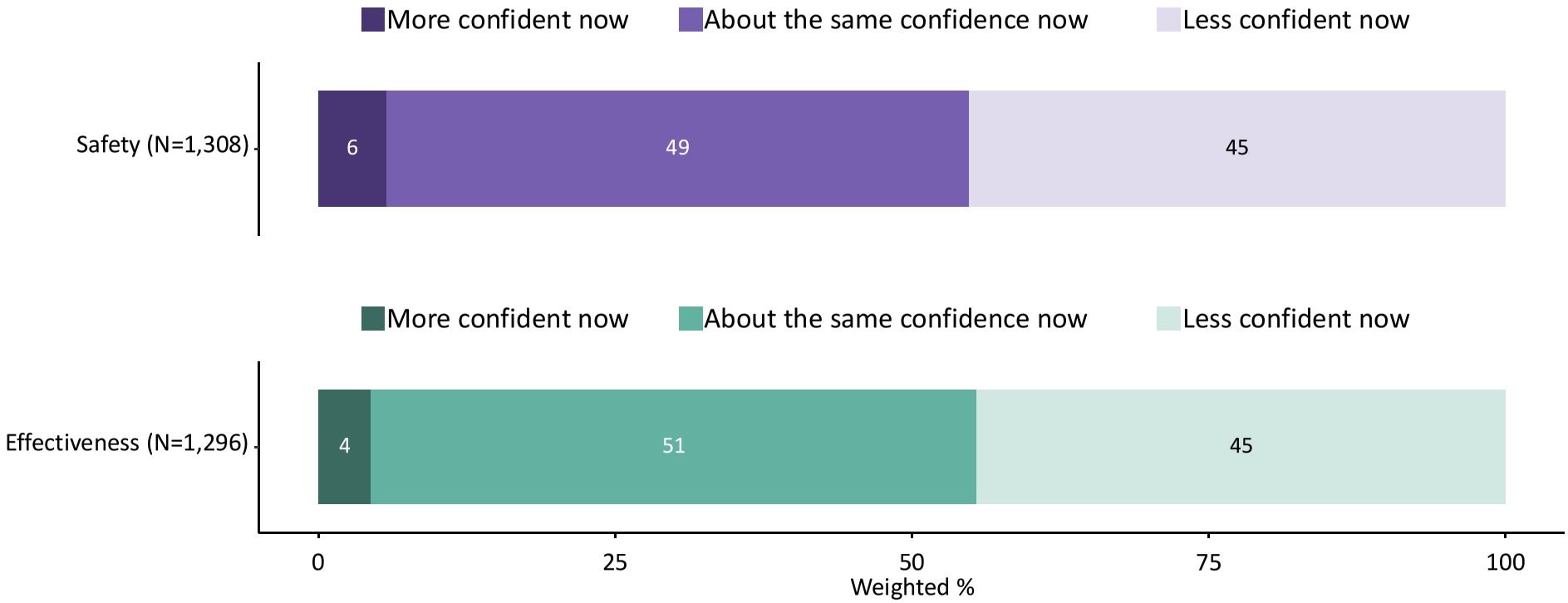
"Are you more or less confident in the safety/effectiveness of COVID-19 vaccines for children *now* compared to when they first came out?" Results Among Parents of Child Ages 0–17 Years Who Have Never Received a COVID-19 Vaccine, Omnibus Surveys, December 5, 2024—January 27, 2025



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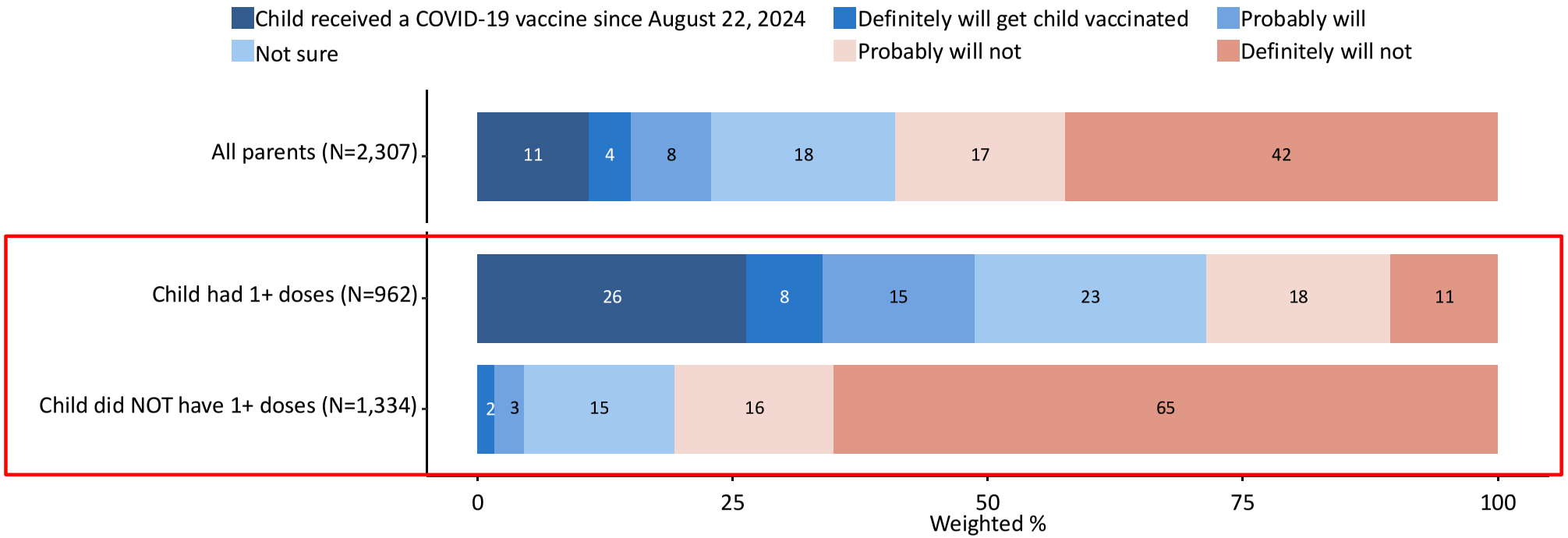
Child's 2024-2025 COVID-19 Vaccination Status And Parental Intent to Get Their Child Vaccinated, Results Among Parents of Children Ages 0–17 Years, by Receipt of Prior COVID-19 Vaccine(s), Omnibus Surveys, December 5, 2024–January 27, 2025 (N=2,312)



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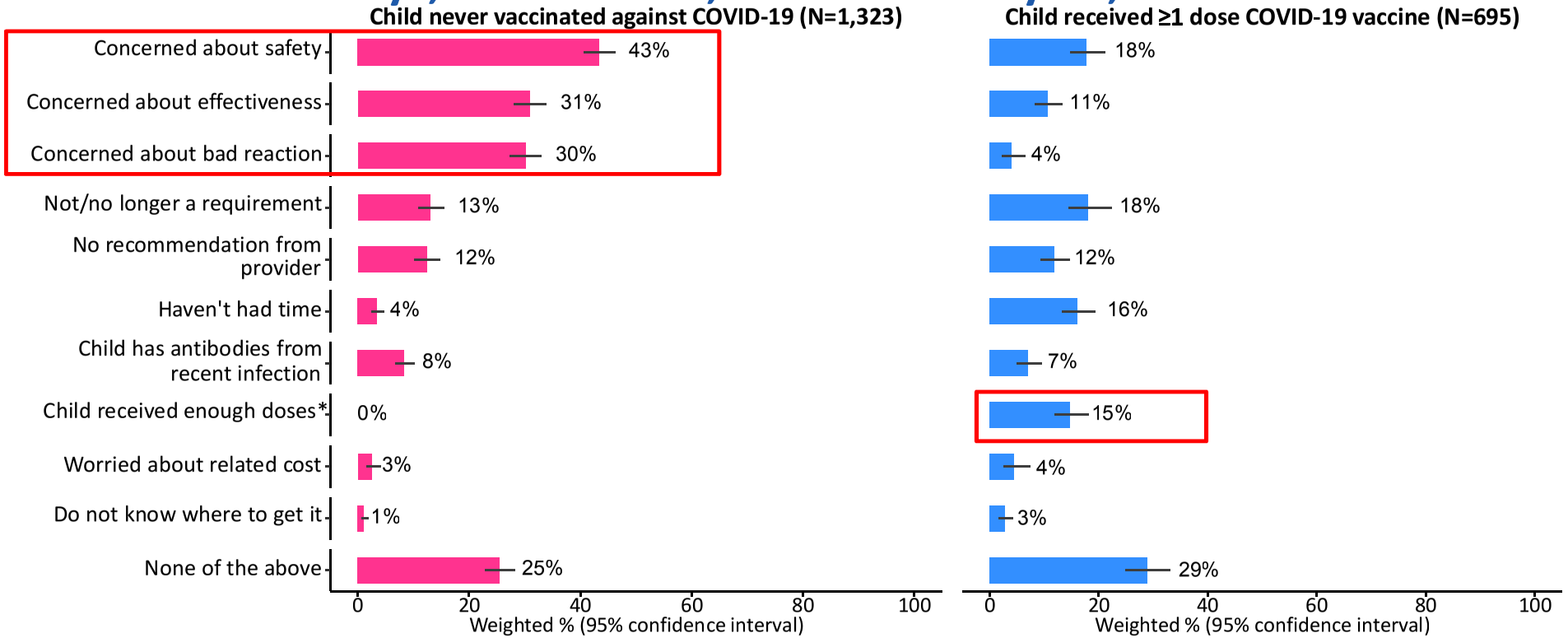
Reasons for Not Getting Child a 2024-2025 COVID-19 Vaccine, Among Parents of Child Ages 0–17, by Receipt of Prior COVID-19 Vaccine(s), Omnibus Surveys, December 5, 2024—January 27, 2025



*Option "Child received enough doses" only offered to parents of children who have received at least one dose of any COVID-19 vaccine.

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Recommendations in other countries

Summary of international COVID-19 booster* recommendations

	UK[1]	Canada[2]	Australia[3]	WHO	US
Older adults	**≥65 years:** 12 months **≥75 years and long-term care facility residents:** 6 months	**≥80 years and long-term care facility residents:** 6 months **65-79 years:** 12 months; *may receive every 6 months*	**≥75 years:** 6 months **≥65 years:** 12 months, *may receive every 6 months*	**Country dependent, often ≥75 or ≥80 years:** 6–12-month interval **Country dependent, often 50 or 60 years**: 12-month interval	**≥65 years:** 6 months
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* Booster refers to people who have already completed an initial series. For people who are unvaccinated, more doses may be needed than are shown in this table

** Adults and children at increased risk of SARS-CoV-2 exposure **or** severe COVID-19 disease.

*** Ideally during in the second trimester or at any opportunity

Italics indicate discretionary/shared clinical decision-making recommendations

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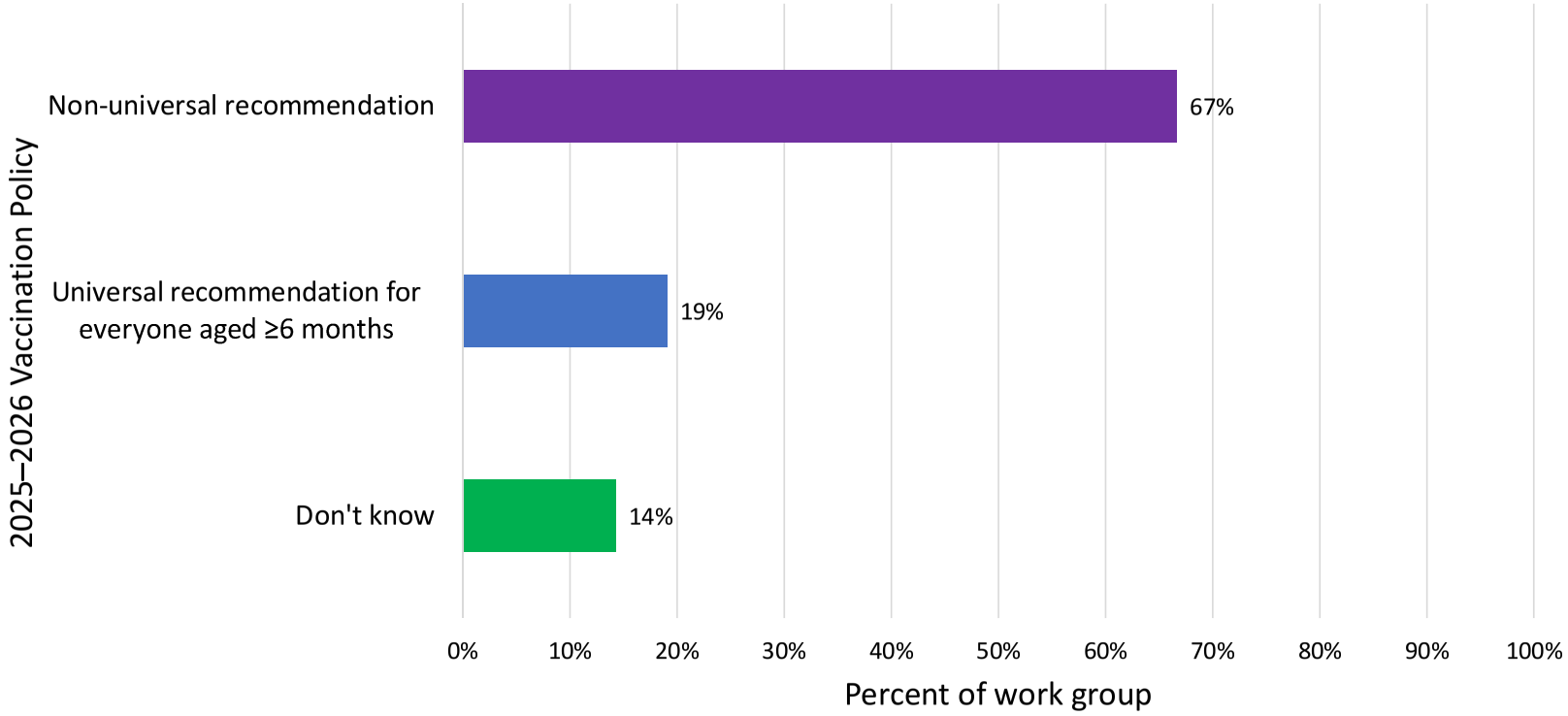
Work Group Interpretations

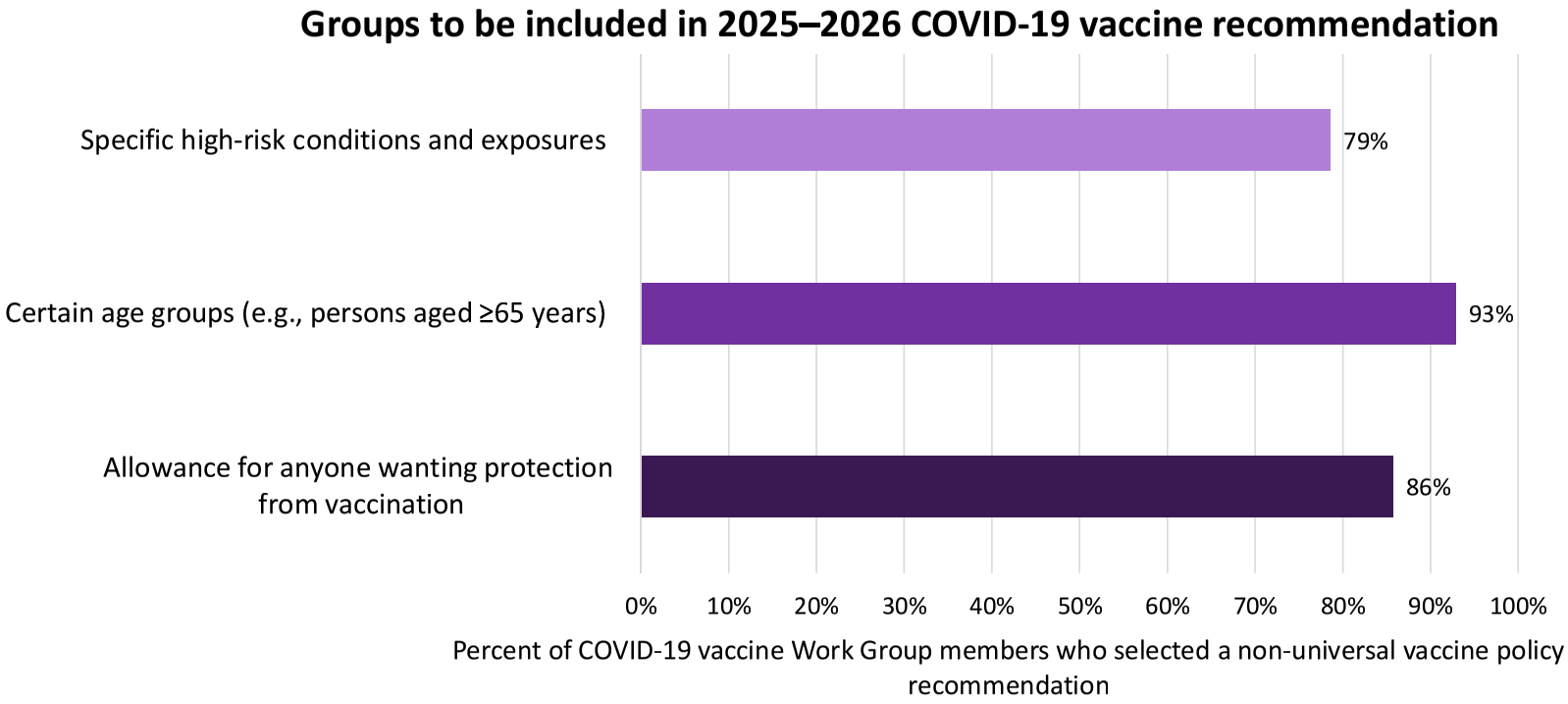
Initial Work Group interpretations

- When initially presented with 2025–2026 COVID-19 vaccine policy options in November 2024, the Work Group appreciated pros and cons of both risk-based and universal vaccine recommendations.
- At that time, there was not yet a consensus on what the recommendation for the 2025–2026 COVID-19 vaccine should be.
- The Work Group requested additional information to help inform the decision-making process on risk-factors for severe COVID-19, transmission and immunity, vaccine implementation and access, and cost-effectiveness.

When polled on February 13, 2025, the majority of the work group supported a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



When polled on February 13, 2025, the Work Group supported all non-universal policy options*



* More than one response option could be selected.

Additional data presented to the Work Group (March – April 2025)

- 2024-2025 COVID-19 vaccine effectiveness
- Seroprevalence of SARS-CoV-2
- Long COVID
- COVID-19 vaccine coverage update
- Multisystem Inflammatory Syndrome in Children (MIS-C)

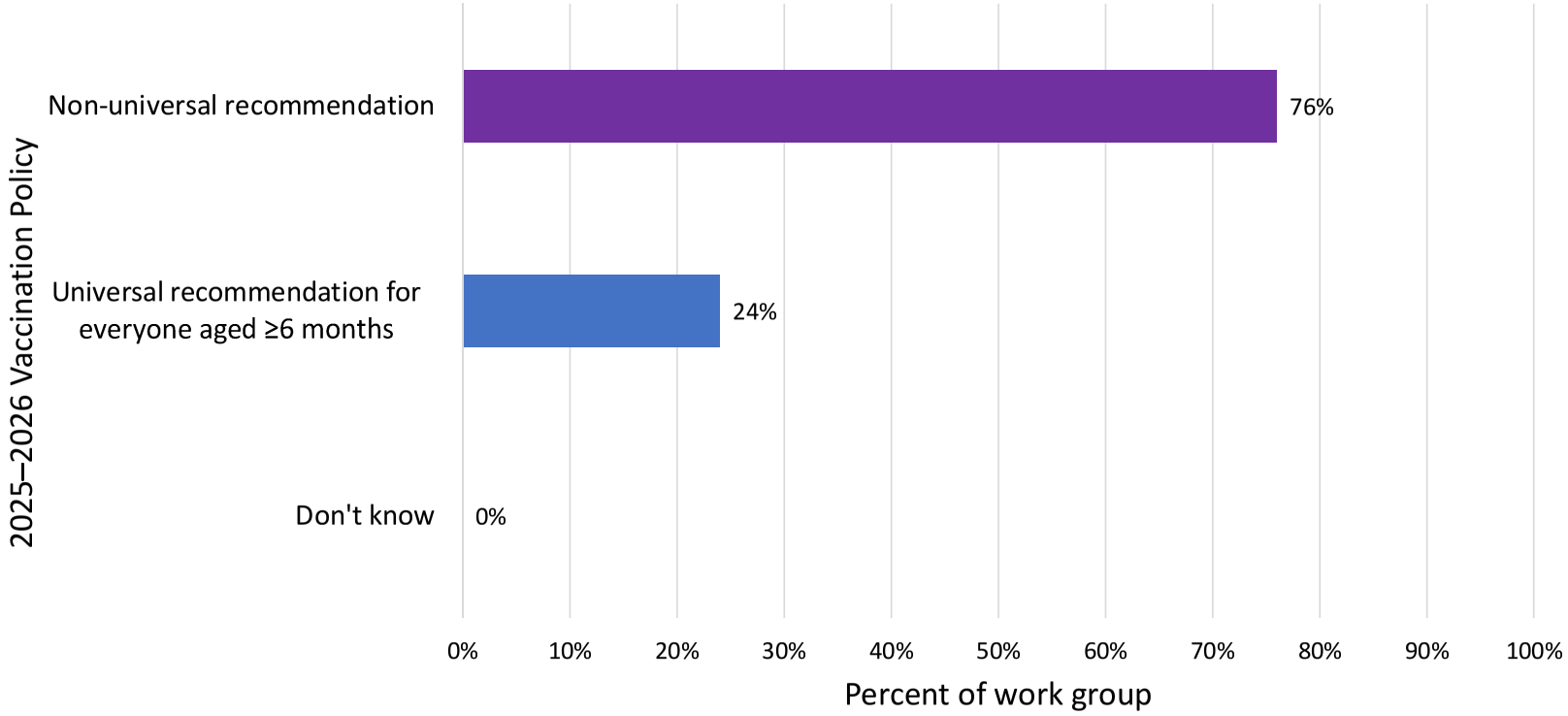
- Liaison feedback (see next slide)

Liaison feedback on a potential risk-based recommendation obtained from the following organizations (March – April 2025)

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- Association of Immunization Managers (AIM)
- American College of Physicians (ACP)
- American Pharmacists Association (APhA)
- American College of Obstetricians and Gynecologists (ACOG)

- Concerns were raised regarding implementation, communication, confidence in recommendations and equitable access to vaccination with a potential risk-based recommendation

When polled on April 3, 2025, the majority of the work group continued to support a non-universal (risk-based) recommendation for 2025–2026 COVID-19 vaccination



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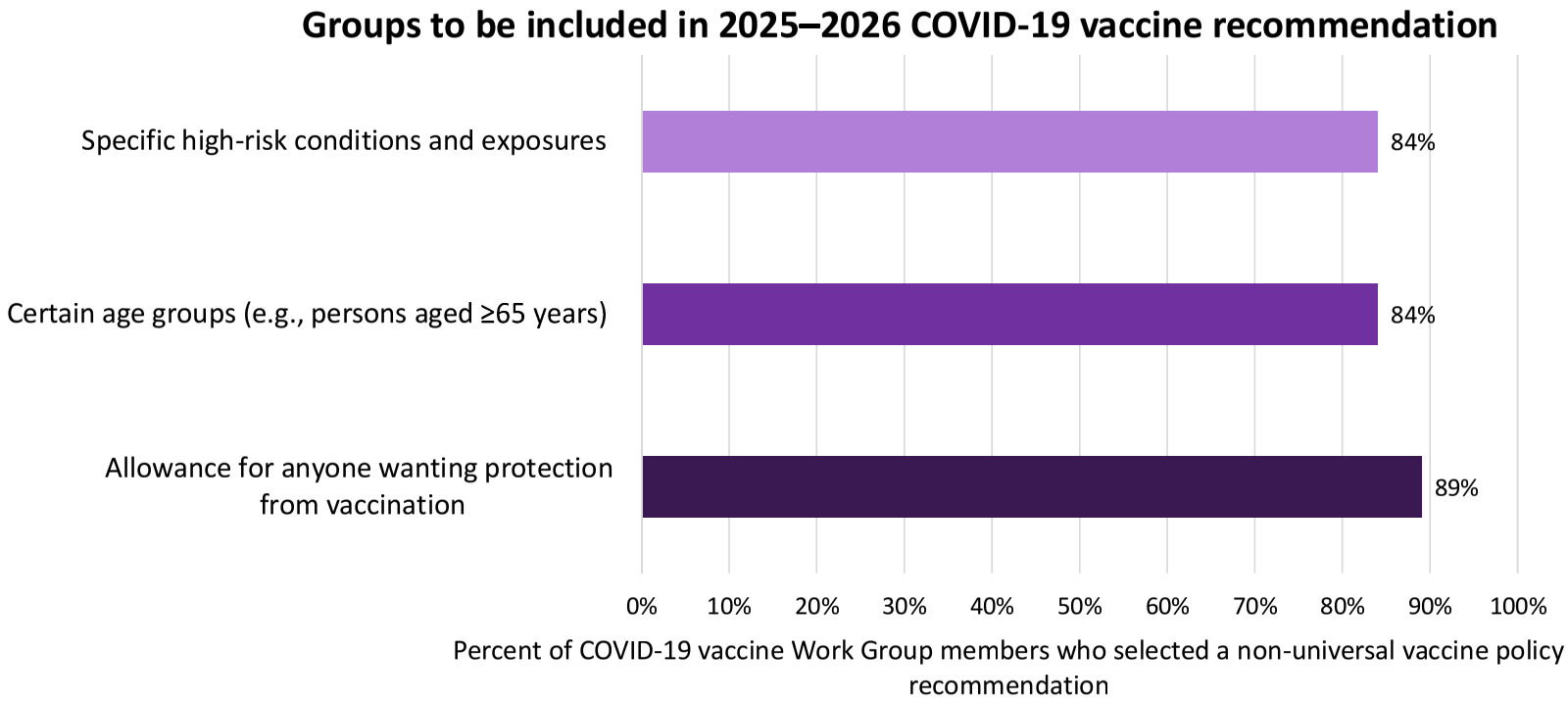
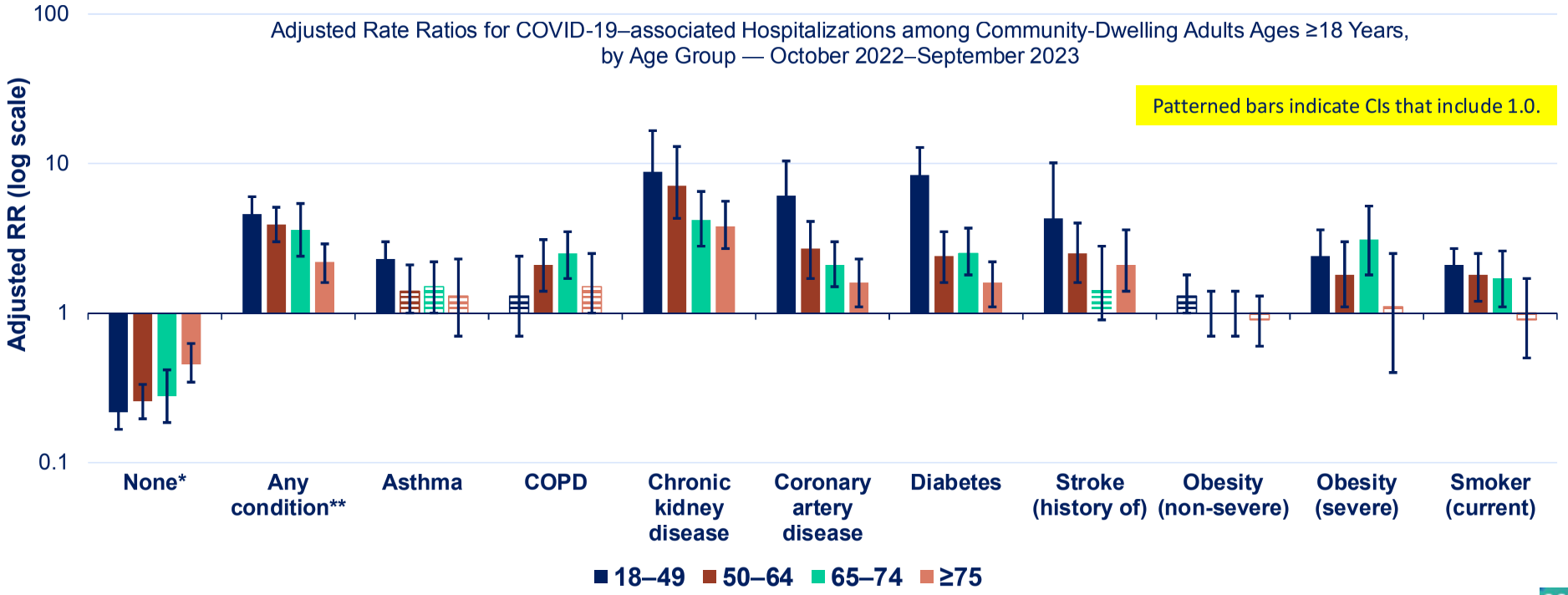
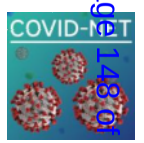


* More than one response option could be selected.

Risk for COVID-19–associated hospitalization is increased among community-dwelling adults ages ≥18 years with underlying medical conditions.



Abbreviations: RR, rate ratio; CI, confidence interval; COPD, chronic obstructive pulmonary disease.
* "None" refers to having none of the conditions examined in this analysis (asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking).
** "Any condition" refers to having at least 1 of these conditions. Notes: Non-severe obesity is defined as BMI 30–39kg/m². Severe obesity is defined as BMI ≥40kg/m². "Any condition" includes asthma, COPD, diabetes, chronic kidney disease, coronary artery disease, stroke, severe obesity, and current smoking. Rate ratios were estimated using multivariable Poisson models adjusted for sex, and race/ethnicity. "Smoker (current)" Includes people who quit smoking within the past 12 months. Data are limited to hospitalizations where COVID-19 is the likely reason for admission.



Discussion

- General thoughts on universal vs. risk-based recommendation for COVID-19 vaccination
  - Are there groups that clearly should **not** be recommended for vaccination with the 2025–2026 vaccine?
  - What data would be helpful in your decision making?
  - Is it still helpful to have a risk-based recommendation if most of the population (>74%) is considered “at risk”?
  - Should people at higher risk of infection and transmission (e.g., healthcare workers) be included in a risk-based recommendations?
- Will stable (i.e., universal) recommendations increase uptake with time?
- Concerns about implementation challenges with risk-based recommendations?
- Any potential unintended implications or consequences of a recommendation change?
- Are there key decision points we have not captured here?

Acknowledgements

- Lauren Roper
- Farida Ahmad
- Carla Black
- Kayla Calhoun
- Angela Campbell
- Mary Chamberland
- Nicole Dowling
- Jonathan Duffy
- Monica Godfrey
- Susan Goldstein
- Fiona Havers
- Jefferson Jones
- Ruth Link-Gelles
- Meredith McMorrow
- Sarah Meyer
- Pedro Moro
- Danielle Moulia
- Matthew Oster
- Hilda Razzaghi
- Sharon Saydah
- Sierra Scarbrough
- Zachary Schneider
- Benjamin Silk
- Christopher Taylor
- Natalie Thornburg
- Evelyn Twentyman
- Eric Weintraub
- Anna Yousef
- Coronavirus and other Respiratory Viruses Division
- COVID-NET Team
- Immunization Safety Office
- Immunization Services Division
- National Center for Immunization and Respiratory Diseases

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Electronic Record and Signature Disclosure: Accepted: 3/27/2025 9:07:33 AM ID: 5cb42f12-50ab-4347-9050-62ebc090a0c7		
Jennifer Cross JCross@ebglaw.com Legal Assistant Chicago Security Level: Email, Account Authentication (None)	COPIED	Sent: 3/2/2026 11:26:21 AM Resent: 3/2/2026 11:32:27 AM Viewed: 3/2/2026 11:33:00 AM
Electronic Record and Signature Disclosure: Not Offered via Docusign		

Carbon Copy Events	Status	Timestamp
Kathleen Barrett KBarrett@ebglaw.com Income Partner - Attorney Chicago Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 3/2/2026 11:26:21 AM

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ii. send us an email to docusignEBG@ebglaw.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

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EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

I, José R. Romero, M.D., FAAP, FIDSA, FAAAS, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge.

2. Attached hereto as Exhibit A is my current curriculum vitae ("CV"). I served on the Advisory Committee on Immunization Practices ("ACIP") from 2014 – 2021. (Ex. A., p. 11). I was the unofficial Vice Chair of the ACIP from 2015 – 2018. (*Id*., p. 10). I was Chair of the ACIP from June, 2018 through August 3, 2021. (*Id*., p. 9).

3. I am currently a member of the American Academy of Pediatrics ("AAP"), am a Fellow of the American Academy of Pediatrics (FAAP), and have been an AAP member since 1995. (*Id.*, p. 21).

4. I am currently a member of the Infectious Diseases Society of America ("IDSA"), am a Fellow of the Infectious Diseases Society of America (FIDSA), and have been an IDSA member since 1997. (*Id*., p. 21).

5. I am also a Fellow of the American Association for the Advancement of Science (FAAAS).

6. Per the ACIP Charter, ACIP members, including the Chair, "shall be selected by the Secretary and shall be invited to serve for overlapping terms of up to four years …" Attached hereto as Exhibit B are the two ACIP Charters that were in effect when I was Chair of the ACIP. They are identical. The ACIP Charter must be renewed every two years, as set forth in the "Termination" section on page 3: "[u]nless renewed by appropriate action, the ACIP will terminate two years from the date this charter is filed." The Federal Advisory Committee Act regulations (41 CFR § 102-3.60(b)(3)) provide that a Membership Balance Plan ("MBP") "must be uploaded to the FACA database when the agency files the Federal advisory committee act charter with" the General Services Administration. Attached hereto as Exhibit C are the ACIP's MBPs for 2018 and 2020, which are identical.

7. As set forth in the MBP, "[a]pplications for membership are reviewed in depth by the ACIP Steering Committee, which requires that interested applicants submit a current, complete CV and at least one letter of recommendation from a non-HHS source. The ACIP Steering Committee selects two proposed candidates for each vacant position based on the quality of the candidate's technical expertise, balance of specialty areas … and geographic distribution of recommended candidates." Attached hereto as Exhibit D is a schedule containing dates of ACIP Steering Committee meetings in the years 2018-2020. When I was Chair, the Steering Committee met in August to select nominees for ACIP membership (the "selection meeting"). The goal of the selection meeting was to select two candidates for each opening to send to the Secretary of Health and Human Services ("HHS Secretary") to make the final selection decision. When I was unofficial Vice Chair, I also participated in selection meetings of the Steering Committee.

8. The Steering Committee understood that it was required by regulation to follow the ACIP Charter and the MBP in selecting proposed candidates for the HHS Secretary's consideration.

9. Applications for ACIP membership were accepted "in a continuous process throughout the year." (Exhibit C, MBP § (6) CANDIDATE IDENTIFICATION PROCESS). At the selection meeting, the Steering Committee reviewed a master list of candidates in a spreadsheet that contained information on all candidates who had submitted applications. In our review of candidates, we paid close attention to the requirement that the ACIP be fairly balanced in a manner that was consistent with the ACIP's function of providing "advice and guidance to the Director, CDC, regarding the use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population." (Exhibit C, MBP § (3) MISSION/FUNCTION).

10. The most critical balance factor to consider was whether the candidate had the expertise to replace the expertise that was leaving the ACIP. Attached hereto as Exhibit E is an agenda for the ACIP Candidate Review Meeting of the Steering Committee on August 24, 2017, that identified the members who were rolling off of the ACIP and what their specialties were. As the document states, "we will aim to select candidates whose area of expertise/specialty/board certification is similar to that of outgoing members." Thus, if we knew we needed to replace an epidemiologist, we would identify the best two candidates who were epidemiologists. Another consideration we took into account was what we knew would be discussed at upcoming ACIP meetings. Thus, if we were aware that vaccines for those 65 and over would be discussed at upcoming ACIP meetings, we would take into account whether there were any physicians specializing in the care of the elderly in the candidate pool who met the qualifications in the Charter and MBP.

11. A second balance factor we considered was geographic balance. Ideally, the ACIP consisted of members from around the country.

12. The third balance factor that we considered was balance among the different medical disciplines who care for the civilian population, such as "pediatrics, internal medicine, family medicine, nursing, consumer representative, state health department expertise, public health" (Ex. C, MBP § (6) CANDIDATE IDENTIFICATION PROCESS).

13. We also made sure that each candidate whom we proposed to the Secretary satisfied at least one of the criteria stated in the MBP: "expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents; knowledge of vaccine development, evaluation, safety and delivery; or in the case of the consumer representative, knowledge about consumer perspectives and/or social and community aspects of immunization programs."

14. Attached hereto as Exhibit F is a .pdf copy of a spreadsheet (with names redacted) that summarized the ratings that the primary and secondary reviewers of the candidates gave to applicants for the term spanning the years 2020-2024.

15. The nomination package that was sent to the HHS Secretary consisted of two candidates for each position on the ACIP to be filled. Thus, as stated in Exhibit E, with four members rolling off of the ACIP, "[w]e will nominate one principal and one alternative nominee for each position, for a total of eight nominees. The nomination package will be sent to DHHS, through CDC/OD, for their decision regarding appointments."

16. When I served on the ACIP from 2014-2021, the Secretary of Health and Human Services never bypassed the selection procedure set forth in the MBP and made ACIP selections on his or her own.

17. When I was Vice Chair and Chair of the ACIP, the ACIP Steering Committee and ACIP Secretariat always followed the selection procedure set forth in the MBP to identify and select two nominees for each open seat on the ACIP. The Secretary never bypassed the ACIP Steering Committee to personally select the members of the ACIP when I was Vice Chair and Chair.

18. When I was Vice Chair or Chair of the ACIP, the Steering Committee never utilized the services of an outside law firm or any other outside consultant to vet candidates for the ACIP.

19. The ACIP is required by the Charter to have a "person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs." (Exhibit B). The community representative is a voting member and is on the ACIP to voice concerns about how a recommended vaccine will be received by the public. The community representative is on the ACIP to give voice to community views on vaccines, both for and against. However, it is my opinion, based on my years of service on the ACIP, that it is inappropriate to have an ACIP membership consist of a majority of members who have publicly stated views that are skeptical of, if not anti, vaccines, or to have members on the ACIP who are affiliated with anti-vaccine organizations. This is inconsistent and in conflict with the mission and function of the ACIP as set forth in the Charter and MBP.

20. I have read the Memorandum from Matthew Memoli, Principal Director, NIH, and Sara Brenner, Principal Deputy Commissioner, FDA, to the Secretary, dated May 12, 2025, with the subject "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age." I have also read the Memorandum from Tracy Beth Hoeg to Secretary Robert F. Kennedy, Jr., dated May 12, 2025, with the subject of COVID-19 vaccine safety in pregnant women. I also have reviewed the

Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women, dated May 19, 2025. Based on my years of service on the ACIP, I find both of these memos to be highly irregular, inappropriate, and a striking departure from the procedure that had been uniformly followed for decades on how the use of vaccines were recommended for inclusion in CDC's immunization schedules. When I was on the ACIP, I never experienced or heard of the Secretary obtaining an opinion and recommendation from an official at the NIH or the FDA to justify a unilateral change to the CDC's immunization schedules without going through the ACIP. I think it improper and detrimental for the healthcare system for any official from the NIH or FDA to intrude on the ACIP and the CDC's area of expertise in this manner and for the Secretary to make unilateral changes to the CDC's immunization schedule without following the process to make immunization recommendations that runs through the ACIP.

21. I am extremely concerned about the cumulative impact on America's healthcare system and the public's health of the individual actions Secretary Kennedy has taken with regard to the ACIP and the CDC's immunization schedules. It is my opinion, based on my years as a practicing pediatric infectious diseases subspecialist, pediatrician, and ACIP member, that Secretary Kennedy's departure from a trusted process—the ACIP making recommendations to the CDC Director of concerning how and which immunizations should be listed on CDC schedules—is causing harm in many different ways throughout the entire American healthcare system and to the public. Whether intentional or not, making unilateral changes to the CDC's immunization schedules and justifying those changes by questioning the safety of vaccines that have already gone through the FDA approval and licensure process as well as the ACIP recommendation process is stoking greater distrust and skepticism in the American public about vaccines, which is dangerous to every single resident of this country. The less people who are vaccinated, the more

infectious diseases will spread throughout the country and the world, and the more people will become seriously ill or die. The ongoing measles outbreaks in this country are unfortunate examples of what happens when vaccine skepticism and/or denial spreads throughout a community. In 2026, I have not heard Secretary Kennedy himself encourage people to get vaccinated against measles, which is one of the most contagious of infectious diseases. It is my opinion that the United States Secretary of Health and Human Services should be using his office to loudly and frequently encourage the American public to get vaccinated not just against measles, but in general.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on March 2, 2026, in Omaha, Nebraska.

Jose R. Romero, M.D.

José R. Romero, M.D., FAAP, FIDSA, FAAAS

EXHIBIT A

Updated 2.24.2026

CURRICULUM VITAE

Name:	José Rafael Romero
Address:	520 S. 36th CT Omaha, NE
E-mail:	Jose.Romero1955@iCloud.com
Date of Birth:	June 8, 1955
Place of Birth:	México D.F., MEXICO
Citizenship:	United States of America (Naturalized)

CONTENTS

ACADEMIC APPOINTMENTS

Primary Academic Appointments

7.1.2008–6.2.2022 Professor of Pediatrics (Tenured)
Pediatric Infectious Diseases Section
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

7.1.2008 Tenure conferred
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

7.1.2004–6.30.2008 Professor of Pediatrics (Tenured)
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Nebraska College of Medicine
Omaha, NE

7.1.2004–6.30.2008 Professor of Pathology and Microbiology
Department of Pathology and Microbiology
University of Nebraska College of Medicine
Omaha, NE

7.1.2001 Tenure conferred
Associate Professor of Pediatrics
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Nebraska College of Medicine
Omaha, NE

7.1.1998–6.30.2004 Associate Professor of Pathology and Microbiology
Department Pathology and Microbiology
University of Nebraska College of Medicine
Omaha, NE

7.1.1998–6.30.2004 Associate Professor of Pediatrics
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Nebraska College of Medicine
Omaha, NE

7.1.1993–6.30.1998 Assistant Professor of Pediatrics
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Nebraska College of Medicine
Omaha, NE

7.1.1993–6.30.1998 Assistant Professor of Pathology and Microbiology
Department Pathology and Microbiology
University of Nebraska College of Medicine

Omaha, NE

7.1.1992–6.30.1993 Assistant Professor of Pediatrics
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Colorado School of Medicine
Denver, CO

7.1.1991–6.30.1992 Instructor of Pediatrics
Section of Pediatric Infectious Diseases
Department of Pediatrics
University of Colorado School of Medicine
Denver, CO

4.1.1987–5.31.1989 Instructor of Pediatrics
Department of Pediatrics
School of Medicine,
State University of New York at Stony Brook
Stony Brook, NY

2.1.1979–1.31.1980 Clinical Instructor of Gastroenterology (Social Service)
Division of Gastroenterology
Department of Medicine
School of Medicine, Universidad Autónoma de Guadalajara
Guadalajara, Jalisco, MEXICO

Adjunct Academic Appointments

7.1.2008–6.30.2009 Adjunct Professor of Pediatrics
Department of Pediatrics
University of Nebraska College of Medicine
Omaha, NE

1.25.2005–6.30.2008 Adjunct Professor of Pediatrics
Department of Pediatrics
Creighton University School of Medicine
Omaha, NE

1.25.2005–6.30.2008 Adjunct Professor of Medical Microbiology and Immunology
Department of Medical Microbiology and Immunology
Creighton University School of Medicine
Omaha, NE

7.1.1998–1.24.2005 Adjunct Associate Professor of Pediatrics
Department of Pediatrics
Creighton University School of Medicine
Omaha, NE

7.1.1998 - 1.24.2005 Adjunct Associate Professor of Medical Microbiology and Immunology
Department of Medical Microbiology and Immunology
Creighton University School of Medicine
Omaha, NE

7.1.1993–6.30.1998 Adjunct Assistant Professor of Pediatrics
Department of Pediatrics
Creighton University School of Medicine
Omaha, NE

7.1.1993–6.30.1998 Adjunct Assistant Professor of Medical Microbiology and Immunology
Department of Medical Microbiology and Immunology
Creighton University School of Medicine
Omaha, NE

ADMINISTRATIVE APPOINTMENTS

6.5.2022–8.25.2023 Director
National Center for Immunization and Respiratory Diseases (NCIRD)
Centers for Disease Control and Prevention (CDC)
Atlanta, GA

8.5.2020–5.6.2022 Arkansas Secretary of Health
Cabinet Member
Governor Asa Hutchinson
Little Rock, AR

8.5.2020–5.6.2022 Director
Arkansas Department of Health
Little Rock, AR

8.12.1919–5.6.2022 Infection Prevention Physician
Conway Arkansas Human Development Center
Arkansas Department of Human Services
Little Rock, AR

7.17.2020–8.5.2020 Interim Secretary of Health
Cabinet Member
Governor Asa Hutchinson
Little Rock, AR

7.17.2020–8.5.2020 Interim Director
Arkansas Department of Health
Little Rock, AR

4.1.2020–8.5.2020 Chief Medical Officer
Arkansas Department of Health
Little Rock, AR

1.7.2011–5.31.2020 Clinical Advisor
Microbiology/Virology/Molecular Diagnostic Laboratories
Arkansas Children's Hospital
Little Rock, AR

7.1.2010–5.31.2020 Medical Director
Pediatric Infectious Diseases Clinics
Arkansas Children's Hospital
Little Rock, AR

7.1.2008–5.31.2020	Director Pediatric Infectious Diseases Section Department of Pediatrics University of Arkansas for Medical Sciences and Arkansas Children's Hospital Little Rock, AR
3.10.2020–3.31.2020	Infectious Diseases Consultant Arkansas Department of Health Little Rock, AR
7.1.2017–8.14.2019	Director Pediatric Infectious Diseases Fellowship Program Pediatric Infectious Diseases Section University of Arkansas for Medical Sciences Little Rock, AR
7.1.2008–6.30.2019	Director Clinical Trials Research Arkansas Children's Research Institute *(Formerly Arkansas Children's Hospital Research Institute)* Little Rock, AR
7.1.2008–6.30.2019	Medical Director Pediatric Clinical Research Unit Arkansas Children's Hospital and Arkansas Children's Research Institute *(Formerly Arkansas Children's Hospital Research Institute)* Little Rock, AR
9.7.2005–6.30.2008	Director Section of Pediatric Infectious Diseases Department of Pediatrics University of Nebraska Medical Center Omaha, NE
5.1.2001–6.1.2008	Medical Advisor Douglas County Health Department Omaha, NE
3.1.1999–6.30.2008	Director Pediatric Infectious Diseases Fellowship Program Division of Pediatric Infectious Diseases Departments of Pediatrics University of Nebraska Medical Center/Creighton University Omaha, NE
10.1.2002–10.31.2007	Director Latino Health-Related Research Affairs Minority Health Education and Research Office University of Nebraska Medical Center Omaha, NE

7.1.2006–2.28.2007 Director
Minority Health Education and Research Office
University of Nebraska Medical Center
Omaha, NE

7.1.2005–6.30.2006 Interim Director
Minority Health Education and Research Office
University of Nebraska Medical Center
Omaha, NE

1.1.2003–9.7.2005 Director
Combined Section of Pediatric Infectious Diseases
Departments of Pediatrics
University of Nebraska Medical Center/Creighton University
Omaha, NE

7.10.2001–12.31.2003 Chief Recruitment Officer for Latino Students
University of Nebraska College of Medicine
Omaha, NE

4.20.2001–2.28.2003 Interim Director
Combined Division of Pediatric Infectious Diseases
Departments of Pediatrics
University of Nebraska Medical Center/Creighton University
Omaha, NE

7.1.1998–12.31.2000 Co-Director
Medical Education
Children's Hospital
Omaha, NE

7.1996–2.28.1999 Associate Director
Pediatric Infectious Diseases Fellowship Program
Combined Division of Pediatric Infectious Diseases
Departments of Pediatrics
University of Nebraska Medical Center/Creighton University
Omaha, NE

CLINICAL APPOINTMENTS

3.1.2012–5.8.2022 Pediatric Tuberculosis Physician
Arkansas Health Department
Little Rock, AR

1998–5.31.2008 Volunteer Staff
OneWorld Community Health Center
(Formerly Indian-Chicano Health Center)
Omaha, NE

1.1990–6.30.1992 Attending Physician
Kids Care Clinic
Denver General Hospital
Denver, CO

COMMITTEE APPOINTMENTS: STATE, NATIONAL, AND INTERNATIONAL

State

6.15.2021–5.6.2022	Member Arkansas Cyber Advisory Council Office of the Governor Little Rock, AR
5.11.2021–5.6.2022	Member Arkansas American Rescue Plan Act of 2021 Steering Committee Office of the Governor Little Rock, AR
11.12.2020–5.6.2022	Member Governor's COVID-19 Winter Task Force Little Rock, AR
7.17.2020–5.6.2022	Member State Board of Health Arkansas Department of Health Little Rock, Arkansas
4.20.2020–8.5.2020	Co-Chair Arkansas Secretary of Health's COVID-19 Dental Advisory Group Arkansas Department of Health Little Rock, Arkansas
4.20.2020–8.5.2020	Member Governor's COVID-19 Test Capacity Working Group Little Rock, Arkansas
4.14.2020–8.5.2020	Member Governor's Medical Advisory Committee for Post-Peak COVID-19 Response Little Rock, Arkansas
2016–6.2022	Member Childhood Immunization Task Force/Workgroup Natural Wonders Partnership Council Little Rock, AR
8.2015–7.2018	Member Congenital Zika Subgroup Arkansas Department of Health Little Rock, AR
5.2015–6.2020	Chairman Vaccine Medical Advisory Committee Arkansas Department of Health Little Rock, AR
2008–6.2020	Member

Vaccine Medical Advisory Committee
Arkansas Department of Health
Little Rock, AR

3.7.2005–6.30.2008 Member
Governor's Pandemic Influenza Committee
Office of the Governor
Department of Health and Human Services System
State of Nebraska
Lincoln, NE

3.2004–5.01.2008 Member
Tuberculosis Advisory Committee
Department of Health and Human Services System
State of Nebraska
Lincoln, NE

8.2002–12.2004 Member
Ad Hoc Committee to Prioritize for Limited Smallpox Vaccination
Department of Health and Human Services System
State of Nebraska
Lincoln, NE

National

2024–Present Member
Committee on Infectious Diseases (COID)
American Academy of Pediatrics
Itasca, IL

2022–2023 Liaison
CDC National Center for Immunization and Respiratory Diseases to
Committee on Infectious Diseases (COID)
American Academy of Pediatrics
Itasca, IL

6.3.2021–8.25.22 Member
Committee on Infectious Diseases (COID)
American Academy of Pediatrics
Itasca, IL

2021–4.2022 Chair
United States Poliovirus National Certification Committee
Center for Vaccine Equity
The Task Force for Global Health
Decatur, GA

7.17.2020–5.6.2022 Member
Association of State and Territorial Heath Officers (ASTHO)
Arlington, VA

6.25.2020–5.6.2022 Member
ASTHO Infectious Diseases Policy Committee

Association of State and Territorial Heath Officers
Arlington, VA

4.7.2020–6.2.2022 Member
COVID-19 Vaccine Work Group
Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
Atlanta, GA

2.6.2020–2022 Member
Hilleman Lecture Selection Committee
CDC Foundation
Atlanta, Georgia

2.3.2020–5.1.2021 Member
Perinatal Infections Working Group
CDC/HRSA Advisory Committee (CHAC) on HIV, Viral Hepatitis and STDs Prevention and Treatment
Centers for Disease Control and Prevention

2020 Vice Chair
United States Poliovirus National Certification Committee
Center for Vaccine Equity
The Task Force for Global Health
Decatur, GA

9.4.2019–6.1.2022 Member
Pilot and Feasibility Selection Committee
U54 Congenital and Perinatal Infections Consortium (CPIC)
National Institutes of Health, Collaborative Antiviral Study Group

2019 Member
Acute Flaccid Myelitis Protocol Committee
National Institutes of Health, Collaborative Antiviral Study Group
Rockville, MD

5.6.2019 Participant (Invited)
HPV Vaccine Strategy Workshop
St. Jude's Children's Research Hospital
Memphis, TN

2018–8.3.2021 Liaison
Advisory Committee on Immunization Practices to
Board of Scientific Counselors
Centers for Disease Control and Prevention

6.2018–8.3.2021 Chairman
Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention
Atlanta, GA

2018–2020	Member Rabies Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2018	Liaison Advisory Committee on Immunization Practices to National Vaccine Advisory Committee (NVAC) United States Department of Health and Human Services
2017–2018	Member Mumps Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2016–8.3.2021	Member Steering Committee Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2017–2020	Member Hepatitis Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2015–4.2022	Member United States Poliovirus National Certification Committee Center for Vaccine Equity The Task Force for Global Health Decatur, GA
2017–2018	Chairman Hepatitis Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2015–6.2018	Vice Chairman Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2014–2019	Member Childhood and Adolescent Immunization Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA

2014–2018	Chairman Childhood and Adolescent Immunization Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2014–2019	Member Human Papilloma Virus Work Group Advisory Committee on Immunization Practices Centers for Disease Control and Prevention Atlanta, GA
2014–8.3.2021	Member Advisory Committee on Immunization Practices (ACIP) Centers for Disease Control and Prevention Atlanta, GA
5.30.2014–6.16.2014	Member* Committee on Infectious Diseases (COID) American Academy of Pediatrics Elk Grove Village, IL **Resigned due to conflict of interest with serving on the CDC Advisory Committee on Immunization Practices (ACIP) at request*
2009–2012	Member Step 1 Microbiology Test Material Development Committee (TMDC) United States Medical Licensing Examination Philadelphia, PA
8.2008–2012	Member Microbiology Test Committee National Board of Medical Examiners Philadelphia, PA
2.8.2011–1.31.2012	Chairman Vaccines and Related Biological Products Advisory Committee (VRBPAC) Center for Biologics Evaluation and Research (CBER) Food and Drug Administration (FDA)
2009–1.31.2012	Liaison Vaccines and Related Biological Products Advisory Committee to National Vaccine Advisory Committee (NVAC) United States Department of Health and Human Services
8.2007–1.31.2012	Member Vaccines and Related Biological Products Advisory Committee (VRBPAC) Center for Biologics Evaluation and Research (CBER) Food and Drug Administration (FDA)

9.22–23.2011	Consultant (Voting) Pediatric Advisory Committee to the Food and Drug Administration Food and Drug Administration (FDA)
7.7–8.2011	Participant (Invited) Anthrax Vaccine Workshop Anthrax Vaccine Working Group National Biodefense Science Board Washington, DC
5.17.2011	Consultant (Voting) Pediatric Advisory Committee to the Food and Drug Administration Food and Drug Administration (FDA)
2009–2010	Member Pediatric Musculoskeletal Conditions Strategic Planning Specialty Group United States Bone and Joint Decade
10.28–29.10	Consultant (Voting) Transmissible Spongiform Encephalopathies Advisory Committee Center for Biologics Evaluation and Research (CBER) Food and Drug Administration (FDA)
5.21–23.10	Member Respiratory Syncytial Virus Consensus Panel National Medical Association Washington, DC
2003–2005	Member American Board of Pediatrics Chapel Hill, NC
2002–2006	Member Natural History of Myocarditis in Children Study Protocol Design Team National Institutes of Health, Collaborative Antiviral Study Group
2001–2005	Member Infectious Diseases Credentials Committee American Board of Pediatrics Chapel Hill, NC
2000–2005	Member Pediatric Infectious Diseases Sub-Board American Board of Pediatrics Chapel Hill, NC
2000–2002	Associate Member American Board of Pediatrics Chapel Hill, NC

International

2025–Present	Vice-Chair Strategic Advisory Group Vaccine Preventable Diseases Pan American Health Organization/World Health Organization Washington, D.C.
10.30.2024–Present	Member Strategic Advisory Group Vaccine Preventable Diseases Pan American Health Organization/World Health Organization Washington, D.C.
8.1.2011–9.30.2011	Advisor Selection Committee Advisory Council of the Institute for Mexicans Abroad Mexican Ministry of Foreign Affairs
6.2008–9.2008	Member Selection Committee- Advisor Advisory Council of the Institute for Mexicans Abroad Mexican Ministry of Foreign Affairs
2002–2005	Policy Advisor Administration of Mexican President Vicente Fox Subcommittee on Health-Related Affairs Advisory Council of the Institute for Mexicans Abroad Mexican Ministry of Foreign Affairs

EDUCATION

Medical School 1974–12.10.1977	Universidad Autónoma de Guadalajara Guadalajara, Jalisco, MEXICO
High School 1969–1973	Bellarmine College Preparatory San Jose, California

POSTDOCTORAL TRAINING

7.21.2004	Strengths 101 The Gallop University Workshop Omaha, NE
1.22–23.2003	Smallpox Vaccine Adverse Event Workshop State Health Department Training Centers for Disease Control and Prevention Atlanta, GA
7.1.1991–6.30.1993	Fellow, Robert Wood Johnson Foundation Minority Medical Faculty Development Program Section of Pediatric Infectious Diseases Department of Pediatrics, University of Colorado School of Medicine,

Denver, Colorado

6.1.1989–6.30.1992 Clinical Fellow, PGY-9, PGY-10
Pediatric Infectious Diseases
Section of Pediatric Infectious Diseases, Department of Pediatrics,
University of Colorado School of Medicine,
Denver, CO

6.1.1989–6.30.1990 Research Fellow, PGY-8
Neurovirology Training Program
Section of Pediatric Infectious Diseases
Department of Pediatrics,
University of Colorado School of Medicine,
Denver, CO

7.1.1987–6.30.1989 Fellow, Robert Wood Johnson Foundation-
Minority Medical Faculty Development Program
Department of Pediatrics
School of Medicine
State University of New York at Stony Brook
Stony Brook, NY

7.1.1984–3.31.1987 Research Fellow, PGY-5, PGY-6, PGY-7
Molecular Microbiology
Departments of Microbiology and Pediatrics
School of Medicine
State University of New York at Stony Brook
Stony Brook, NY

7.1.1983–6.30.1984 Chief Resident, PGY-4
Department of Pediatrics, University Hospital,
School of Medicine, State University of New York at Stony Brook
Stony Brook, NY

7.1.1981–3.31.1983 Pediatric Resident, PGY-2, PGY-3
Department of Pediatrics, University Hospital,
School of Medicine, State University of New York at Stony Brook
Stony Brook, NY

7.1.1980–6.30.1981 Pediatric Intern, PGY-1
Department of Pediatrics, University Hospital,
School of Medicine, State University of New York at Stony Brook
Stony Brook, NY

3.24.1980–6.30.1980 Postdoctoral Research Associate
Surgery/Transplantation
State University of New York at Stony Brook
Stony Brook, NY

1.1.1978–12.31.1978 Rotating Internship
Centro Médico del Noroeste
Hermosillo, Sonora, MEXICO

DEGREES, CERTIFICATIONS, AND LICENSURES

11.26.2021	Collaborative Institutional Training Initiative (Record ID 44558247) Good Clinical Practical Good Clinical Practice Basic Course 1- Basic Course
12.16.2020	Pediatric Infectious Diseases Maintenance of Certification American Board of Pediatrics
2.12.2020	Collaborative Institutional Training Initiative (Record ID 34249791) Human Research- Biomedical Research 5- Refresher Course
11.28.2018	Collaborative Institutional Training Initiative (Record ID 28431473) Good Clinical Practical Good Clinical Practice Basic Course 2- Refresher Course
2.14.2017	Collaborative Institutional Training Initiative (Record ID 21345401) Human Research- Biomedical Research 4- Refresher Course
12.11.2015	Pediatric Infectious Diseases Maintenance of Certification American Board of Pediatrics
11.29.2015	Collaborative Institutional Training Initiative (Record ID 17890686) Good Clinical Practical Good Clinical Practice Basic Course Basic Course
1.31.2014	Collaborative Institutional Training Initiative (Record ID 11618086) Human Research- Biomedical Research 3- Refresher Course
1.25.2012	Collaborative Institutional Training Initiative (Record ID 6478630) Human Research- Biomedical Research 2- Refresher Course
11.10.2009	Collaborative Institutional Training Initiative (Record ID 3587114) Human Research- Biomedical Research 1- Basic Course
12.15.2008	Pediatric Infectious Diseases Sub-Specialty Board Recertification American Board of Pediatrics
10.3.2008	Arkansas State Medical License- Issued
9.5.2007	Collaborative Institutional Training Initiative (Record ID 1162990) Human Research: Group 1 Biomedical Investigator and Key Personnel 3- Refresher Course
5.14.2004	Collaborative Institutional Training Initiative (Record ID 630910)

	Human Research: Group 1 Biomedical Investigator and Key Personnel Basic Course
5.21.2000	Pediatric Infectious Diseases Sub-Specialty Board Recertification American Board of Pediatrics
11.15.1994	Pediatric Infectious Diseases Sub-Specialty Board Certification American Board of Pediatrics (Certificate No. 393)
11.1994	Elected Fellow Graduate College of the University of Nebraska, University of Nebraska Medical Center, Omaha, NE
7.28.1993	Nebraska State Medical License- Issued
10.12.1989	Colorado State Medical License- Issued
4.1.1988	Pediatrics Board Certification American Board of Pediatrics
4.30.1988	American Board of Pediatrics Oral Exam- Passed
9.12.1986	American Board of Pediatrics Written Exam- Passed
3.25.1985	New York State Medical License- Issued
12.6.1984	FLEX Examination- Passed
11.2.1983	ECFMG Certificate- Issued
6.25.1981	Mexican Medical License- Issued
1.21.1979	Mexican Medical Licensure Examination- Passed
12.10.1977	Médico Cirujano Universidad Autónoma de Guadalajara Guadalajara, Jalisco, MEXICO
7.27.1977	ECFMG Examination- Passed

AWARDS AND HONORS

2023	NHMA Government Award of the Year *'For outstanding leadership and service to the Hispanic community'* National Hispanic Medical Association Washington, DC
2022	Galardón Lic. Antonio Leaño Alvarez del Castillo Categoría: Salud 'Galardón otorgado por la Universidad Autónoma de Guadalajara a egresados que se han destacado de forma extraordinaria en los diversos ámbitos de la sociedad (investigación, educación, deporte, salud, medio ambiente, grandes trayectorias, arte y cultura, responsabilidad social)."

Universidad Autónoma de Guadalajara
Guadalajara, Jalisco, Mexico

The Galardón is bestowed by the Universidad Autónoma de Guadalajara to graduates who have distinguished themselves in an extraordinary manner in diverse areas of society (research, education, sports, health, environment, arts and sciences, social responsibility)

2021 Service Award
Chairman
Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
Atlanta, GA

2021 Ohtli Award
'*Ohtli Award recognizes individuals who have aided, empowered, or positively affected the lives of Mexican nationals in the United States and other countries.'*
Institute of Mexicans Abroad (Instituto de Mexicanos en el Extranjero)
Mexican Secretariat of Foreign Affairs (Secretaría de Relaciones Exteriores)

2021 Friends of Children Award
'Honoring the power of advocacy in improving the lives of children and families across the state'
Arkansas Advocates for Children and Families
Little Rock, AR

2021 American Association of Physicians of Indian Origin Award
'Honoring outstanding contribution and leadership for services to the state and nation'
AAPI Arkansas
Little Rock, AR

2021 2021 Influencers of the Year Award
'Each member of the 2021 class has influenced his or her field in significant ways.'
Arkansas Money and Politics
Little Rock, AR

2021 Leadership During the COVD-19 Pandemic
Arkansas STEM Festival
LISA Academy
Little Rock, AR

2020 2020 Change Champion Award,
'For leadership in making Arkansas a more equitable and inclusive state.'
Arkansas United

2020 Red Sash Award
Awarded by Senior Class to individual faculty members who "had the most significant input into their medical education."
Senior Medical School Class
University of Arkansas for Medical Sciences

Little Rock, AR

2019 Elected Fellow
American Association for the Advancement of Science

2019 Joan Cranmer Mentor of the Year Award, First Runner Up
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

2018 Letter of Commendation
From Arkansas Governor Asa Hutchinson for vaccine efforts
Little Rock, AR

2018 2018 CDC Childhood Immunization Champion Award, Arkansas,
Centers for Disease Control and Prevention Foundation (CDC) and National Center for Immunization and Respiratory Diseases (NCIRD)
Atlanta, GA

2016 Elected Fellow
Pediatric Infectious Diseases Society

2015 Elected Fellow
Infectious Diseases Society of America

2012 Red Sash Award
Awarded by Senior Class to individual faculty members who "had the most significant input into their medical education."
Senior Medical School Class
University of Arkansas for Medical Sciences
Little Rock, AR

2001–2020 Named to *Best Doctors in America*

2011 Service Award
Chairman
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research

2010 Service Award
Member
Vaccines and Related Biological Products Advisory Committee (VRBPAC)
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research

2009 Elected Member
American Pediatric Society

2008–2022 Horace C. Cabe Endowed Chair of Pediatrics
Department of Pediatrics, School of Medicine
University of Arkansas for Medical Sciences

Little Rock, AR

2008 Outstanding Academic Faculty Member Teaching Award
Pediatric Residency Program
Creighton/Nebraska Universities Health Foundation
Omaha, NE

2008 Nominated for Hobart E. Wiltse, MD, PhD Excellence in Medical Education Award
Nebraska-Creighton Universities Joint Pediatric Residency Program
Omaha, NE

2006 Included in *Who's Who in American Education*

2005 Nominated for Robert D. Sparks Award in Public Health and Preventative Medicine
University of Nebraska Medical Center and
University of Nebraska at Omaha
Omaha, NE

2005 Nominated for Golden Apple Teaching Award
School of Medicine- Creighton University
Omaha, NE

2005 Included in *Who's Who in Medical Sciences Education*

2004 Distinguished Service Award
The Nebraska Infection Control Network
State of Nebraska

2003 Elected Faculty Member
Alpha Omega Alpha National Honor Society
Alpha of Nebraska Chapter

2003 2003 Latinos on the Move Community Award
Human Relations Department
City of Omaha, NE

2003 Nominated for Hirschmann Prize for Teaching Excellence
University of Nebraska Medical Center
Omaha, NE

2002 2002 Milagro Award Recipient
Indian-Chicano Health Center
Omaha, NE

2002 Dr. Stephen A. Chartrand Memorial Award for Outstanding Faculty
Creighton-Nebraska Universities Joint Pediatric Residency Program
Omaha, NE

1999 Included in *Who's Who in Medicine and Healthcare*

1999	Nominated for Outstanding Investigator University of Nebraska Medical Center Omaha, NE
1996	Nominated for Golden Apple Teaching Award University of Nebraska Medical Center, Omaha, NE
11.1995	Charles A. Monasee Faculty Development Award Creighton University Omaha, NE
4.1995	Outstanding Faculty Teaching Award Departments of Pediatrics Joint Residency Program Creighton/Nebraska Universities Health Foundation Omaha, NE
1995	Elected Fellow American Academy of Pediatrics
6.11.1993	Gary Way Award for Outstanding Teaching 1992-1993 Department of Pediatrics, University of Colorado Denver, Colorado
7.1.1991–6.30.1993	Fellow, Minority Medical Faculty Development Program Robert Wood Johnson Foundation Princeton, NJ
7.1.1987–6.30.1989	Fellow, Minority Medical Faculty Development Program Robert Wood Johnson Foundation Princeton, NJ
2.2.1980	Outstanding Clinical Instructor, Department of Gastroenterology Universidad Autónoma de Guadalajara Guadalajara, Jalisco, MEXICO
12.31.1978	Outstanding Intern Centro Médico del Noroeste Hermosillo, Sonora, MEXICO
12.10.1977	Graduated Top 1% of Medical School Class Universidad Autónoma de Guadalajara Guadalajara, Jalisco, MEXICO

PATENTS

2.16.2010	Patent number: 7,662,939 Molecular determinants of tropism and virulence in enteroviruses
1999–2010	Provisional Patent Application No. 60/143,104 Molecular determinants of tropism and virulence in enteroviruses.

MEMBERSHIPS IN PROFESSIONAL SOCIETIES:

Alpha-Omega-Alpha National Honor Society (2003-Present)- Life Member
American Academy of Pediatrics (1995-Present) (#)
American Association for the Advancement of Science (1993-Present) (#)
American Board of Pediatrics (2000)
American Pediatric Society (2009-Present) (#)
American Society for Microbiology
American Society for Virology- Life Member
Arkansas Chapter, American Academy of Pediatrics (2009-Present)
Association for Academic Minority Physicians- Associate Member
Infectious Diseases Society of America (1997-Present) (#)
Nebraska Chapter, American Academy of Pediatrics (1994-2008)
National Hispanic Medical Association (2004)
Pan American Society for Clinical Virology (1996-Present)- Life Member
Pediatric Infectious Diseases Society (1996-Present) (#)
Section on Infectious Diseases, American Academy of Pediatrics (2007-Present)
Society for Advancement of Chicanos & Native Americans in Science- Life Member (#)
Society for Pediatric Research- Member (#)

STUDY SECTIONS, GRANT REVIEWER, SITE REVIEWER

2015 — Reviewer
CCTS Multidisciplinary Pilot Program- Study Section
University of Alabama at Birmingham Center for Clinical and Translational Science
Birmingham, AL

2015 — Reviewer
Children's University Medical Group (CUMG) Fund Grant Program
University of Arkansas for Medical Sciences
Little Rock, AR

6.23.2015 — Co-Chair
Special Emphasis Grant Review Panel:
IP11-0100501PPHF15: Enhanced Surveillance for New Vaccine Preventable Disease-A Program Expansion for Acute Respiratory Illness Surveillance
Centers for Disease Control and Prevention
Atlanta, GA

2014 — Reviewer
Vaccine Research Proposals
US Army Medical Research and Materiel Command (USAMRMC)
American Institute for Biological Sciences
Reston, VA

2004–2014 — Reviewer
Research Proposals
Viral and Rickettsial Diseases Panel:
Military Infectious Diseases Research Program (MIDRP)
United States Army Medical Research and Material Command
American Institute for Biological Sciences

Reston, VA

3.16.14 Member
Special Emphasis Grant Review Panel:
IP14-001: Effectiveness of Empiric Antiviral Treatment for Hospitalized Community Acquired Pneumonia during the Influenza Season
Centers for Disease Control and Prevention
Atlanta, GA

2013 Reviewer
Research Proposals
Communicable Diseases Public Health Research Grant (CD-PHRG)
National Medical Research Council
Ministry of Health
Singapore

2013 Reviewer
Research Proposals
Military Vaccine (MILVAX) Agency
American Institute for Biological Sciences
Reston, VA

4.19.12 Reviewer
American Heart Association

3.16.12 Member
Special Emphasis Grant Review Panel:
IP12-003 The Incidence of Community Associated Influenza and other Respiratory Infections in the United States
IP12-006 Epidemiology, Prevention and Treatment of Influenza and Other Respiratory Infections in Panama and Central America Regions
Centers for Disease Control and Prevention
Atlanta, GA

2012 Reviewer
VIDI programme (Innovational Research Incentive Scheme) 2011
The Netherlands Organization for Health Research and Development (ZonMw)
The Netherlands

2012 Reviewer
Abstracts- Infectious Diseases
Southern Society for Pediatric Research

7.26.11–11.15.11 Chairman
Site Visit- Laboratory of Method Development
Division of Viral Products
Office of Vaccines Research and Review (OVRR)
Center for Biologic Evaluation and Research
Food and Drug Administration

10.15–20.2011	Reviewer Abstracts- Infectious Diseases Southern Region Meetings
4.7.2011	Member Special Emphasis Grant Review Panel: IP11-003: Annual Estimates of Influenza Vaccine Effectiveness for Preventing Laboratory-Confirmed Influenza in the United States Centers for Disease Control and Prevention Atlanta, GA
6.15.2010	Member Special Emphasis Grant Review Panel: IP10-007: Effectiveness of Empiric Antiviral Treatment for Hospitalized Community-Acquired Pneumonia During Influenza Season Centers for Disease Control and Prevention Atlanta, GA
2010	Reviewer Research Proposals Military Vaccine (MILVAX) Agency American Institute for Biological Sciences
6.11–12.2009	Alternate Chair Site Visit- Laboratories of Retroviruses, Immunoregulation, and Respiratory Viruses FDA Laboratory Research Program Review Office of Vaccines Research and Review (OVRR) Center for Biologic Evaluation and Research Food and Drug Administration
3.2009–4.2009	Member Special Emphasis Grant Review Panels: Incidence & Etiology of Influenza Associated Pneumoniae in Hospitalized Persons (IP09-001) Virologic Evaluation of the Modes of Influenza Virus Transmission Among Humans (IP09-003) Centers for Disease Control and Prevention Atlanta, GA
2004–2009	Member Infectious Diseases Review Panel Congressionally Directed Peer Reviewed Medical Research Program United States Army Medical Research and Material Command American Institute of Biological Sciences
2006–2007	Co-Chairman MedImmune Pediatric Fellowship Grant Program MedImmune, Inc. Gaithersburg, MD
2004–2007	Reviewer

MedImmune Pediatric Fellowship Grant Program
MedImmune, Inc.
Gaithersburg, MD

9.21–22.2006 Member
USMLE Step 1 Standard Setting Panel
National Board of Medical Examiners
Philadelphia, PA

2005 Reviewer
Task Research Plans
Integrating Integrated Product Team (IIPT)
Military Infectious Diseases Research Project (MIDRP)
American Institute of Biological Sciences

2003 Reviewer
Research Proposals
Institute Pasteur
Paris, France

2001–2002 Reviewer
Abstracts- Infectious Diseases
Pediatric Academic Societies

2001 Site Reviewer
Department of Pediatrics Training Program External Review
Wayne State University/Children's Hospital of Michigan
Detroit, Michigan

1999 Reviewer
Research Proposals
South Dakota Health Research Foundation

1993 Study Section Member
Research leading to improved measles vaccine
National Institute of Allergy and Infectious Diseases
RFA: AI-93-06

MEETINGS ORGANIZED, CONVENOR, MODERATOR

2014 Member
Planning Committee
Pediatric Infectious Diseases Update
Arkansas Children's Hospital
Little Rock, AR

2009–2013 Chairman
Planning Committee
Pediatric Infectious Diseases Update
Arkansas Children's Hospital
Little Rock, AR

8.31.10	Member Planning Committee Faculty Development Conference: Ethics at the Beside and Benchside Arkansas Children's Hospital Little Rock, AR
9.8.09	Member Planning Committee Faculty Development Conference: Writing for Success Arkansas Children's Hospital Little Rock, AR
12.14–15.2007	Chairman Respiratory Syncytial Virus Managed Care Advisory Board MedImmune, Inc Washington, DC
10.10–11.2007	Co-Chairman Perspectives on Assessing the Value of RSV Prophylaxis MedImmune Advisory Board Chicago, IL
2.03.2006	Moderator Health Disparities: Cancer and Heart Disease Fifth Social Equity Leadership Conference National Academy of Public Administration Omaha, NE
10.10–11.2006	Co-Chairman Pediatric Infectious Diseases Advisory Board MedImmune Advisory Board Toronto, Canada
10.2005–3.2007	Co-Chairman Pediatric Infectious Diseases Advisory Board MedImmune, Inc. Gaithersburg, MD
9.25.2003	Moderator Education and Healthcare Challenges Facing Latino Immigrants Lunch and Learn Series Nebraska Medical Center Omaha, NE
11.12.2002	Moderator Enhancing Latino Participation in Clinical Trials Panel Discussion Third Annual Heartland Latino Leadership Conference Omaha, NE
1994-2001	Co-organizer Nebraska Intercampus Virology Conferences

9.4.2002 Moderator
Reaching Out to Our Minority Populations
Nebraska Rural Health Association Annual Conference
Kearney, NE

10.8.2000 Convener
Viral Pathogenesis/Host Resistance Session
Tenth Annual Nebraska Intercampus Virology Meeting
Mahoney State Park, NE

7.12.1999 Convener
Picornavirus Workshop.
18th Annual Meeting of the American Society for Virology,
University of Massachusetts, Amherst, MA

EDITORIAL BOARDS

2023–Present Editor
Principles and Practice of Pediatric Infectious Diseases
7th Edition
Elsevier

2025 Editor (Guest)
Vaccines
Pediatric Annals 2025

11.11.2009–11.11.2025 Medical Reviewer
UpToDate
www.uptodate.com

2023 Editor (Guest)
Vaccines
Pediatric Annals 2023:52(3);e81-e121

10.21.2021–1.1.2023 Member
Steering Committee on Vaccine Preventable Diseases
Medscape

2020 Editor (Guest)
Vaccines
Pediatric Annals 2020:49(12);e506-e542

2016–1.1.2025 Member
Editorial Board
Pediatric Annals

2009–1.1.2023 Member
Editorial Board
Infectious Diseases in Children

1999–2001 Medical Editor
eMedicine Pediatric Infectious Diseases
www.eMedicine.com

***AD HOC* JOURNAL REVIEWER:**

Previous Journals

Clinical Therapeutics
Clinical Infectious Diseases
Emerging Infectious Diseases
Journal of Clinical Virology
Journal of Pediatrics
Journal of the Pediatric Infectious Diseases Society
Pediatric Infectious Disease Journal
Ambulatory Pediatrics
American College of Physicians Medicine
Annals of Epidemiology
Archives of Pediatrics & Adolescent Medicine
Biotechniques
Canadian Journal of Microbiology
Clinical and Vaccine Immunology
Doody Publishing Book Review Service
Journal of Antimicrobial Agents and Chemotherapy
Journal of Clinical Investigation
Journal of Infectious Diseases
Journal of Pediatrics
Journal of Medical Virology
Journal of Virology
Journal of Virological Methods
Journal of Clinical Microbiology
Molecular and Cellular Probes
Pediatrics
Pediatric Research
The American Journal of Managed Care
Virus Research

CONSULTANT

5.6.24–Present Consultant
Vaxcyte- Pneumococcal vaccine

3.1.24–Present Consultant
Pfizer Advisory Boards- RSV, Pneumococcal, Lyme vaccines

10.30.2023 Consutant
Minervax- GBS vaccine

11.12.2021 Consultant
Sanofi-Pasteur Advisory Board

1.2015 Consultant
Astellas Pharma Global Development
Northbrook, IL

8.2012 Consultant
Dynavax Technologies
Berkeley, CA

3.12.2010	Consultant MedImmune, Inc. Gaithersburg, MD
7.2008–4.2009	Member Meningococcal Advisory Board Novartis
7.2006–6.2008	Consultant Mead Johnson & Company Evansville, Indiana
2004–2008	Medical Consultant Tuberculosis Control Program Department of Health and Human Services System State of Nebraska Lincoln, NE
2001–2008	Medical Consultant Nebraska Medicaid Department of Health and Human Services System, State of Nebraska Lincoln, NE
2003–2007	Pediatric Infectious Disease Advisory Board MedImmune, Inc. Gaithersburg, MD
10.2006–2007	Consultant Elan Pharmaceuticals, Inc. San Diego, CA
2006	Member Clinical Advisory Board Cepheid Sunnyvale, CA
2005	Member Advisory Board Impact of Implementing a Pertussis Booster GlaxoSmith Kline Research Triangle Park, NC
4.2005–2007	Member Advisory Council El SIDA Program Nebraska AIDS Project Omaha, NE
2002–2004	Member Pediatric National Advisory Board GlaxoSmith Kline Research Triangle Park, NC

2002–2005 Member
The Synagis® Outcomes Registry Advisory Board
MedImmune, Incorporated
Gaithersburg, MD

1995–2003 Consultant
ViroPharma, Incorporated
Exton, PA

UNIVERSITY SERVICE

12.2008–1.2019 Interviewer
Medical School Admissions Committee
University of Arkansas for Medical Sciences
Little Rock, AR

11.2014–2.2015 Member
Search Committee- President
Arkansas Children's Hospital Research Institute (ACHRI)
Little Rock, AR

2000–6.2008 Member
Graduate Medical Education Committee
College of Medicine
University of Nebraska Medical Center
Omaha, NE

8.2007–6.2008 Member
Diversity Advisory Steering Committee
University of Nebraska Medical Center and University of Nebraska at Omaha
Omaha, NE

8.2005–5.2008 Vice Chairperson
Institutional Biosafety Committee
University of Nebraska Medical Center and University of Nebraska at Omaha
Omaha, NE

11.2004–5.2008 Member
Institutional Biosafety Committee (UNMC/UNO Biosafety Committee)
University of Nebraska Medical Center and University of Nebraska at Omaha
Omaha, NE

7.2004–2006 Member
Nebraska Biocontainment Unit Advisory Committee
University of Nebraska Medical Center
Omaha, NE

2002–2007 Member
Continuing Medical Education Committee
University of Nebraska College of Medicine

Omaha, NE

2002–3.2008 Member
Institutional Review Board
University of Nebraska Medical Center
Nebraska Health System (University Hospital & Clarkson Hospital)
Omaha, NE

1998–3.2008 Member
Pharmacy and Therapeutics Committee
Nebraska Health System (University Hospital & Clarkson Hospital)
Omaha, NE

2002–2007 Member
Minority Health Research Group
University of Nebraska Medical Center
Omaha, NE

4.2005–12.2006 Member
Task Force on Research
Chancellor's NCACS Accreditation Steering Committee
University of Nebraska Medical Center
Omaha, NE

3.2005–6.2005 Chairman
Pain Management Fellowship Internal Review
Graduate Medical Education Committee
College of Medicine
University of Nebraska Medical Center
Omaha, NE

2004–2006 Member
Science and Technology Advisory Committee
University of Nebraska Medical Center
Omaha, NE

8.2003–11.2003 Chairman
Hematology/Oncology Fellowship Internal Review
Graduate Medical Education Committee
College of Medicine
University of Nebraska Medical Center
Omaha, NE

3.2001–6.2003 Member
Executive Cultural Competence Steering Committee
College of Medicine
University of Nebraska Medical Center
Omaha, NE

4.1996–2011.04 Member
Biosafety Committees
University of Nebraska Medical Center and

University of Nebraska, Omaha
Omaha, NE

9.2002–12.2002 Chairman
Minority Access to Research Subcommittee
Institutional Review Board
University of Nebraska Medical Center
Omaha, NE

12.2001–6.2004 Member
Bioterrorism Steering Committee
Nebraska Health System (University Hospital and Clarkson Hospital)
Omaha, NE

4.2001–6.2002 Member
Pediatric Department Chairperson Search Committee
Creighton University
Omaha, NE

10.2001–3.2002 Chairman
Pulmonary Fellowship Internal Review
Graduate Medical Education Committee
College of Medicine
University of Nebraska Medical Center
Omaha, NE

5.1998–8.1998 Member
Search Committee for Director of the Office of Student Equity and Multicultural Affairs
University of Nebraska Medical Center
Omaha, NE

2.1995–2.1998 Member
Pharmacy and Therapeutics Committee
University of Nebraska Medical Center
Omaha, NE

1993–1995 Member
Task Force on Culturally Competent Care
University of Nebraska Medical Center
Omaha, NE

1992–1993 Member
Minority Resident Recruitment Committee
School of Medicine, University of Colorado
Denver, CO

1987–1989 Member
Admissions Committee, School of Medicine
School of Medicine, Health Sciences Center,
State University of New York at Stony Brook
Stony Brook, NY

1986–1989 Member
University Health Service Advisory Board
State University of New York at Stony Brook
Stony Brook, NY

1983–1989 Member
House Staff Committee
University Hospital at Stony Brook,
State University of New York at Stony Brook
Stony Brook, NY

DEPARTMENTAL SERVICE

5.2009 –3.2020 Member
Promotion and Tenure Committee
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

7.2012–7.2013 Member
Chairman's Cabinet on Education
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

2001–6.2008 Member
Promotion and Tenure Review Committee
Department of Pediatrics
University of Nebraska Medical Center
Omaha, NE

8.1998–1.2001 Member
Tri-Institutional Education Committee
Children's Hospital, Creighton University &
University of Nebraska Medical Center
Omaha, NE

1992–1993 Coordinator of Medical Education
Section of Pediatric Infectious Diseases
University of Colorado
Denver, CO

1986–1989 Member
Residency Review Committee
Department of Pediatrics
School of Medicine State University of New York at Stony Brook
Stony Brook, NY

HOSPITAL SERVICE

11.1.2016–6.1.2020 Chair
Pharmacy and Therapeutics, Stewardship Committee
Arkansas Children's Hospital

Little Rock, AR

2015–6.1.2020 Member
Patient Care Oversight Committee
Arkansas Children's Hospital
Little Rock, AR

9.2011–6.1.2020 Member
Infection Control Committee
Arkansas Children's Hospital
Little Rock, AR

8.2008–6.1.2020 Member
Pharmacy and Therapeutics Committee
Arkansas Children's Hospital
Little Rock, AR

9.10.2015–2019 Member
Academic Conflict of Interest Committee
Arkansas Children's Research Institute
Little Rock, AR

3.2016–2017 Member
Computerized Practitioner Order Entry Order Set Approval Committee
Arkansas Children's Hospital
Little Rock, AR

10.2014–3.2015 Member
Search Committee
President of the Arkansas Children's Hospital Research Institute
Arkansas Children's Hospital Research Institute
Little Rock, AR

7.2012–2015 Member
Outreach Workgroup
Arkansas Children's Hospital
Little Rock, AR

8.2009–2014 Member
Influenza Task Force
Arkansas Children's Hospital
Little Rock, AR

5.2010–6.2012 Pediatric Representative
Medical Staff Executive Committee
Arkansas Children's Hospital
Little Rock, AR

8.12.2008–9.30.2011 Member
ACHRI Scientific Advisory Committee
Arkansas Children's Hospital Research Institute
Little Rock, AR

1.2006–2.2008 Member
Medical Executive Committee
Children's Hospital
Omaha, NE

2.1997–2.2008 Chairman
Pharmacy and Therapeutics Committee
Children's Hospital
Omaha, NE

1.1995–2.2008 Member
Pharmacy and Therapeutics Committee
Children's Hospital
Omaha, NE

12.1994–2.1996 Member
Febrile Infant Task Force Committee
Children's Hospital
Omaha, NE

1988–1989 Member
Infection Control Committee
University Hospital at Stony Brook,
State University at Stony Brook
Stony Brook, NY

COMMUNITY SERVICE

Active

1.7.2025–Present Member At Large
Blackstone Homeowners Association
Omaha, NE

5.1999–Present Executive Director, President, and Founder
Foundation for Molecular Virology Research
Omaha, NE

Previous

12.2010–10.1.2024 Commissioner
River Ridge Pointe Improvement District
Little Rock, AR

6.1997–5.2008 Co-Founder and Health Care Provider
Tuberculosis Clinic
Indian-Chicano Clinic (The OneWorld Community Health Center)
Omaha, NE

2006–4.2008 Member
Planning, Allocation and Community Development Cabinet
United Way of the Midlands
Omaha, NE

3.2004–4.2008	Member Board of Directors United Way of the Midlands Omaha, NE
3.2003–4.2008	Member Board of Directors The OneWorld Community Health Center Omaha, NE
11.2005–2.2008	Member Board of Directors Catholic Charities Omaha, NE
3.2005–3.2006	Ex-officio President Board of Directors Chicano Awareness Center Omaha, NE
10.27.2005	Member Rx for Kids: Nebraska Connects Panel Nebraska Educational Television Lincoln, NE
3.2001–2.2005	President Board of Directors Chicano Awareness Center Omaha, NE
3.2000–3.2001	Vice-President Board of Directors Chicano Awareness Center Omaha, NE
2.1999–2.2005	Member Board of Directors Chicano Awareness Center Omaha, NE
12.2001–4.2004	“Health Watch” Physician KETV Channel 7 Omaha, NE
4.2002–9.2002	Member Search Committee for Medical Director Douglas County Health Department Omaha, NE
11.02.2001	Master of Ceremonies Heartland Latino Leadership Conference

Omaha, NE

2.1997–12.2000 Member
United Latino Endowment Scholarship Committee
Omaha, NE

1997–2000 Speaker
"Careers in Medicine"- Career Speaking Program
Omaha Job Clearinghouse, School-To-Career Program
South High School, Omaha, NE (Program terminated)

1994–1996 Mentor
Summer Research Enrichment Program
University of Nebraska Medical Center
Omaha, NE (Program terminated)

1993–1996 Mentor
The Minority and Women Health Research Initiative
University of Nebraska Medical Center
Omaha, NE (Program terminated)

1987–1989 Medical Advisor
The Committee on Special Education-
AIDS Related Issues
Connetquot Central School Districts of Islip and Miller Place
Long Island, NY

TEACHING ACTIVITIES

Courses Co-Organized:

1995–1999 The Molecular Biology of Viruses-PAMM 890
University of Nebraska Medical Center
Omaha, NE

Lecturer:

Active

2016–Current Brain and Behavior-
"Bacterial Meningitis"
College of Medicine
University of Arkansas for Medical Sciences
Little Rock, AR

2014–Current Brain and Behavior-
"Enteroviruses"
College of Medicine
University of Arkansas for Medical Sciences
Little Rock, AR

Previous

2008–2014 Medical Microbiology and Immunology- IDW 226
"Enteroviruses"
College of Medicine

University of Arkansas for Medical Sciences
Little Rock, AR

2010 Applied Pharmacology for Advanced Practice Nurses- NRSG 883
College of Nursing
University of Nebraska Medical Center
Omaha, NE

2005–2008 Management of the High Risk Neonate – COM NRSG 831
"Early Onset Neonatal Infections"
College of Nursing
University of Nebraska Medical Center
Omaha, NE

2005–2008 Management of the High Risk Neonate – COM NRSG 831
"Neonatal Herpes Simplex and Enteroviral Infections"
College of Nursing
University of Nebraska Medical Center
Omaha, NE

2002–2008 Clinical Research Symposium for Fellows
University of Nebraska Medical Center
Omaha, NE

2000–2008 Pulmonary/Endocrine Core Course - M-ID 641
"Pediatric Respiratory Tract Viral Infections"
College of Medicine
University of Nebraska Medical Center
Omaha, NE

1997–2008 Introduction to Disease Processes - M-ID 630
"Vial Exanthems"
College of Medicine
University of Nebraska Medical Center
Omaha, NE

1996–2008 Applied Pharmacology for Advanced Practice Nurses – NU 883
College of Nursing
University of Nebraska Medical Center
Omaha, NE

1996–2008 Neurology/Ophthalmology/Psychology - Core 7 Course
College of Medicine
University of Nebraska Medical Center
Omaha, NE

1993–2008 Microbiology and Pathology - M-ID-630
"Bacterial Meningitis and Brain Abscess"
College of Medicine
University of Nebraska Medical Center
Omaha, NE

1993–2008	Microbiology and Pathology - M-ID-630 "Viral Encephalitis and Meningitis" College of Medicine University of Nebraska Medical Center Omaha, NE
1993–2008	Pediatric Clerkship Combined Department of Pediatrics Creighton University and University of Nebraska Medical Center Omaha, NE
1997–2006	Infectious Disease System (Inter-Departmental) - IDC 233 "Picornaviruses and Their Diseases" Creighton University School of Medicine Omaha, NE
2002–2005	Speaker- Cultural Competency Workshop for the Health Professional Rural Health Education Network University of Nebraska Medical Center Omaha, NE
2000–2005	Advanced Pediatric Course – PDT 473 Creighton University School of Medicine Omaha, NE
2000–2005	Pediatric/Aging Core Course – IDC 231 Creighton University School of Medicine Omaha, NE
2003	Public Health & Bioterrorism/Related Disasters Course Masters in Public Health Program University of Nebraska Medical Center and University of Nebraska at Omaha Omaha, NE
2000	Introduction to Computational Molecular Biology - PAMM 950B University of Nebraska Medical Center Omaha, NE
1993–1997	Medical Microbiology and Immunology - MIC 221 Creighton University School of Medicine Omaha, NE
1992	Plagues, People, and Microorganisms - MCDB 1030 University of Colorado at Boulder Boulder, CO
1989–1993	Infectious Diseases Child Health Associate Program, University of Colorado Health Sciences Center Denver, CO

1987–1989 Medical Microbiology
Department of Microbiology, School of Medicine,
State University of New York at Stony Brook
Stony Brook, NY

1987–1989 Developmental Physiology of the Perinatal Period
Department of Pediatrics, School of Medicine,
Health Sciences Center, State University of New York at Stony Brook
Stony Brook, NY

1986–1989 Newborn Intensive Care Unit Nursing Orientation
University Hospital at Stony Brook,
State University of New York at Stony Brook
Stony Brook, NY

1985–1989 Clinical Pharmacology for Graduate Nurses (HBH 535)
Department of Pharmacological Sciences,
Health Sciences Center, State University of New York at Stony Brook
Stony Brook, NY

1983–1989 Clinical Medicine Course- Pediatric Unit
Physician's Assistant Program, School of Allied Professions
Health Sciences Center, State University of New York at Stony Brook
Stony Brook, NY

1983–1989 Pediatric Intensive Care Lecture Series
Department of Pediatrics, School of Medicine,
Health Sciences Center, State University of New York at Stony Brook
Stony Brook, NY

1982–1989 Pediatric Year III Clerkship Lectures
Department of Pediatrics, School of Medicine,
Health Sciences Center, State University of New York at Stony Brook
Stony Brook, NY

Preceptor:

1984–1989 Pediatric Year III Clerkship
Outpatient Care
Coram Health Center
Coram, New York

1980–1989 Introduction to Clinical Medicine- Pediatric Session Group
School of Medicine, Health Sciences Center,
State University of New York at Stony Brook
Stony Brook, NY

SUPERVISION OF GRADUATE/UNDERGRADUATE STUDENTS, FELLOWS, RESIDENTS

Residents- University of Arkansas for Medical Sciences:

2020–2021 Ehssan Faraji, MD (Chief Resident, Pediatrics)
Fellowship advisor
(Pediatric Cardiology Fellowship, Children's Hospital of Philadelphia)

2019–2020 Ashleah Courtney, MD (Resident, Pediatrics)
Fellowship advisor
(Pediatric Infectious Diseases Fellowship)

2018–2019 Sarah A. Auerbach, DO (Resident, Pediatrics)
Fellowship advisor
(Pediatric Infectious Diseases Fellowship, University of Michigan)

Graduate Students- University of Nebraska Medical Center

2006–8.2009 Anthony R. Sambol, MA, SM (NRM), SV (ASCP), CBSP (ABSA)
Graduate program advisor (Doctor of Philosophy Degree)
Medical Science Interdepartmental Area
(Withdrew from program)

1999–2002 Shelton Bradrick, PhD (Doctoral Studies in Pathology/Microbiology)
Graduate studies advisor
Supervision of dissertation research and thesis
(Degree conferred)

2001 Zachary Boyd, BS (Masters Studies in Pathology/Microbiology)
Graduate studies advisor
Supervision of dissertation research and thesis
(Withdrew from program)

1996–2000 James J. Dunn, PhD (Doctoral Studies in Pathology/Microbiology)
Graduate studies advisor
Supervision of dissertation research and thesis
(Degree conferred)

1996–1998 Elizabeth Lieben, MS, MD (Masters Studies in Pathology/Microbiology)
Graduate studies advisor
Supervision of dissertation research and thesis
(Degree conferred)

Fellows and Residents- University of Nebraska Medical Center:

2001–2003 Jason G. Newland, MD (Resident, Pediatrics)
Research advisor and sponsor
Supervision of research funded by AAP Resident Research Grant
(Residency completed)

2001–2003 Meera Varman, MD (Fellow, Pediatric Infectious Diseases)
Research advisor
Supervision of research project
(Fellowship completed)

1994–1995 Donald Winters, MD (Resident, Pediatrics)
Research advisor and sponsor
Recipient of the George Myazaki Award for Research
(Residency completed)

Medical Students

2014–2016 Blake Haller
Research advisor
College of Medicine Honors Research Program
University of Arkansas for Medical Sciences
Little Rock, AR

Undergraduate Students- Nebraska Wesleyan University:

1999–2001 Elizabeth A. Bures (Undergraduate studies)
Research advisor
Supervision of Howard Hughes Foundation funded research project
(Undergraduate degree conferred; Medical degree conferred)

THESIS COMMITTEE MEMBER

University of Nebraska Medical Center:

2006–8.2009 Anthony R. Sambol, MA (Doctor of Philosophy Degree)

1999–2002 Shelton Bradrick, BS (Doctoral Studies in Pathology/Microbiology)

2001–2002 Jason Glanzer (Doctoral Studies student in Pharmacology)

2001 Zachary Boyd, BS (Masters Studies in Pathology/Microbiology)

1996–2000 James J. Dunn, BE, BSMT (Doctoral Studies in Pathology and Microbiology)

1996–1998 Elizabeth Lieben, BA (Masters Studies in Pathology/Microbiology

1995–1999 Sandra Willian (Doctoral Studies student in Pathology/Microbiology)

1994–1997 Anna Reglan (Master's Studies in Pathology/Microbiology Master's Thesis)

Creighton University:

1.1995–6.1996 Rauzatullah Waheed (Doctoral Studies Medical Microbiology/Immunology)

PRECEPTOR/MENTOR- MEDICAL STUDENTS

University of Nebraska Medical Center:

2006–2008 Chantal Afuh (Longitudinal Clinical Experience Course)

2006–2008 Daniel Smith (Longitudinal Clinical Experience Course)

8.2005–3.2006 Marie Belin (PBL Course)

2004–2006 Roni Jacobsen (Longitudinal Clinical Experience Course)

FELLOW RESEARCH OVERSIGHT COMMITTEE

University of Arkansas for Medical Sciences

2015–2018 Matthew Digman, MD (Pediatric Emergency Medicine Fellow)

FACULTY MENTORING COMMITTEES

Chairman

2017–2018 T. Andrew Burrow, M.D.
Division of Genetics/Metabolism
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

2016–2019 Sukesh Sukumaran, MD, DPMR, FACR
Section of Rheumatology
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR
(Early Promotion and Tenure granted)

Member

2016–2017 Jason Farrar, MD
Division of Hematology/Oncology
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR

2013–2016 Yuri A. Zarate, MD
Division of Genetics/Metabolism
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR
(Early Promotion and Tenure granted)

2013–2015 Elizabeth M. McDonough, MD
Division of Pediatric Gastroenterology, Hepatology, and Nutrition
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR
(Moved to new institution prior to review for Promotion and Tenure)

2009–2011 Ronald Saunders, MD
Critical Care Section
Department of Pediatrics
University of Arkansas for Medical Sciences
Little Rock, AR
(Promotion to Associate Professor and Tenure conferred)

PUBLICATIONS

228. *Auerbach S,* ***Romero JR****. Aseptic and Viral Meningitis. In: Kimberlin D, Prober CG, Ratner AJ, Romero JR (eds). Principles and Practice of Pediatric Infectious Diseases, 7th Edition. Philadelphia: Elsevier; XXXXZ. pp. XXX-XXX. In editorial review.*

227. **Committee on Infectious Diseases***. Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents: Policy Statement. Pediatrics. **2025**;156:e2025073924. *PMID: 40826495*. ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

226. **Committee on Infectious Diseases***. Recommendations for the Prevention of RSV Disease in Infants and Children: Policy Statement. Pediatrics. **2025**;156:e2025073923. *PMID: 40826311.* ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

225. Acosta EP, Aban I, Ryan KJ, Sánchez PJ, Rodriguez CA, **Romero JR,** Sood SK, Abughali N, Arav-Boger R, DeBiasi RL, Storch GA, Vanchiere JA, Peri K, Whitley RJ, Kimberlin DW. Dosing in Premature Infants Receiving Treatment for Congenital Cytomegalovirus Infection: Results of a Prospective Pharmacokinetic Study. J Infect Dis. **2025** Oct 10:jiaf528. doi: 10.1093/infdis/jiaf528. Epub ahead of print. *PMID: 41071930.*

224. Hackell JM, Brothers K, Bode S, Costello LM, Kafer LM, O'Leary ST; Committee on Practice and Ambulatory Medicine; **Committee on Infectious Diseases***; Committee on State Government Affairs; Council on School Health. Medical vs Nonmedical Immunization Exemptions for Child Care and School Attendance: Policy Statement. Pediatrics. **2025**;156:e2025072714. *PMID: 40716772.* ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

223. **Committee on Infectious Diseases***. Recommendations for Prevention and Control of Influenza in Children, 2025-2026: Technical Report. Pediatrics. **2025**;156:e2025073622. *PMID: 40717224.* ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

222. **Committee on Infectious Diseases***. Recommendations for Prevention and Control of Influenza in Children, 2025-2026: Policy Statement. Pediatrics. **2025**;156:e2025073620. *PMID: 40717223*. ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

221. **Romero JR**. Parechoviruses. In: Bennet JE, Dolin R, Blaser MJ (eds.), Principles and Practice of Infectious Diseases, 10th edition. Elsevier, Philadelphia, Pennsylvania, **2025**, pp XXXX - XXXX.

220. **Romero JR**. Coxsackieviruses, Echoviruses and Numbered Enteroviruses. In: Bennet JE, Dolin R, Blaser MJ (eds.), Principles and Practice of Infectious Diseases, 10th edition. Elsevier, Philadelphia, Pennsylvania, **2025**, pp XXXX - XXXX.

219. **Romero JR**. Polioviruses. In: Bennet JE, Dolin R, Blaser MJ (eds.), Principles and Practice of Infectious Diseases, 10th edition. Elsevier, Philadelphia, Pennsylvania, **2025**, pp XXXX - XXXX.

218. **Romero JR**. Introduction to the Human Enteroviruses and Parechoviurses. In: Bennet JE, Dolin R, Blaser MJ (eds.), Principles and Practice of Infectious Diseases, 9th edition. 10th edition. Elsevier, Philadelphia, Pennsylvania, **2025**, pp XXXX - XXXX.

217. Auerbach S, **Romero JR.** Enterovirus and Parechovirus Infections. In: Kline MW, Orange JS, Giardino AP, Rathore MM, Harris ZL, Cabrera A. (Eds.), Rudolph's Pediatrics. 24th edition. McGraw-Hill, New York; **2025**.

216. Popfsky S, **Romero JR**. Response: Koplik, Comby, and Stimson: Three Observed Physical Signs in Measles. Pediatr Ann. 2025;54:e256. *PMID: 40772939.*

215. Popfsky S, **Romero JR**. Measles: An ongoing threat. Pediatr Ann **2025**;54:e81-e82. *PMID: 40305636.*

214. **Romero JR**, Bernstein HH. Vaccinations matter. Pediatr Ann **2025**;54:e152-e153. *PMID: 40305637.*

213. **Committee on Infectious Diseases***. Recommended Childhood and Adolescent Immunization Schedule: United States, 2025: Policy Statement. Pediatrics. **2025**;155:e2024069987. *PMID: 39570788.* ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

212. Bucayu RFT, Boge CLK, Yildirim I, Avilés-Robles M, Vora SB, Berman DM, Sharma TS, Sung L, Castagnola E, Palazzi DL, Danziger-Isakov L, Yin DE, Roilides E, Maron G, Tribble AC, Soler-Palacin P, López-Medina E, **Romero J**, et al. Transition to enteral triazole antifungal therapy for pediatric invasive candidiasis: Secondary analysis of a multicenter cohort study conducted by the Pediatric Fungal Network. J Pediatric Infect Dis Soc. **2024**;13:633-638. *PMID: 39513400.*

211. Kimberlin DW, Banerjee R, Barnett ED, Lynfield R, Sawyer MH (eds.) Red Book: 2024-2027. Report of the Committee on Infectious Diseases*. 33nd edition., Itasca, IL: American Academy of Pediatrics: **2024**: ***Dr. Romero was content reviewer and contributor while at the Centers for the Disease Control and Prevention, Liaison to the Committee on Infectious Diseases**

210. Katz SE, Banerjee R; **Committee on Infectious Diseases***; Council on Environmental Health and Climate Change. Use of antibiotics in animal agriculture: Implications for pediatrics: Technical Report. Pediatrics. **2024**;154:e2024068467. *PMID: 39308322.* ***Dr. Romero is a member of the AAP Committee on Infectious Diseases.**

209. O'Leary ST, Opel DJ, Cataldi JR, Hackell JM; **Committee on Infectious Diseases***; Committee on Practice and Ambulatory Medicine; Committee on Bioethics. Strategies for Improving Vaccine Communication and Uptake. Pediatrics. **2024**;153(3):e2023065483. *PMID: 38404211*. ***Dr. Romero was the Centers for the Disease Control and Prevention Liaison to the Committee on Infectious Diseases.**

208. **Romero JR**. Enteroviruses. In: Goldman, L, Cooney KA, (eds), Goldman-Cecil Medicine. 27th ed. Elsevier, Philadelphia, Pennsylvania, **2024**, pp 2256-2261.

207. Pough K, Cornaghie M, Rabenhorst B, Maples H, **Romero J**. Lomentospora prolificans septic arthritis and osteomyelitis in a pediatric patient. Pediatr Infect Dis J. **2024**. doi: 10.1097/INF.0000000000004295. Epub ahead of print. *PMID: 38363146*.

206. Wattier RL, Bucayu RFT, Boge CLK, Ross RK, Yildirim I, Zaoutis TE, Palazzi DL, Vora SB, Castagnola E, Avilés-Robles M, Danziger-Isakov L, Tribble AC, Sharma TS, Arrieta AC, Maron G, Berman DM, Yin DE, Sung L, Green M, Roilides E, Belani K, **Romero J**, et al. Adjunctive diagnostic studies completed following detection of candidemia in children: Secondary analysis of observed practice from a multicenter cohort study conducted by the Pediatric Fungal Network. J Pediatric Infect Dis Soc. **2023**;12:487-495. *PMID: 37589394.*

205. **Committee on Infectious Diseases***. Recommendations for prevention and control of influenza in children, 2023-2024. Pediatrics. **2023**;152:e2023063773. *PMID: 37641884.* ***Dr. Romero was the Centers for the Disease Control and Prevention Liaison to the Committee on Infectious Diseases.**

204. Stellrecht KA, Lamson DA, **Romero JR**. Enteroviruses and Parechoviruses. In: Carroll KC, Pfaller MA, Karlowsky JK, et al. (eds), Manual of Clinical Microbiology, 13th ed. American Society for Microbiology, Washington, DC, **2023**, pp 1762-1779.

203. Onarecker TR, **Romero JR.** Aseptic and Viral Meningitis. In: Long SS, Prober CG, Fischer M, et al. (eds). Principles and Practice of Pediatric Infectious Diseases, 6th Edition. Philadelphia: Elsevier; **2023**. pp. 310-315.

202. **Committee on Infectious Diseases***. Recommendations for prevention and control of influenza in children, 2023-2024. Pediatrics. **2023**;152:e2023063772. *PMID: 37641879*. ***Dr. Romero was the Centers for the Disease Control and Prevention Liaison to the Committee on Infectious Diseases.**

201. Caserta MT, O'Leary ST, Munoz FM, Ralston SL; **Committee on Infectious Diseases***. Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Pediatrics. **2023**;152:e2023061803. *PMID: 37357729*. ***Dr. Romero is a member of the Committee on Infectious Diseases.**

200. Rosenberg A, Sawhney M, Bernstein HH, **Romero JR**. COVID-19 Vaccines for Children: An Update. Pediatr Ann. **2023**;52(3):e83-e88. *PMID: 36881800*.

199. Bernstein HH, **Romero JR**. The Unique Science and Art of Health Promotion and Disease Prevention with Vaccination. Pediatr Ann. **2023**;52:e81-e82. *PMID: 36881795*.

198. Machicao MF, Yashar-Gershman S, **Romero JR**, Bernstein HH. International Travel Vaccine Recommendations for Children. Pediatr Ann. **2023**;52:e106-e113. *PMID: 36881794.*

197. Woolf AD, Stierman BD, Barnett ED, Byron LG; COUNCIL ON ENVIRONMENTAL HEALTH AND CLIMATE CHANGE; **Committee on Infectious Diseases***. Drinking Water From Private Wells and Risks to Children. Pediatrics. **2023**;151:e2022060644. PMID: 36995187. ***Dr. Romero is a member of the Committee on Infectious Diseases.**

196. Shihabuddin BS, Faron ML, Relich RF, Van Heukelom P, Mayne D, Staat MA, Selvarangan R, Hueschen LA, Wolk DM, House S, Harnett G, McGann K, Steele MT, **Romero JR**, Arms J, Lander O, Loeffelholz M, Strouts F, Cohen D. Cepheid Xpert Xpress Flu/RSV evaluation performed by minimally trained non-laboratory operators in a CLIA-waived environment. Diagn Microbiol Infect Dis. **2022**;104:115764. *PMID: 35917666*

195. Sarmiento Clemente A, Kaplan S, Barson W, Lin P, **Romero J**, Bradely J, Tan T, Pannaraj P, Givner L, Hulten K. Decrease in pediatric invasive pneumococcal disease during the COVID-19 pandemic. J Pediatr Infect Dis Soc. **2022**;11:426-428. *PMID: 35731619*

194. Cima MJ, McCormick D, Porter A 3rd, Zohoori N, Alsbrook S, **Romero JR**. COVID-19 vaccine uptake among Arkansas public K-12 school teachers and staff. Vaccine. **2022**;40:5523-5528. *PMID: 35965240*

193. Fisher BT, Boge CLK, Xiao R, Shuster S, Chin-Quee D, Allen J, Shaheen S, Hayden R, Suganda S, Zaoutis TE, Chang YC, Yin DE, Huppler AR, Danziger-Isakov L, Muller WJ, Roilides E, **Romero J**, Sue PK, Berman D, Wattier RL, Halasa N, Pong A, Maron G, Soler-Palacin P, Hutto SC, Gonzalez BE, Salvatore CM, Rajan S, Green M, Doby Knackstedt E, Hauger SB, Steinbach WJ. Multicenter Prospective Study of Biomarkers for Diagnosis of Invasive Candidiasis in Children and Adolescents. Clin Infect Dis. **2022**;7:248-259. Erratum in: Clin Infect Dis. **2023**;76:972. *PMID: 35134165*

192. Shihabuddin BS, Faron ML, Relich RF, Van Heukelom P, Mayne D, Staat MA, Selvarangan R, Hueschen LA, Wolk DM, House S, Harnett G, McGann K, Steele MT, **Romero JR**, Arms J, Lander

O, Loeffelholz M, Strouts F, Cohen D. Cepheid Xpert Xpress Flu/RSV evaluation performed by minimally trained non-laboratory operators in a CLIA-waived environment. Diagn Microbiol Infect Dis. **2022**;104:115764. *PMID: 35917666*

191. Rao AK, Deborah D, Moore S; Whitehill F, Campos-Outcalt D, Morgan RL, Wallace RM, **Romero JR**, Bahta L, Frey SE, Blanton JD. Use of a Modified Vaccine Schedule for Pre-exposure Prophylaxis to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices – United States, 2022. MMWR Morb Mortal Wkly Rep. **2022**;71:619-627. *PMID: 35511716*

190. Murthy N, Wodi AP, Bernstein H, Ault KA; **Advisory Committee on Immunization Practices***. Recommended Adult Immunization Schedule, United States, **2022**. Ann Intern Med. **2022**;175:432-443. *PMID: 35175828* ***Dr. Romero is Chair of the Advisory Committee on Immunization Practices.**

189. Burney JA, Roberts SC, DeHaan LL, Shimizu C, Bainto EV, Newburger JW, Dominguez S, Jone PN, Jaggi P, Szmuszkovicz JR, Rowley AH, Samuy N, Scalici P, Tremoulet AH, Cayan DR, Burns JC; KIDCARE Study Investigators*. Epidemiological and clinical features of Kawasaki Disease during the COVID-19 pandemic in the United States. JAMA Netw Open. **2022**;5:e2217436. PMID: 35713905. ***Dr. Romero was a KIDCARE Study investigator.**

188. Maldonado YA, O'Leary ST, Ardura MI, Banerjee R, Bryant KA, Campbell JD, Caserta MT, John CC, Gerber JS, Kourtis AP, Ratner AJ, **Romero JR**, Shah SS, Zangwill KM. Recommendations for Prevention and Control of Influenza in Children, 2021-2022. Pediatrics. **2021**;148:e2021053745. *PMID: 34493538*

187. Burns JC, Roberts SC, Tremoulet AH, He F, Printz BF, Ashouri N, Jain SS, Michalik DE, Sharma K, Truong DT, Wood JB, Kim KK, Jain S, **KIDCARE Multicenter Study Group***. Infliximab versus second intravenous immunoglobulin for treatment of resistant Kawasaki disease in the USA (KIDCARE): a randomised, multicentre comparative effectiveness trial. Lancet Child Adolesc Health. **2021**;5:853-861. *PMID: 34715057* ***Dr. Romero is a member of the KIDCARE Multicenter Study Group.**

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PRESENTATIONS (Primary and Co-authored), CONFERENCES, INVITED LECTURES

International

23. Challenges to Public Health Authorities during the COVID-19 Pandemic: Reflections from a Past State Health Official. Presented at the International Conference on Emerging Infectious Diseases, Atlanta, GA, August 8, 2022.

22. Keynote Address: Equity Access and Challenges to the Distribution and Acceptance of COVID-19 Countermeasures at the State Level. Presented at the **46th National Infectious Diseases and Clinical Microbiology Congress**, San Luis Potosi, San Luis Potosi, Mexico, May 28, 2022. (Web-based presentation due to the SARS-CoV-2 pandemic.)

21. Keynote Address: Weakness and Success in the US Response to the COVID-19 Pandemic. Presented at the **Production Operations Management Society Conference**, Sam W. Walton College of Business, University of Arkansas, Fayetteville, AR, April 30, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

20. The Race for a Vaccine: A Global Scientific, Entrepreneurial, and Technological Showdown. Presented at the **Harvard Project for Asian and International Relations 2021 Harvard College Conference**, Cambridge, MA, January 18, 2021. (Web-based presentation to international venues due to SARS-CoV-2 pandemic.)

19. Current Situation of the Development of SARS-CoV-2 Vaccines. Presented at the **XVII International Update Seminar on Vaccines**, Instituto Balmis de Vacunas, Almería, Spain, November 5, 2020. (Web-based presentation due to the SARS-CoV-2 pandemic.)

18. Parálisis Flácida Aguda de Origen Viral (Acute Flaccid Paralysis of Viral Origen). Presented at the **35º Congreso Nacional de Pediatria - Asociación Mexicana de Pediatria (35th National Congress of Pediatric- Mexican Association of Pediatrics)**, Mexico City, Mexico, June 25-28, 2017.

17. Actualizacion en Inmunizaciones (Immunization Update). Presented at the **35º Congreso Nacional de Pediatria - Asociación Mexicana de Pediatria (35th National Congress of Pediatric- Mexican Association of Pediatrics)**, Mexico City, Mexico, June 25-28, 2017.

16. Cambios en los Calendarios Vacunales 2017 a Uno y Otro Lado del Atlántico. (Changes in the Vaccine Schedules on each Side of the Atlantic.). Presented at the **II Curso de Verano IHP de Actualización en Vacunas** (Second IHP Summer Course on Vaccines Update), Real e Ilustre Colegio de Médicos de Sevilla, Seville, Spain, June 16 & 17, 2017.

15. Cambios en Enfermedad Neumocócica Después de la Introducción de las Vacunas Conjugadas. (Trends in Pneumococcal Disease after the introduction of Conjugate vaccines.) Presented at Mesa Redonda. Nuevas Vacunas frente a Enfermedades Bacterianas Graves. (Roundtable: New Vaccines against Severe Bacterial Infections.) **XIII Jornadas De Actualización en Vacunas (XIII**

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14. Recomendaciones del ACIP: Una Referencia Mundial. (ACIP Recommendations: A Global Prespective). Presented at Mesa redonda. Calendarios vacunales. (Roundtable. Immunizations Schedules.) **XIII Jornadas De Actualización en Vacunas (XIII Update Seminar on Vaccines),** Colegio Oficial de Médicos de Almería and Instituto Balmis de Vacunas, Almería, Spain, October 6, 2016.

13. Clinical Characteristics of Infants <6 Months of Age Hospitalized with 2009 H1N1 Influenza Virus Infection. Presented at the **Pediatric Academic Societies' Meeting,** Vancouver, Canada, May 2, 2010.

12. Impact of 2009 H1N1 Influenza on a Pediatric Emergency Department. Presented at the **Pediatric Academic Societies' Meeting**, Vancouver, Canada, May 1, 2010.

11. Superior Detection of *Kingella kingae* and *Staphylococcus aureus* in Paediatric Osteoarticular Infections using Molecular Assays. Presented at the **19th European Congress of Clinical Microbiology and Infectious Diseases**, Helsinki, Finland, May 19, 2009.

10. Workshop on Health and Migration: Chronic and Emerging Diseases. Presented at the **Fourth Annual Binational Policy Forum on Migration and Health**, León, Guanajuato, Mexico, October 12, 2004.

9. Keynote address: Pleconaril for the treatment of enterovirus infections. Presented at the **Chang Gung Children's Hospital 10th Anniversary Symposium Enterovirus 71 in Taiwan: Past and Future**, Taipei, Taiwan, March 29, 2003.

8. Identification of a genomic determinant of cardiovirulence for clinical isolates of coxsackievirus B3. Presented at the **Chang Gung Children's Hospital 10th Anniversary Symposium Enterovirus 71 in Taiwan: Past and Future**, Taipei, Taiwan, March 29, 2003.

7. Respiratory syncytial virus: A review of its molecular virology and clinical aspects. Presented at Pediatric Grand Rounds **Chang Gung Children's Hospital**, Taipei, Taiwan, March 28, 2003.

6. RSV: Outcomes data. Presented at the **International Congress on Respiratory Syncytial Virus**, Washington, DC, June 22, 2002.

5. Pleconaril therapy of enteroviral infections in adults and children. Presented at the **22nd International Congress of Chemotherapy**, Amsterdam, The Netherlands, June 30, 2001.

4. The 5' Untranslated Region (5'UTR) of a Wild-Type Coxsackievirus B3 (CBV3) Strain Attenuates the Cardiovirulent Phenotype of CBV3/20. Presented at **17th Annual Meeting of the American Society for Virology**, University of British Columbia, Vancouver, BC, Canada, July 13, 1998.

3. Chimeric coxsackievirus B3 as a vehicle to study the echovirus 5' nontranslated region (5'NTR). Presented at the **15th Annual American Society for Virology Meeting**, New London, Ontario, Canada, July 14, 1996.

2. Pediatric AIDS. Presented at the conference on **Tópicos Selectos en Infectología Pediátrica (Selected Topics in Pediatric Infectious Diseases)** held by the College of Pediatrics of Nuevo Leon. Neuvo Leon, Monterrey, México. June 15-16, 1990.

1. Hepatitis E. Presented at the conference on **Tópicos Selectos en Infectología Pediátrica (Selected Topics in Pediatric Infectious Diseases)** held by the College of Pediatrics of Nuevo Leon. Neuvo Leon, Monterrey, México. June 15-16, 1990.

National Presentations and University Research Seminars

104. Influenza Update. Presented at the **Meet the Redbook,** American Academy of Pediatrics , September 18, 2022. (Web-based presentation)
103. Challenges and Limitations to Use Wastewater Surveillance Data for Public Health Surveillance Systems. Presented at **Committee on Community Wastewater-based Infectious Diseases of The National Academies of Sciences, Engineering, and Medicine Deskside Media Briefing**, April 21, 2022. (Web-based presentation due to the SARS-CoV-2 pandemic.)

102. State Health Officials Discuss COVID-19 Pfizer Vaccine Approval for Children and J&J / Moderna Booster Rollout. Presented at **ASTHO Deskside Media Briefing**, November 4, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

101. Effects of the Pandemic on Children. Presented as panelist at **American Academy of Pediatrics (AAP) Town Hall Addressing COVID-19**, Virtual meeting, October 14, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

100. Role of the ACIP in Vaccine Recommendations. Presented at the **Meet the Redbook; Session AAP National Conference and Exhibition,** Philadelphia, PA, October 11, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

99. **Romero JR**, Warden DE, Impact of the SARS-CoV-2 Variant on the Spectrum of Pediatric COVID-19 Disease in Arkansas. Oral presentation. Presented at the **Late Breaker Session IDWeek 2021**(Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), October 1, 2022. Submission ID: 1106141 (Webinar presentation due to COVID-19 pandemic.)

98. Sarmiento-Clemente A et al. Decrease in Invasive Pneumococcal Disease in 7 United States Children's Hospitals during the COVID-19 Pandemic. Oral presentation. Presented at the **Late Breaker Session IDWeek 2021**(Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), September 29-October 1, 2022. Submission ID: 1067969 (Webinar presentation due to COVID-19 pandemic.)

97. Porter A, Brown C, Tilford M, Cima M, Zohoori N, McCormick D, Wilson MP, Amick B, **Romero J**. Association of the COVID-19 Pandemic and Dying at Home Due to Ischemic Heart Disease. Oral Presented at: **2021 American Public Health Association Annual Meeting and Expo**. October 24-27, 2011. Denver, CO.

96. COVID-19 Vaccine Updates. Panelist presented at **the trc Healthcare Emerging Recommendations Panel Webinar**, October 19, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

95. Bipartisan Discussion of the COVID-19 Pandemic. Presented at the **Spouses Organization of the US Association of Former Members of Congress** Webinar, September 22, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

94. Additional COVID-19 Vaccine Doses. Presented as panelist at the **trc Healthcare Emerging Recommendations** Panel Webinar, September 21, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

93. ACIP Role in U.S. Vaccine Policy. Presented at the **Association of Medical Laboratory Immunologists National Meeting**, Austin, TX, August 16, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

92. Sharing Best Practices around K-12 Reopening efforts. Presented at the **State & Territory Alliance for Testing** (**STAT) K-12 Action Network Bi-Weekly Discussion Webinar**, August 10, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

91. Path Forward: About the Delta Variant. Presented at the **U.S. Chamber of Commerce Foundation**, Washington, DC, July 20, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

90. COVID-19: Achieving Vaccine Equity and Overcoming Vaccine Hesitancy Panelist. Presented at **US News Live Events**, US News & World Report, July 20, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

89. Keynote Address, COVID-19 Vaccines and Children: What Do We Need to Know? Presented at the **Johns Hopkins/University of Washington Symposium on COVID Immunization in Children and Adolescents. COVID-19 and Kids: Impacts, Uncertainties and the Role of Vaccines**, June 30, 2021. (Web-based presentation due to SARS-CoV-2 pandemic.)

88 Emerging Recommendations Panel. Presented at the **trc Healthcare Webinar**, June 17, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

87. COVID-19 Vaccine Town Hall. Hosted by the **Adult Vaccine Access Coalition and the United Food and Commercial Workers International Union**. May 6, 2021. (Web-based presentation due to SARS-CoV-2 pandemic.)

86. COVID-19 Vaccine: Panel- Academia, Think Tank & Medical Experts. Presented at **The Hill, COVID-19 Vaccine & the New Era of Manufacturing**, March 25, 2021. (Web-based presentation due to SARS-CoV-2 pandemic.)

85. COVID-19 Vaccination: Where Are We Now? Where Are We Going? Presented at the **ASTHO Washington Week**, March 4, 2021. (Web-based presentation due to SARS-CoV-2 pandemic.)

84. A COVID-19 Vaccination Discussion with Dr. José Romero and Farm Worker Leaders. Hosted by the **United Farm Workers Foundation**. Little Rock, AR. December 10, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

83. Selected Impact of the 13-Valent Pneumococcal Conjugate Vaccine (PCV13) on Invasive Pneumococcal Disease (IPD) at Eight Children's Hospitals in the United States. 2014-2019. Presented at the **IDWeek** 2020TM, October 21-25, 2020. Submission ID: 909704

82. Preparing for COVID-19 Vaccine – From Supply Chain to Public Messaging: What the Public Needs to Know. Presented at the **National Emergency Management Association Virtual Summit**. Webinar, September 24, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

81. Understanding the CDC's Advisory Committee on Immunization Practices (ACIP). Presented at the **Vaccine Boot Camp**, National Press Foundation. Webinar, August 5, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

80. Equitable Allocation of Vaccine for Novel Coronavirus. Presented at the **National Academies of Sciences**, Washington DC, July 23, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

79. Non13-Valent Pneumococcal Conjugate Vaccine Serotypes Predominate as Causes of Pneumococcal Otitis Media in Children. Presented at **IDWeek 201**9 (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), Washington, DC, October 5, 2019. Presentation Number 2707

78. Analysis of Invasive Pneumococcal Infections Due to 13-Pneumococcal Conjugate Vaccine Serotypes at 8 US Children's Hospitals During 2014 to 2016. Presented at **IDWeek 2017** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Diego, CA, October 7, 2017. Presentation Number 2494

77. Blood Viral Load (VL) Not Clinically Meaningful in Symptomatic Congenital Cytomegalovirus (cCMV) Infection. Presented at **IDWeek 2017** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Diego, CA, October 6, 2017. Presentation Number 947

76. Pneumococcal Invasive Disease in Infants Younger than 60 Days in the United States in the 13-valent Pneumococcal Conjugate Vaccine Era. Presented at **IDWeek 2016** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), New Orleans, LA, October 28, 2016. Presentation Number 956

75. Safety, Tolerability and Pharmacokinetics (PK) of Intravenous Zanamivir (IVZ) Treatment in Hospitalized Pediatric and Adolescent Patients with Influenza: A Phase II Open-Label, Multicenter, Single- Arm Study. Presented at **IDWeek 2016** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), New Orleans, LA, October 27, 2016. Presentation Number 90b

74. Picornaviruses in Pediatrics: Small Viruses with a Big Impact. Presented at **Viruses Forever II Symposium**, State University of New York, Stony Brook, New York, June 3, 2016.

73. Enteroviruses Old and New. Presented at **Infectious Diseases in Children Symposium**, New York, NY, November 22, 2015.

72. Molecular Characterization of Invasive Streptococcus pneumoniae Serotype 3 Isolates in Pediatric Patients from 2008-2013. Presented at **IDWeek 2014** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), Philadelphia, PA, October 10, 2014. Presentation Number 957

71. A Randomized, Double-Blind, Placebo-Controlled Trial of Pleconaril for the Treatment of Neonates with Enterovirus Sepsis. Presented at **IDWeek 2014** (Annual meeting of the Pediatric Infectious

Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), Philadelphia, PA, October 9, 2014. Presentation Number 80

70. Pneumococcal Meningitis among 8 Children's Hospitals in the United States in the 13-Valent Pneumococcal Conjugate Vaccine Era. Presented at **IDWeek 2014** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), Philadelphia, PA, October 9, 2014. Presentation Number 78

69. Continued Decline in Invasive Pneumococcal Infections in Children Among 8 Children's Hospitals in the United States 2011 to 2013. Presented at **IDWeek 2014** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), Philadelphia, PA, October 9, 2014. Presentation Number 77

68. Six months versus six weeks of oral valganciclovir for infants with symptomatic congenital cytomegalovirus (CMV) disease with and without central nervous system (CNS) involvement: Results of a Phase III, randomized, double-blind, placebo-controlled, multinational study. Presented at **IDWeek 2013** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Francisco, CA, October 5, 2013.

67. Age-specific Reductions in the Proportion of Pediatric Invasive Pneumococcal Disease Caused by Serotype 19A and Other PCV13 Serotypes, 2008-2011. Presented at **IDWeek 2013** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Francisco, CA, October 3, 2013.

66. Multicenter Surveillance of Streptococcus pneumoniae isolates from middle ear cultures in the 13-valent Pneumococcal Conjugate Vaccine Era. Presented at **IDWeek 2013** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Francisco, CA. October 4, 2013.

65. An Investigation of Genes Encoding Potential Vaccine Targets Across Genetically Unrelated Pediatric Clinical Streptococcus pneumoniae Isolates in the Post Pneumococcal Conjugate Vaccine Era. Presented at **IDWeek 2013** (Annual meeting of the Pediatric Infectious Diseases Society, the Infectious Diseases Society of America, the HIV Medical Association, and the Society for Healthcare Epidemiology of America), San Francisco, CA. October 4, 2013.

64. A Multicenter evaluation of the performance characteristics of the BD Veritor System for rapid RSV detection. Presented at the **50th Annual Meeting of the Infectious Diseases Society of America**, San Diego, CA, October 18, 2012.

63. Neutrophil Profile at Diagnosis of Invasive Meningococcal Infection in Children. Presented at the **Pediatric Academic Societies' Meeting**, Boston, MA, April 29, 2012.

62. Parental Perceptions about Mandatory Influenza Immunization of Pediatric Healthcare Workers. Presented at the **Pediatric Academic Societies' Meeting**, Boston, MA, April 29, 2012.

57. Early Trends for Invasive Pneumococcal Infections in Children Following the Introduction of the 13-

Valent Pneumococcal Conjugate Vaccine. Presented at the **49th Annual Meeting of the Infectious Diseases Society of America**, Boston, MA October 22, 2011.

56. Serious Early Childhood Wheezing Following Respiratory Syncytial Virus Lower Respiratory Tract Infection During Infancy Among Preterm Infants. Presented at the **2009 American Academy of Pediatrics National Conference and Exhibition**, Washington, DC October 17-20, 2009.

55. Total health care cost of preterm infants with medically attended respiratory syncytial virus lower respiratory tract infection. Presented at the **46nd Annual Infectious Diseases Society of America Meeting,** Washington, DC October 25-28, 2008.

54. Multi-Center Evaluation of a Real Time NASBA Best for Detection of Enterovirus in Cerebrospinal Fluid from Pediatric Patients. Presented at the **24th Annual Clinical Virology Symposium**, Daytona Beach, FL April 27-30, 2008.

53. Health Disparities: Cancer and Heart Disease. Coordinator of Small Group Session at the **5th Social Equity Leadership Conference, National Academy of Public Administration**, Omaha, NE, February 2-3, 2006.

52. An overview of economic and health indicators among Heartland Latinos. At the **Fifth Annual Binational Health Policy Forum**, Chicago, IL, October 12, 2005.

51. Diagnostic virology practices for respiratory virus (RSV): Comparison between teaching and non-teaching hospitals caring for children. Presented at the **42nd Annual Infectious Diseases Society of America Meeting**, Boston MA September 30-October 3, 2004.

50. Experience with limited Phase I smallpox vaccination in a Midwestern children's hospital. Presented at the **Pediatric Academic Societies' Meeting**, San Francisco, CA May 1-4, 2004.

49. Respiratory Syncytial Virus (RSV) prophylaxis in minority populations; results from the Palivizumab Outcomes Registry 2002-2003. Presented at the **Pediatric Academic Societies' Meeting**, San Francisco, CA May 1-4, 2004.

48. Evaluation of phase I vaccination in Douglas County, Nebraska. Presented at the **41st Annual Infectious Diseases Society of America Meeting**, San Diego, CA October 9-12, 2003.

47. Time to detection of respiratory viruses using mixed cell shell vial cultures: 2 vs. 5 days. Presented at the **41st Annual Infectious Diseases Society of America Meeting**, San Diego, CA October 9-12, 2003.

46. Viral Central Nervous System Infections. Presented as part of the **Microbiology Series of The University of Texas Health Sciences Center** at San Antonio, TX, September 3, 2003.

45. Impact of PCR detection of enteroviral infection of the management of febrile neonates. Presented at **Pediatric Academic Societies' Meeting**, Seattle, WA, May 4, 2003.

44. Spectrum of neonatal enteroviral disease over an 8-year period. Presented at the **40th Annual Infectious Diseases Society of America Meeting**, Chicago, IL, October 26, 2002.

43. Enteroviral vesiculo and papular exanthems. Presented at the **CDC/APHL-sponsored Meeting on Poxvirus and other Febrile Vesicular Rash Illness Diagnostic Testing**, San Diego, CA, October 1, 2002.

42. Not so wild a dream. Co-presented at the **25th Annual Rural Health Association Meeting**, Kansas City, MO, May 17, 2002.

41. Changing susceptibility of group B Streptococcus from a community hospital in a mid-sized Midwestern city. Presented at **Pediatric Academic Societies' Meeting**, Baltimore, MD, May 5, 2002.

40. Common viral meningoencephalidities in children. Presented at the **5th Annual Pediatric Acute Care Symposium, The Pediatric Hospitalist Conference**, Las Vegas, NV, April 4, 2002.

39. Encephalitis associated with influenza B infections: a case series in children. Presented at the **38th Annual Infectious Diseases Society of America Meeting**, San Francisco, CA, November 25-28, 2001.

38. Mutations within the IRES of echovirus 12 confer a novel pathogenic phenotype to and echovirus 12-coxsackeivirus B3 chimera. Presented at the **30th Annual Meeting of the American Society for Virology**, Madison, WI, 2001

37. Evaluation of the foreign-born adoptee: Infectious disease issues. Presented at the **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation**, Hilton Head, NC, June 28, 2001.

36. Viral diagnostics for the practicing clinician. Presented at the **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation**, Hilton Head, NC, June 28, 2001.

35. Hepatitis C infection in children. Presented at the **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation**, Hilton Head, NC, June 27, 2001.

34. 0% disparity when all our children are healthy. Panelist in a discussion at meeting sponsored by **CityMatch**, a national organization of public health leaders, Omaha, NE, May 3, 2001.

33. Molecular epidemiology of Coxsackievirus B3 in the United States: 1949-1998. Presented at **Pediatric Academic Societies' Meeting**, Baltimore, MD, April 29, 2001.

32. Use of naturally occurring coxsackievirus B3 isolates to map virulence determinants. **Department of Biological Sciences, Purdue University**, West Lafayette, IN, January 31, 2001.

31. Further mapping of the coxsackievirus B3 5' nontranslated region cardiovirulence determinant. Presented at **19th Annual Meeting of the American Society for Virology Meeting**, Fort Collins, CO, July 8, 2000.

30. Identification of the major determinant of cardiovirulence of coxsackievirus B3. Presented at platform session **Pediatric Academic Societies' Meeting**, Boston, MA, May 13, 2000.

29. Coxsackievirus B3 Genotypes in the United States. Presented at **37th Annual Infectious Diseases Society of America Meeting,** Denver, CO, November 20, 1999.

28. Picornaviral Infections in High-Risk Patients. Presented as part of the Satellite Symposium **Advances in Management of Common Viral Infections: Meningitis to Respiratory Infection** at the American College of Emergency Room Physicians annual meeting, Las Vegas, NV, October 12, 1999.

27. Molecular Epidemiology of Coxsackievirus B3 in the United States: 1954-1979. Presented at the **18th Annual Meeting of the American Society for Virology**, University of Massachusetts, Amherst, MA, July 13, 1999.

26. Cardiovirulence determinants among naturally occurring isolates of coxsackievirus B3 reside within the 5' nontranslated region. Presented at **Pediatric Academic Societies' Meeting**, San Francisco, CA, May 4, 1999**.**

25. Pleconaril treatment of vaccine-acquired poliovirus. Presented at **Pediatric Academic Societies' Meeting**, San Francisco, CA, May 4, 1999**.**

24. RT-PCR for the Detection of Pediatric Enteroviral Infections. Presented at the **8th Annual DNA Technology in the Clinical Laboratory Symposium**, William Beaumont Hospital, Royal Oak, MI, March 25-27, 1999.

23. Molecular and phenotypic characterization of a Myocarditic Coxsackievirus B3 (CVB3) Isolate. Presented at **36th Annual Infectious Diseases Society of America Meeting,** Denver, CO, November 14, 1998.

22. Reverse Transcription-Polymerase Chain Reaction Diagnosis of Enterovirus Infections in Febrile Children Results in Reduced Health Care Expenditures. Presented at **36th Annual Infectious Diseases Society of America Meeting**, Denver, CO, November 13, 1998.

21. Diagnostic Needs, Screening and Surveillance of Viral Meningitis. Presented at **Clinical and Pharmacologic Considerations for Viral Meningitis Roundtable**, in Denver, CO, November 11, 1998

20. Update on Enteroviral Infections of Children. Presented at **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation**, Lake Buena Vista, FL, October 16, 1998.

19. Prevention of Perinatal Transmission of HIV and Follow-up of the HIV-Exposed Infant. Presented at **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation**, Lake Buena Vista, FL, October 16, 1998.

18. Poliovirus, Polio Vaccines and Vaccine Policy Controversies. Presented at **Pediatric Infectious Disease Seminar, The Lloyd Noland Foundation,** Lake Buena Vista, FL, October 15, 1998.

17. Reverse Transcription-Polymerase Chain Reaction Diagnosis of Enterovirus Infections in Febrile Children Reduces Duration of Hospitalization, Antibiotic Administration and Results in Reduced Health Care Costs. Presented at **15th Annual Meeting of the Minority Medical Faculty Development Program**, Princeton, NJ, October 8, 1998.

16. Impact of Reverse Transcription-Polymerase Chain Reaction Diagnosis of Enterovirus Infections on the Care of Febrile Children. Presented at **Pediatric Academic Societies' Meeting**, New Orleans, LA, May 4, 1998**.**

15. Complete capsid amino acid sequences of 14 wild-type coxsackievirus B3 isolates. Presented as poster at the **16th American Society for Virology Meeting**, Bozeman, MT, July 21, 1997.

14. Echovirus-coxsackievirus chimeras for the evaluation of the role of the echovirus 5' nontranslated region in pathogenesis. Presented as platform session at the **Pediatric Academic Society's Meeting,** Washington DC, May 5, 1997.

13. Genetic diversity and molecular epidemiology among coxsackievirus B2 during a community outbreak. Presented at the **Pediatric Academic Societies' Annual Meeting**. Washington D.C., May 1996.

12. Potential health care cost savings from PCR-based rapid diagnosis of enteroviral meningitis. Presented at the **Pediatric Academic Societies' Annual Meeting**. Washington D.C., May 1996.

11. Detection of enteroviral meningitis by molecular methods. Presented at the **Pan American Society for Clinical Virology Symposium,** Clearwater, FL, April 26, 1996.

10. Sinusitis: Clinical Considerations and Management. Presented at the **Twenty-third Annual Physician Assistant Conference**. Las Vegas, NV. May 29-June 3, 1995.

9. Amino Acid Variation in the Major Surface Loop (VP2 E-F) of the Cell Receptor From 8 Clinical Isolates of Coxsackievirus B3. Poster session presented at the **Society for Pediatric Research Annual Meeting**. San Diego, CA. May 7-11, 1995.

8. Genomic Variation of Coxsackievirus B3. Presented at the **13th Annual Meeting American Society for Virology**. University of Wisconsin, Madison, WI. July 9-13, 1994.

7. Pediatric Tuberculosis. Presented at the **Eleventh Annual Conference on Infectious Disease**. Aspen, Colorado. August 16-20, 1993.

6. Selective Amplification and Partial Sequence Analysis of the 5'NTR of Seven Enteroviruses With Different Neurovirulence Phenotypes. Romero, J.R. and Rotbart, H.A. Workshop Session presented at the **12th Annual Meeting American Society for Virology**. University of California, Davis, California. July 10-14, 1993.

5. Sequence Diversity Among Enteroviruses with Different Neurovirulence Phenotypes. Romero JR and Rotbart HA. Platform session presented at the **Society for Pediatric Research Annual Meeting**. Washington D.C. May 3-6, 1993.

4. Tick-Borne Diseases of the United States- Update 1992. Presented at the **Tenth Annual Conference on Infectious Disease**. Aspen, Colorado. August 10-14, 1992.

3. Discriminant Enteroviral Replication in U937 Cells: a Candidate Model for Monocyte/ Enterovirus Interactions. Romero JR and Rotbart HA. Presented at the **30th Interscience Conference on Antimicrobial Agents and Chemotherapy**. Atlanta, Georgia. October 21-24, 1990.

2. Enteroviral Capsid Protein VP3 as a Group Antigen for the Enteroviruses. Romero JR, Putnak R, Wimmer E. Platform session presented at the **Society for Pediatric Research Annual Meeting**. Washington D.C. May 2-5, 1988.

1. The Use of Poliovirus Proteins VP3 and 2C as Group Antigens for the Detection of Enteroviral Infections by Indirect Immunofluorescence. Romero, J.R., Putnak, R., Wimmer, E. Poster session presented at the **Society for Pediatric Research Annual Meeting**. Washington D.C. May 5-8, 1986.

Regional and State

100. The Status of Polio Eradication and the Threat of Reemerging Vaccine Preventable Diseases. Presented at the **2022 Immunization Update: Getting Routine Immunizations Back on Track**, North Little Rock, AR, August 19, 2022.

99. Human Parechovirus Infection in Neonates and Infants. Presented at the American Academy of Pediatrics, California District IX's **42nd Annual Las Vegas Seminars Pediatric Update**, Las Vegas, NV, November 21, 2021.

98. There Are Still Other Viruses to Worry About. Presented at the American Academy of Pediatrics, California District IX's **42nd Annual Las Vegas Seminars Pediatric Update**, Las Vegas, NV, November 20, 2021.

97. The COVID-19 Pandemic: A Complete Update with All of Your Questions Answered. Presented at the American Academy of Pediatrics, California District IX's **42nd Annual Las Vegas Seminars Pediatric Update**, Las Vegas, NV, November 19, 2021.

96. Epidemiology and Clinical Findings in Pediatric COVID-19. Presented at the American Academy of Pediatrics, California District IX's **42nd Annual Las Vegas Seminars Pediatric Update**, Las Vegas, NV, November 19, 2021.

95. Keynote Address: Consequential Approaches to COVID-19 Vaccine Hesitancy. Presented at the **Emerging Infections in Clinical Practice and Public Health Conference**, Live Webinar hosted by the University of Minnesota Medical School, Minneapolis, MN, November 19, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

94. Vaccines, Vaccination, and Variants – A COVID 19 Update. Presented at the **University of Arkansas for Medical Sciences, College of Medicine, 2021 Family Medicine Update**. October 28, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

93. COVID-19 Pediatric Update. Presented at the **Arkansas Chapter American Academy of Pediatrics (ARAAP),** Little Rock, AR, August 28, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

92. COVID-19 Panel Discussion. Presented at the 2021 **Arkansas Emergency Management and Public Safety Conference**, Rogers, AR, August 27, 2021

91. COVID-19 Pediatric Update. Presented at the **Back-to-School Webinar, Arkansas Chapter of the American Academy of Pediatrics**, Little Rock, AR, August 3, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

90. COVID: Current Status. Presented at **Arkansas Electric Cooperatives Director's Summer Conference**, Hot Springs, AR, August 2, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

89. SARS-CoV-2. Presented at **Arkansas Association of Educational Administrators (AAEA) Summer Conference**, Little Rock, AR. July 27, 2021.

88. Epidemiology of Respiratory Syncytial Virus in Arkansas from weeks 4.19.21 to 6.21.21. Presented at the Arkansas Chapter of the American Academy of Pediatrics, Little Rock, AR, July 9, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

87. COVID-19 Update. Presented at **Arkansas Medical Society Annual Membership Meeting**, Little Rock, AR. May 14, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

86. COVID-19 Vaccines Update and Vaccination Status in Arkansas. Presented at **2021 Family Medicine Spring Review – University of Arkansas for Medical Sciences**, Little Rock, AR. October 21, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

85. COVID Vaccines: A Primer for Clinicians. Presented at **24th Annual Family Medicine Update – University of Arkansas for Medical Sciences**, Little Rock, AR. October 21, 2020. (Web-based presentation due to SARS-CoV-2 pandemic.)

84. Public Health in Arkansas: The COVID-19 Pandemic. Presented at **Arkansas Trucking Association 2020 Annual Business Conference**, Rodgers, AR. August 18, 2020. Non-CME

83. Pediatric SARS-CoV-2 Infections in Arkansas and Multisystem Inflammatory Syndrome in Children (MIS-C). Presented at **PedsPlace**, Arkansas Children's Hospital, June 9, 2020, Little Rock, AR. (Web-based presentation due to SARS-CoV-2 pandemic.)

82. COVID19: How Arkansas is Preparing for Community Transmission- Ask the Experts Panel. Presented at **Connecting Across Professions, Arkansas Public Health Association, Arkansas Department of Health, University of Arkansas for Medical Sciences**, March 10, 2020, Jack Stephens Spine Institute, Little Rock, AR.

81. The Advisory Committee on Immunization Practice's Role in US Vaccine Policy. Presented at the **Arkansas Department of Health County Public Health Officers Symposium**, Winthrop Rockefeller Institute, September 27-29, 2019, Morrilton, AR

80. ACIP Update and Who are the ACIP and FDA VRBPAC. Presented at the **2019 Immunization Update**, August 16, 2019, North Little Rock, AR

79. Advisory Committee on Immunization Practices (ACIP) HPV Update. Presented at **2019 HPV Update**, March 1, 2019, Little Rock, AR

78. Enteroviruses and Parechoviruses: New Syndromes. Presented at **"It's Just a Virus" Tropical and Infectious Disease Conference, Texas A&M University**, April 20-21, 2018, Corpus Christi, TX.

77. Neonatal Viral Infection Update: Zika Virus and Parechoviruses. Presented at the **Controversies Neonatal Clinical Care, 10th Annual District Six Association of Neonatologists**, October 14, 2017, Chicago, IL.

76. Immunization Update: 2015-2016. Presented at the **Pediatric Infectious Diseases Update**, April 9, 2016, Ridgedale, MO.

75. Pediatric Tuberculosis. Presented at the **Pediatric Infectious Diseases Update**, April 18, 2015, Ridgedale, MO.

74. Care of the Infant Born ot an HIV-Infected Woman. Presented at the **ONE Team Diseases Teleconference**, March 13, 2015, Little Rock, AR.

73. Diagnosis and Management of Chronic Hepatitis. Presented at the **Pediatric Infectious Diseases Update**, April 26, 2014, Ridgedale, MO.

72. Pediatric Tuberculosis. Presented at the **Arkansas APIC 46 Conference**, April 21, 2014, Little Rock, AR.

71. Update on Pediatric Tuberculosis. Presented at the **Pediatric Infectious Diseases Update**, April 19, 2013, Ridgedale, MO.

70. HIV Testing in Labor and Delivery; Update on Care of Mother and Baby. Presented at the **High Risk Obstetrics Teleconference**, November 8, 2012, Little Rock, AR

69. Review of Updated Recommendations for Perinatal Prophylaxis of HIV Infection in the Newborn. Presented at the **Pediatric Infectious Diseases Update**, May 4, 2012, Ridgedale, MO.

68. Infections Caused by Human Parechoviruses. Presented at the **Southern Regional Meeting**, February 11, 2012, New Orleans, LA.

67. Methicillin-resistant Staphylococcus Aureus Epidural Abscesses in Children. Presented at the **Southern Regional Meeting**, February 11, 2012. New Orleans, LA.

66. Human Parechoviruses. Presented at the **Pediatric Infectious Diseases Update**, April 9, 2011, Ridgedale, MO.

65. Vaccine Update. Presented at the **Pediatric Infectious Diseases Update**, April 8, 2011, Ridgedale, MO.

64. Pediatric Immunizations: New Guidelines and Treatment of Common Reactions to Immunizations. Presented at **The 14th Annual Family Medicine Update**, October 8, 2010, Little Rock, AR.

63. Raising Resilient Children in a Super Bugged World. Presented at the **Arkansas Public Health Association Annual Meeting**, May 13, 2010, Hot Springs, AR.

62. Pediatric Vaccines Update. Presented at the **Pediatric Infectious Diseases Update**, April 16, 2010, Hot Springs AR.

61. Enteroviruses. Presented at the 24th **Symposium on Critical Care and Emergency Medicine**, March 26, 2009, Hot Springs, AR.

60. Update on Pediatric Vaccines. Presented at the **Pediatric Summit-Arkansas Chapter of the American Academy of Pediatrics**, September 12-14, 2008, Rogers, AR.

59. Diagnosis of Viral Encephalitis and Meningitis. Presented at the **2007 ASCP/CLMA/IACLS/NSCLS Spring Meeting**, April 19, 2007, Council Bluffs, IA.

58. The Spectrum of Enteroviral Infections in Children. Presented at the **10th Annual Infectious Diseases Seminar**, Driscoll Children's Hospital, October 22, 2005, Corpus Christi, TX.

57. Molecular Diagnosis of Pertussis. Presented at the **Iowa/Nebraska Association for Clinical Laboratory Science Spring Conference**, April 27, 2005, Council Bluffs, IA.

56. Respiratory Infections in Children. Presented at the **14th Annual Nebraska Nurse Practitioner Conference**, February 25, 2005, Kearney, NE

55. Trends in Tuberculosis: A Focus on Age, Immigration, and Ethnicity. Presented in **Distinguished Lecturer Series at Children's Hospital**, January 28, 2005, Omaha, NE

54. Overview of the Findings of the Douglas County Minority Behavioral Risk Survey. Keynote address presented at the **2004 Nebraska Health and Human Services Minority Health Conference**, October 26, 2004, Lincoln, NE

53. Trends in Tuberculosis: A Focus on Age, Immigration, and Ethnicity. Presented at the **2004 Nebraska Health and Human Services Minority Health Conference**, October 26, 2004, Lincoln, NE

52. Respiratory Syncytial Virus: What's New. Presented at the **2004 Pediatric Respiratory Update,** October 19, 2004, Toledo, OH

51. Current Concepts in Pediatric Bacterial Meningitis. Presented at the **Infectious Diseases Conference 2004**, September 21, 2004, Sioux City, IA

50. Bioterrorism and "New" Infectious Diseases. Presented at **Nebraska Association of Physicians Assistants 29th Annual Spring CME Conference**, April 16, 2004, Kearney, NE

49. SARS: Our Current Understanding. Presented at the **ASCP/CLMA/NSCLS Spring Meeting**, April 15, 2004, Omaha, NE

48. Group B Streptococcus and Neonatal Sepsis: A Changing Landscape. Presented at **2004 Perinatal, Neonatal Women's Health Conference**, March 26, 2004, Sioux Falls, SD

47. Effectively Treating Otitis Media in Children. Presented at **An Update on Adult and Pediatric Infectious Diseases**, October 25, 2003, Tampa FL

46. Understanding Otitis Media in Children. Presented at **Sinusitis and Otitis Media**, October 25, 2003, Tampa FL

45. Resistance and Susceptibility- Influence on Treatment Decisions. Presented at **Sinusitis and Otitis Media**, August 9, 2003, Seattle, WA

44. Understanding Otitis Media in Children. Presented at **Sinusitis and Otitis Media Conference**, August 9, 2003, Seattle, WA

43. Group B Streptococcus: Changing Antibiotic Spectrum and New Screening Recommendations. Presented at the **Twenty-Sixth Annual Black Hills Seminar on Advances in Clinical Pediatrics**, June 12, 2003, Rapid City, SD

42. Breakfast with the Specialists: ID Potpourri. Presented at the **Twenty-Sixth Annual Black Hills Seminar on Advances in Clinical Pediatrics**, June 12, 2003, Rapid City, SD

41. Clinical Aspects and Prophylaxis of Respiratory Syncytial Virus Infections. Presented at the **Twenty-Sixth Annual Black Hills Seminar on Advances in Clinical Pediatrics**, June 11, 2003, Rapid City, SD

40. Overview of "Newer" Vaccines for Pediatric Use. Presented at the **Twenty-Sixth Annual Black Hills Seminar on Advances in Clinical Pediatrics**, June 11, 2003, Rapid City, SD

39. Enhancing Latino Participation in Clinical Trials. Co-presented at the **Third Annual Heartland Latino Leadership Conference**, Omaha, NE, November 1, 2002

38. Reaching our Minority Populations. Presented at the **2002 Nebraska Rural Health Conference, *Harnessing the Winds of Change: Meeting the Challenges in Rural and Frontier Healthcare*.** Kearney, NE, September 4, 2002.

37. Otitis Media: Trends in Antibiotic Resistance—An Update on CDC Recommendations. Presented at **Continuing Medical Education Conference, Good Samaritan Hospital**, Kearney, NE, April 11, 2001.

36. Immunization Update. Presented at **Nebraska Academy of Physician's Assistants Convention**, Kearney, NE, April 5, 2001.

35. Hepatitis C in Children. Presented at **Practical Pediatrics: 2001 Update**, **Children's Hospital**, Omaha, NE, February 16, 2001.

34. Therapy of Otitis Media: CDC Recommendations. Presented at **Midwinter Family Practice Conference, Nebraska Chapter of American College of Osteopathic Family Physicians, Inc**., Des Moines, IA, January 12, 2001.

33. Management of HIV-infected Women & Children. Presented at **Update for HIV Care Providers and Educators, University of Nebraska at Omaha**, Omaha, NE, November 8, 2000.

32. Adolescent and Adult Immunizations. Presented at **Nebraska Family Health Conference** sponsored by the **Nebraska Department of Health and Human Services**, Kearney, NE, March 15, 2000.

31. Childhood Immunizations. Presented at **Nebraska Family Health Conference** sponsored by the **Nebraska Department of Health and Human Services**, Kearney, NE, March 15, 2000.

30. Pediatric Infections. Presented at **Nebraska Health System Primary Care Physician Update on Infectious Diseases Program**, Omaha, NE, November 5, 1999.

29. Respiratory Syncytial Virus. Presented at the **15th Annual Maternal Child Conference, Mary Lanning Hospital**, Hastings, NE, April 8, 1999.

28. Antibiotic Update. Presented at the **15th Annual Maternal Child Conference, Mary Lanning Hospital**, Hastings, NE, April 8, 1999.

27. Pediatric Update on Immunizations. Presented at the **15th Annual Maternal Child Conference, Mary Lanning Hospital**, Hastings, NE, April 8, 1999.

26. Penicillin Resistant Pneumococcus. Presented at **Infectious Disease Seminar, Faith Regional Medical Center**, Norfolk, NE, October 4, 1997.

25. Antiviral Therapy. Presented at **Infectious Disease Seminar, Faith Regional Medical Center,** Norfolk, NE, October 4, 1997.

24. Respiratory Syncytial Virus Infection and bronchiolitis. Presented at **Children's Healthcare Symposium, Sioux Valley Hospital**, Sioux Falls, SD, October 3, 1997.

23. Enterovirus Infections in Pediatrics. Presented at **Children's Health Care Symposium, Sioux Valley Hospital**, Sioux Falls, SD, October 3, 1997.

22. Pediatric AIDS. Presented at **Children's Health Care Symposium, Sioux Valley Hospital,** Sioux Falls, SD, October 3, 1997.

21. Antibiotics and Emerging Microbial Resistance. Presented at **University of South Dakota School of Medicine's 20th Annual Black Hills Pediatric Seminar**, Rapid City, SD, June 11-12, 1997.

20. Tick-Borne Diseases. Presented at **University of South Dakota School of Medicine's 20th Annual Black Hills Pediatric Seminar**, Rapid City, SD, June 11-12, 1997.

19. Enteroviral Infections in Pediatrics. Presented at **University of South Dakota School of Medicine's 20th Annual Black Hills Pediatric Seminar**, Rapid City, SD, June 11-12,1997.

18. Evaluation of the febrile infant less than 36 months of age with no identifiable focus. Presented at **University of Nebraska Medical Center Family Practice Review Course**, Omaha, NE, April 7, 1997.

17. Potpourri on infectious disease. Presented at **Emergency medicine: Skills and knowledge for the practicing physician. University of Nebraska Medicine Center,** Omaha, NE, September 27, 1996

16. Management of perinatal and neonatal viral infections. Presented at the **Annual Nebraska Neonatal Conference.** Kearney, NE, April 12, 1996.

15. Pneumococcus in the 90's. Presented at the **Nebraska Academy of Physician Assistants Annual Continuing Medical Education Convention.** Grand Island, NE, April 11, 1996.

14. Evaluation of the Febrile Infant <36 Months of Age With No Identifiable Focus. Presented at **Family Practice Review Course, University of Nebraska Medical Center**, Omaha, NE, March 18, 1996 and April 15, 1996.

13. Emerging Organisms Related to Pediatric Infectious Diseases. Presented to the **Nebraska Society of Pediatric Nurses**, Omaha, NE, November 9, 1995.

12. Strategies for Treatment of Non-HIV Viral Infections. Presented at **Iowa Physician Assistant Society 21st Annual Fall Continuing Medical Education Conference,** Iowa City, IA, October 4, 1995.

11. Common viral infections. Presented as part of the **Great Plains Regional Medical Center's Continuing Medical Education Program.** North Platte, NE. November 21, 1994.

10. Mechanisms of Antimicrobial Resistance. Presented at the **Nebraska Academy of Physician Assistants Summer Conference**, Ogallala, NE, July 21, 1995.

9. Management of the febrile infant. Presented at **University of Nebraska Medical Center Family Practice Review Course.** Omaha, NE. April 28, 1995.

8. RSV Update. Presented at the **Dakota Medical Center Fifteenth Annual Pediatric Update**. Fargo, ND. April 6-7, 1995.

7. Vaccines for children. Presented at **University of Nebraska Medical Center Family Practice Review Course.** Omaha, NE. March 31, 1995.

6. Immunization Update 1995: A Review of the Significant Recent Immunization Successes, Shortfalls, and Future Possibilities. Presented at the **Third Annual Medical Update for Primary Care Physicians.** Omaha, NE. March 3, 1995.

5. RSV bronchiolits and treatments. Presented as part of the **Great Plains Regional Medical Center's Continuing Medical Education Program.** North Platte, NE. November 21, 1994.

4. Sepsis in the Neonate. Presented at NICU Infections: Diagnosis, Treatment and Infection Control Conference of the **Mid Plains Association of Neonatal Nurses**. Omaha, NE. October 26, 1994.

3. Update on Pediatric Tuberculosis: The Latest AAP and CDC Recommendations. Seminar presented to 62nd Annual Postgraduate Assembly of the **Omaha Mid-West Clinical Society**. Omaha, NE. October 5, 1994.

2. Management of the Febrile Infant Less Than 36 Months of Age. Presented at **Family Practice Review Course**, University of Nebraska Medical Center. Omaha, NE. March 18 and April 22, 1994.

1. The Current Epidemiology of Childhood Meningitis. Presented at **Infection Control Comedies and Tragedies- Ninth Symposium Sponsored by the Association for Practitioners in Infection Control.** Smithtown, New York. October 29, 1993.

Grand Rounds

56. COVID-19: An Overview of Current Epidemiology, Vaccination Recommendations and Outpatient Therapy. Presented at **Houston Methodist Hospital Grand Rounds**, Houston, TX, October 12, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

55. COVID-19 in Pediatrics Overview and Vaccine Update. Presented at **Pediatric Grand Rounds, University of Oklahoma,** Tulsa, OK, September 28, 2021. (Web-based presentation due to the SARS-CoV-2 pandemic.)

54. Updated CDC COVID-19 Vaccination Recommendations in 12 to 15-Year-Olds: Important Considerations as Summer Begins. Presented at ADH Public Health Grand Rounds, **Arkansas Department of Health**, Little Rock, May 27, 2021.

53. COVID-19 Vaccines. Presented at ADH Public Health Grand Rounds, **Arkansas Department of Health**, Little Rock, January 7, 2021. (Web-based presentation due to SARS-CoV-2 pandemic.)

52. Childhood Tuberculosis: Forgotten but Not Gone. Presented at Pediatric Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, January 10, 2016.

51. Childhood Viral Exanthems. Presented at Dermatology Grand Rounds, **University of Arkansas for Medical Sciences**, Little Rock, AR, November 4, 2015.

50. **Human Papillomavirus Vaccine: It's the Cancer Prevention, Stupid.** Jointly resented at Pediatric Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, September 9, 2014.

49. Update on the Diagnosis and Management of CNS Infections. Presented at Neurology Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, January 23, 2014.

48. Update on (Selected) Viral Infections of the Central Nervous System. Presented at Pediatric Grand Rounds, **Cook Children's Hospital**, Fort Worth, TX, September 24, 2013.

47. Human Parechoviruses: Or "Enterovirus Lite". Presented at Pediatric Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, September 6, 2011.

46. Pandemic 2009 H1N1 Influenza: An Overview. Presented at Pediatric Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, October 20, 2009.

45. The Clinical Spectrum of Enteroviral Disease. Presented at Pediatric Grand Rounds, **Arkansas Children's Hospital**, Little Rock, AR, August 12, 2008.

44. Arboviral Infections of the Central Nervous Systems. Presented at Pediatric Grand Rounds, **Children's Hospital**, Omaha, NE, June 22, 2007.

43. Pertussis. Presented at Nursing Grand Rounds, **Children's Hospital**, Omaha, NE, August 10, 2006.

42. Viral Encephalidites of North America. Presented at the University of South Dakota School of Medicine, Department of Pediatrics Grand Rounds, **Sioux Valley Hospital**, Sioux Falls, SD, May 26, 2005.

41. Everything You Wanted to Know About Influenza But Didn't Know Who to Ask. Co-presented at Pediatric Grand Rounds, **Children's Hospital**, Omaha, NE, December 12, 2003.
40. Perinatal Enteroviral Infections. Presented at the Obstetric and Gynecology Grand Rounds, **Creighton University Medical Center**, Omaha, NE, December 10, 2003.

39. Group B Streptococcus: Changing Antibiotic Spectrum and New Screening Recommendations. Presented at University of South Dakota School of Medicine, Department of Pediatrics Grand Rounds, **Sioux Valley Hospital**, Sioux Falls, SD, May 15, 2003.

38. Respiratory syncytial virus: A Review of its Molecular Virology and Clinical Aspects. Presented at Pediatric Grand Rounds **Chang Gung Children's Hospital**, Taipei, Taiwan, March 28, 2003.

37. Lower Respiratory Tract Infections in Children. Presented at Pediatric Grand Rounds **St. Elizabeth Health System**, Lincoln, NE, February 25, 2003.

36. Primary Immunodeficiency in Children: Evaluation of the Child with Suspected Immunodeficiency. Presented at Pediatric Grand Rounds **St. Elizabeth Health System**, Lincoln, NE, January 30, 2003.

35 Mapping a Major Genomic Determinant of Cardiovirulence in Coxsackievirus B3. Presented at the **Weibe Foundation Lecture Series, Children's Hospital**, Omaha, NE, January 24, 2003.

34. Enteroviral Myocarditis: Determinants of Cardiovirulence in Coxscakievirus B3. Presented at Pediatric Grand Rounds, **Mercy Children's Hospital**, Kansas City, MO, October 31, 2002.

33. Respiratory Syncytial Virus: Overview and Developments in Prophylaxis. Presented at Pediatric Grand Rounds, **St. John Hospital and Medical Center**, Detroit, MI, July 22, 2002.

32. Respiratory Syncytial Virus: Overview and Recent Developments. Presented at Pediatric Grand Rounds, **Riley Children's Hospital**, Indianapolis, IN, January 30, 2002.

31. Hepatitis C in Children. Presented at Grand Rounds, **Blank Children's Hospital**, Des Moines, IA, January 18, 2002.

30. Respiratory Syncytial Viral Infections. **Altru Health System**, Grand Forks, ND, October 17, 2001.

29. Respiratory Syncytial Viral Infections in Children and Adults. **MeritCare Health System**, Fargo, ND, October 16, 2001.

28. Hepatitis C. Presented at Pediatric Grand Rounds, **Children's Hospital**, Omaha, NE, May 4, 2001.

27. Postnatal Follow Up of the HIV-Exposed Infant. Presented at Obstetrics and Gynecology Department Grand Rounds, **Creighton University Medical Center**, Omaha, NE, February 14, 2001.

26. Update on AIDS and HIV in Children. Presented at Pediatric Grand Rounds, **University of Tennessee Medical Center**, Knoxville, TN, October 19, 2000.

25. Respiratory Syncytial Virus: Trends and Treatment. Presented at Pediatric Grand Rounds, **Cook Children's Medical Center**, Fort Worth, TX, August 29, 2000.

24. New Anti-Influenza Drugs: The Neuraminidase Inhibitors. Presented at Grand Rounds, **Children's Hospital Pediatric**, Omaha, NE, December 10, 1999.

23. Influenza: Diagnosis and Treatment Options. Presented at Grand Rounds, **Good Samaritan Hospital,** Kearney, NE, December 3, 1999.

22. Respiratory Syncytial Virus Infections: Overview and New Insights. Presented at Pediatric Grand Rounds, **Blank Children's Hospital Pediatric**, Des Moines, IA, October 29, 1999.

21. Overview of RSV Infections. Presented at Pediatric Grand Rounds, **Wesley Medical Center**, Wichita, KS, October 15, 1999.

20. Tri-Institutional Research on Enterovirus-Related Diseases. Presented at Grand Rounds, **Children's Hospital**, Omaha, NE, August 6, 1999.

19. RSV and Asthma: Is there a link? Presented at Pediatric Grand Rounds**, Regions Hospital**, St. Paul, MN, January 29, 1999.

18. Update on Issues in Pediatric Infectious Diseases-1999. Presented at Pediatric Grand Rounds, **Good Samaritan Hospital**, Kearney, NE, January 22, 1999.

17. Seminar on Current Amplified Molecular Techniques in Microbiology. Presented at Grand Rounds, **Children's Hospital**, Omaha, NE, April 17, 1998.

16. Enteroviral RT-PCR Significantly Impacts on the Care of Febrile Infants and Children. Presented at Grand Rounds, **Children's Hospital**, Omaha, NE, August 14, 1998.

15. Pneumococcal Resistance-Molecular to Medical: An Overview. Presented at Pediatric Grand Rounds, **University of Iowa School of Medicine**, Iowa City, IA, February 7, 1997

14. Management of RSV infections. Presented at Grand Rounds, **Olympia Fields Hospital**, Olympia Fields, IL, January 28, 1997.

13. RSV-Bronchiolitis. Presented at Grand Rounds, **Mercy Medical Center**, Des Moines, IA, December 3, 1996.

12. RSV Overview. Presented at Grand Rounds, **St. Anthony Hospital**, Chicago, IL, November 22, 1996.

11. Penicillin resistant pneumococcal infections. Presented at Pediatric Grand Rounds, **Butterworth Hospital,** Grand Rapids, MI, April 23, 1996.

10. Management of the febrile infant: Summary of the Febrile Infant Task Force. Presented at Pediatric Grand Rounds **Children's Hospital.** Omaha, NE, April 19, 1996.

9. Respiratory Syncytial Virus: An Overview. Presented at **Mt. Sinai Hospital** Grand Rounds, Chicago, IL, March 20, 1996.

8. Pneumococcal Resistance in the 90's. Presented at **Hackley Hospital** Grand Rounds, Muskegon, MI, March 11, 1996.

7. Respiratory Syncytial Virus Update. Presented at the **Bismarck Continuing Medical Education Council Grand Rounds**, Bismarck, ND, March 7, 1996.

6. Antiviral Therapy. Presented at **Mason City Clinic Grand Rounds**, Mason City, IA, March 6, 1996.

5. PCR Diagnosis of enterovirus infections: What the clinician needs to know. Presented at Grand Rounds, **Children's Hospital**, Omaha, NE, February 16, 1996.

4. The Rise of Penicillin Resistant Pneumococcal Infections. Presented at **University of South Dakota School of Medicine Department of Internal Medicine Grand Rounds**, Sioux Valley Hospital, Sioux Falls, SD, January 31, 1996.

3. Respiratory syncytial virus infections. Presented at Grand Rounds, **Children's Hospital**. Omaha, NE. November 10, 1995.

2. RSV Related Illness and Current Treatments. Presented at Pediatric Grand Rounds **St. Mary's Hospital,** Rhinelander, WI, January 13, 1995.

1. Update on Immunizations. Presented at Grand Rounds, **Children's Hospital**, Omaha, NE, May 27, 1994.

Local

62. A Secretary's Daily Duties, Tackling the COVID-19 Pandemic in Arkansas, and the Importance of Civic Engagement in Political/Health Policy Processes. Presented at **The Policy Lion. A Town Hall with Arkansas Health Secretary Dr. José Romero**, University of Arkansas, Fort Smith, AR, October 29, 2021.

61. Keynote Address. Presented at **Hispanic Heritage Month**, Arkansas Tech University, Russellville, AR, October 12, 2021.

60. Current Status of COVID-19 Vaccines and Vaccination in Arkansas. Presented at the **UAMS COVID-19 Learn on Demand Lecture Series**, Little Rock, AR, March 17, 2021. (Webinar presentation due to COVID-19.)

59. Community Update on COVID-19 in Arkansas. **Garland County Library**, Hot Springs, AR. August 1, 2020. (Webinar presentation due to COVID-19.)

58. Pediatric TB Case Presentations. Presented at **Essential Skills for the TB Nurse Case Manager**, Arkansas Department of Health, Little Rock, AR, May 3, 2017.

57. Methicillin-resistant Staphylococcus Aureus in the Neonatal Intensive Care Unit. Presented at the **Sharing Lots of Love…Caring for Little Lives**, Willow Creek Women's Hospital Neonatal Conference, Fayetteville, AR, April 15, 2010.

56. Pandemic 2009 H1N1 Influenza. Presented at The Arkansas Medical Dental and Pharmaceutical Association (AMDPA). Little Rock, AR, November 22, 2009.

55. Writing Test Questions. Presented at the **Writing for Success Faculty Development Annual Conference**, Arkansas Children's Hospital, Little Rock, AR September 8, 2009.

54. Respiratory Syncytial Virus: Overview and Prevention. Presented at the **Sharing Lots of Love…Caring for Little Lives**, Willow Creek Women's Hospital Neonatal Conference, Fayetteville, AR, March 5, 2009.

53. CMV, HSV, EV Prenatal Infections. Presented at **Fetal Anomalies Interdisciplinary Management (FAIM) Conference Arkansas Children's Hospital**, Little Rock, AR, September 26, 2008.

52. New Pediatric Vaccines. Presented at **University of Nebraska Medical Center-Clarkson Hospital**, Omaha, NE, October 26, 2007.

51. Winter Viral Illnesses: What's Here and What to Expect this Winter. Presented at **Alegent Health Bergan Mercy Medical Center and Lakeside Hospital**, Omaha, NE, January 17 and 19, 2006

50. Review of RSV Infection in High Risk Infants. Presented at the **Twelfth Newborn and Pediatric Symposium**, Louisville, KY, October 22, 2004.

49. Review of the AAP/AAFP Guidelines for Treatment of Otitis Media. Presented at **The Great Plains Regional Medical Center**, North Platte, NE, April 22, 2004

48. Unspeakable Bugs- The STDs. Presented at the **Bugs, Bumps, Boo-boos Conference-Children's Hospital**, Omaha, NE, October 29, 2003

47. The Management of Serious Infections in Children. Presented at the **9th Annual Infectious Diseases Symposium**, St. Francis Health Center, Topeka, KA, October 2, 2003.

46. Managing Pediatric Upper Respiratory Infections in an Era of Increasing Bacterial Resistance. Presented at the **Platte-Loup Medical Society Meeting**, Columbus, NE, September 23, 2003.

45. Smallpox Overview: Epidemiology to Prevention. Presented at the **Bioterrorism Health Education Consortium Symposium**, Norfolk, NE, June 10, 2003.

44. Group B beta Streptococcal Resistance Among Pregnant Women. Presented at the **Mary Lanning Memorial Hospital Spring CME Conference**, Hastings, NE, May 10, 2003.

43. Current Trends in Antibiotic Resistance Among *S. pneumoniae* and *S. aureus*. Presented at the **Mary Lanning Memorial Hospital Spring CME Conference**, Hastings, NE, May 10, 2003.

42. "Newer" Pediatric Vaccines. Presented at the **Mary Lanning Memorial Hospital Spring CME Conference**, Hastings, NE, May 10, 2003.

41. Smallpox: The Disease and Its Prevention. Presented at the **Mary Lanning Memorial Hospital Spring CME Conference**, Hastings, NE, May 9, 2003.

40. Infectious Disease Update. Presented at **Crawford County Medical Society Annual Meeting**, Denison, IA, May 9, 2002.

39. Otitis Media: Trends in Antibiotic Resistance—An Update on CDC Recommendations. Presented at CME Program for **Good Samaritan Health Systems**, Kearney, NE, April 20, 2001.

38. Immunization Update 2001. Presented at **Nebraska Academy of Physician Assistants Convention**, Kearney, NE, April 5, 2001.

37. Hepatitis C in Children. Presented at **Practical Pediatrics: 2001 Update, Children's Hospital**, Omaha, NE, February 16, 2001.

36. Update on Respiratory Syncytial Virus Infection in Children. Presented at CME Program for **St. John's Regional Medical Center**, Joplin, MO, December 4, 2000.

35. Respiratory Syncytial Virus: Trends and Treatment. Presented at **Methodist Hospital School of Nursing**, Omaha, NE, November 17, 2000.

34. Overview of Community Acquired Pneumonia: Therapeutic Options. Presented to **Northeast Nebraska Medical Society**, Norfolk, NE, April 6, 2000.

33. Community Acquired Infection: Antibiotic Resistant Disease. Presented at **Mercy Hospital**, Council Bluffs, IA, March 20, 2000.

32. Respiratory Syncytial Virus Infection: Overview and New Insights. Presented at **Trinity Regional Hospital**, Fort Dodge, IA, January 26, 2000.

31. Newer Therapies for Influenza Virus Infection. Presented at **Cass County Memorial Hospital**, Atlantic, IA, December 20, 1999.

30. Respiratory Syncytial Virus Infections. Presented at **Alegent Health Mercy Hospital**, Council Bluffs, IA, November 30, 1999.

29. Parenteral Antibiotic Therapy in the Face of Increasing Bacterial Resistance. Presented at **Carroll County Medical Society Meeting**, Carroll, IA, April 26, 1999.

28. Update: Pediatric Antibiotics. Presented at **Annual Pediatric Fellowship, Children's Hospital**, Omaha, NE, December 11, 1998.

27. Treatment of Acute Otitis Media in the Age of Antimicrobial Resistance. Presented to **Platte-Loup Valley Medical Society**, Columbus, NE, March 24, 1998.

26. Overview and Update of RSV in Pediatric Patients. Presented at **AMI Culver-Union Hospital**, Indianapolis, IN, December 11, 1997.

25. Emerging Antibiotic Resistance in Pneumococcal Infections. Presented at the **Children's Hospital Annual Pediatric Fellowship**, Omaha, NE, November 8, 1997.

24. Drug-Resistant *Streptococcus pneumoniae*. Presented to **Lynn County Medical Society,** Cedar Rapids, IA, October 28, 1997.

23. Penicillin-Resistant Pneumococcus: Its Implications for Diagnosis and Therapy. Presented at **Iowa Methodist Medical Center**, Des Moines, IA, October 24, 1997.

22. Management of Otitis Media and Sinusitis in an Age of Increasing Antibiotic Resistance. Presented at **Iowa Methodist Medical Center**, Des Moines, IA, October 23, 1997.

21. RSV Bronchiolitis in the Pediatric Patient. Presented at **Mercy Hospital Medical Center, Des Moines**, IA, September 24, 1997.

20. Update on RSV. Presented at **CME Program, Dakota Heartland Hospital**, Fargo, ND, December 19, 1996.

19. Penicillin-Resistant Pneumococcus and Mechanisms of Antimicrobial Resistance. Presented at **CME Program**, **San Juan Regional Medical Center**, Farmington, NM, November 6, 1996.

18. Pneumococcal Resistance in the 90's. Presented at **Family Medicine CME Course**, for University of Nebraska Medicine Center, in Lincoln, NE, September 28, 1996.

17. Sepsis and infection in children. Presented at the **Children's Hospital Medical-Surgical Units Review Session for Registered Nurses**. Omaha, NE, August 23-30, 1996.

16. Pediatric Infectious Disease Case Presentations. Presented at **Pediatric Grand Rounds Children's Hospital.** Omaha, NE, August 16, 1996.

15. Tuberculosis in the 90's. Presented at **Salina Regional Health Center.** Salina, KS, July 25, 1996.

14. Penicillin Resistant Pneumococcal Infections. Presented at the **Third District Medical Society and Brookings Hospital.** Brookings, SD, June 20, 1996.

13. Antibiotic Resistance. Presented at **Continuing Medical Education Program Pediatric Conference, Trinity Medical Center**. Rock Island, IL, June 7, 1996.

12. The Febrile Infant. Presented at **Metro Community College Common Pediatric Infections Workshop**, Omaha, NE, November 2, 1995

11. RSV. Presented to the **Platte-Loup Medical Society**. Columbus, NE. January 24, 1995.

10. RSV-related illness and current treatments. Presented at **St. Agnes Hospital**. Fond du Lac, WI. January 19, 1995.

9. The febrile infant. Presented at **Lincoln General Hospital**. Lincoln, NE. January 14, 1995.

8. An overview of RSV. Presented at **Mary Lanning Memorial Hospital**. Hastings, NE. January 6, 1995.

7. RSV bronchiolitis. Presented at **Good Samaritan Hospital.** Kearney, NE. December 16, 1994.

6. Recent Developments in Pediatric Infectious Diseases: 1994. **Pediatric Fellowship Program**. Children's Hospital, Omaha, NE. December 10, 1994.

5. Resurgence of Tuberculosis. Presented as part of the conference **Little Kids: Big Problems. A Pediatric Infectious Disease Symposium.** Denver, CO. September 25, 1992.

4. Pediatric HIV and AIDS. Presented at the **Pediatric AIDS Update**. Greeley, CO. April 7, 1992.

3. Meningitis in the Neurosurgical Patient. Presented to the **American Association of Neurosurgical Nurses- Rocky Mountain Chapter**. Denver, CO. February 12, 1992.

2. Tick Talk. Presented as part of the conference **Little Kids: Big Problems. A Pediatric Infectious Disease Symposium.** Denver, CO. June 21, 1991.

1. Neonatal Enterovirus Infection. Presented at **Recognition and Care of the Critically Ill Neonate and Child.** Presented by The Children's Medical Center at Stony Brook, Children's Hospital of the University Hospital, Department of Pediatrics, School of Medicine. September 16-17, 1987.

Community Presentations:

12. Role of Health Department and State Government. Presented at the **Arkansas Governor's Internship Program**, Little Rock, AR, July 19, 2021

11. Equity of COVID-19 Vaccine Distribution. Hosted by the **Mexican Coalition**, New York, NY. April 5, 2021. (Presented as a Webinar due to the COVID-19 pandemic.)

10. Pediatric Tuberculosis. **Quarterly Communicable Disease Nurse Specialist Meeting. Arkansas Department of Health**, Little Rock, AR. December 9, 2016.

9. The Importance of Pediatric Research. **Optimist Club presentation**, Little Rock, AR. March 3, 2015.

8. Cultural Competency for Health Providers. **Binational Health Week Inauguration, Metropolitan Community College**, Omaha, NE, October 9, 2006.

7. Summary of the Findings: Minority Behavioral Health Risk Factor Survey (Douglas and Sarpy County, Nebraska). **Urban League of Nebraska Community Forum**, Omaha, NE, April 28, 2005.

6. Overview of Economic and Health Indicators Among Omaha's Latinos. **The Second Cumbre of the Great Plains: Re-Visioning Latino America: New Perspectives on Migration, Transnationalism and Integration,** Office of Latino/Latin American Studies, University of Nebraska at Omaha, Omaha, NE, April 23, 2005.

5. Addressing Health Care Disparities. Keynote address presented at **Minority Graduate Recognition Reception, University of Nebraska Medical Center**, Omaha, NE, May 8, 2002.

4. Latinos and the Batalla de Puebla. **Cinco de Mayo Lecture, University of Nebraska Medical Center**, Omaha, NE, May 4, 2001.

3. Machismo in the New Millennium. Keynote address presented at **Seventh Annual Latino Conference**, **University of Nebraska at Omaha**, Omaha, NE, March 22, 1999.

2. A young investigator's view of research. Presented at **Grant Skills Institute Meeting**, **University of Nebraska Medical Center**, Omaha, NE, June 5, 1997.

1. Sexually Transmitted Diseases in Adolescents- HIV Infection. Presented to **The Suffolk Coalition for Parents and Children**. October 1987.

APPEARANCES BEFORE THE ARKANSAS STATE LEGISLATURE

7. 3.31.2021 Joint Budget Committee- Personnel
   Topic: Bill Discussion (Attended, but did not speak)

6. 2.9.2021 Joint Budget Committee- Personnel
   Topic: Bill Discussion (Attended, but did not speak)

5. 1.14.2021 Public Health, Welfare, and Labor Committee
   Topic: Vaccine Status Report

4. 9.9.2020 Public Health, Welfare, and Labor Committee
   Topic: Planning for COVID-19 Vaccination

3. 8.31.2020 Insurance and Commerce Committee
   Topic: Overview of the current COVID-19 Statistics for Arkansas
   Topic: Update on Utilization of Contact Tracers

2. 8.20.2020 Public Health, Welfare, and Labor Committee & Education Committee
   Topic: Coronavirus Data Analysis in School Districts

1. 7.27.2020 Public Health, Welfare, and Labor Committee
   Topic: Governor's Mask Executive Order

RESEARCH SUPPORT: GRANTS, CLINICAL STUDIES, INDUSTRY SPONSORED

110. NIH-NIAID Congenital and Perinatal Infections- Rare Diseases Clinical Research Consortium- Neonatal Enterovirus and Human Parechovirus Viral Sepsis: Natural History and Predictors of Morbidity and Mortality, DMID 19-0026.
Funding source: NIH-NIAID
Period of funding: 6.2020 – 6.2.22

109. NIH-NIAID Congenital and Perinatal Infections- Rare Diseases Clinical Research Consortium- A Prospective Study of Acute Flaccid Myelitis (AFM) to Define Natural History, Risk Factors, and Pathogenic Mechanisms.
Funding source: NIH-NIAID
Funding: $22,000
Period of funding: 10.7.19 – 6.2.22

108. NIH-NIAID- Non-Invasive Diagnosis of Pediatric Pulmonary Invasive Mold Infections (NIH Grant # R01AI139032, PI: WJ Steinbach, MD)

Funding Source: NIH-NIAID
Funding:
Period of funding: 4.16.19 – 1.1.22

107. NIH-NCI- Improving HPV Vaccination Using Implementation Strategies in Community Pharmacies (R21CA231180, PI B Teeter)
Funding Source: NIH-NCI
Funding: .05% FTE consultant
Period of funding: 4.16.19 – 3/31/2020

106. Industry Sponsored- The Sentinel Laboratory Influenza and Respiratory Syncytial Virus Surveillance.
Funding source: IQVIA
Funding:
Period of funding: 2018 – 6.2.22

105. NIH-NIAID Collaborative Antiviral Study Group- A Phase II, Single-Stage, Single-Arm Investigation of Oral Valganciclovir Therapy in Infants with Asymptomatic Congenital Cytomegalovirus Infection (DMID 16-0095)
Funding Source: NIH-NIAID Collaborative Antiviral Study Group.
Funding:
Period of funding: 12.8.18 – 6.2.22

104. NIH/NCATS 1U54TR001629-01A1 L. James (PI)
Expanding Translational Research in Arkansas: The Clinical and Translational Science Award (CTSA) at the University of Arkansas for Medical Sciences' (UAMS) Translational Research Institute (TRI) seeks to support high quality translational and clinical research locally, regionally, and nationally and foster innovation in research methods, training, and career development. TRI's vision is to serve as a collaborative, statewide network for translational research that promotes health and reduces disease. Our mission is to further catalyze translational research initiatives in Arkansas and the US that will accelerate and disseminate biomedical discoveries to prevent, diagnose, and treat human illness.
Role: Primary liaison between ACHRI researchers and CTSA research opportunities in LTICS; provide expertise for researchers interested in multidisciplinary research in children (ISP/Hub Research Capacity).
Funding Source: NIH/NCATS
Funding: .05 FTE
Period of funding: 09/26/2017–08/31/2018

103. Industry Sponsored- Nasopharyngeal and Mid-Turbinate Swab Specimen Collection for Use in Development of Rapid Diagnostic Tests for Respiratory Syncytial Virus (RSV) (Protocol 1729601)
Funding Source: Alere Scarborough, Inc.
Funding: $5,000.00
Period of funding: December 14, 2017 – April 30, 2019

102. NIH-NIAID Collaborative Antiviral Study Group- An observational study of acyclovir pharmacokinetics, viral population kinetics, and potential markers of disease severity in neonatal herpes simplex infections. (DMID Protocol 16-0061)
Funding Source: NIH-NIAID Collaborative Antiviral Study Group.
Funding: $7,250.00
Period of funding: November 1, 2017 – September 1, 2019

101. PCORI Sponsored- Kawasaki Disease Comparative Effectiveness Trial (KIDCARE)
Funding Source: Patient-Centered Outcomes Research Institute (PCORI)
Funding: $16,100.00
Period of funding: 1.23.2018 – 8.31.20

100. Industry Sponsored- Nasal Swab and Nasopharyngeal Swab Specimen Collection for use with Xpert® Xpress Flu and/or Flu/RSV Assays (031S).
Funding Source: Cepheid
Funding: $76,334.00
Period of funding: Closed May 2018

99. Industry Sponsored- Cytomegalovirus Research Stage Pre-Clinical Study Protocol- Specimen Collection.
Funding Source: Meridian
Funding: $41,500.00
Period of funding: 2017 – 11.22.17

98. Industry Sponsored- Nasal Swab and Nasopharyngeal Swab Specimen Collection for use with Cepheid Flu and/or Flu/RSV Assays. (026S).
Funding Source: Cepheid
Funding: $19,603.00
Period of funding: February 23, 2017 to September 20, 2017

97. Industry Sponsored- Clinical Evaluation of the Xpert Xpress Strep A Assay on the GeneXpert Xpress System in a CLIA-Waived Environment, Protocol 226.
Funding Source: Cepheid
Funding: $10,962.50
Period of funding: February 23, 2017 to August 8, 2017

96. Industry Sponsored- Clinical Evaluation of the Xpress Flu/RSV CW Assay and Xpress Flu A/B CW Assay on the GeneXpert Xpress System in a CLIA-Waived Environment. (224)
Funding Source: Cepheid
Funding: $82,997.50
Period of funding: October 31, 2016 – August 24, 2018

95. Industry Sponsored- An Open label, Dose-finding, Pharmacokinetics, Safety, and Tolerability Study of a Single Dose Infusion of VABOMERE (Meropenem-Vaborbactam) in Pediatric Subjects from Birth to Less than 18 Years of Age with Serious Bacterial Infections.
Funding Source: Rempex Pharmaceuticals/The Medicines Company
Funding: $31,850.00
Period of funding: 8.3.16 – 9.1.20

94. Industry Sponsored- illumigen Kingella Sample Acquisition
Funding Source: Meridian
Funded: $2,025.00
Period of Funding: 7/1/16 – 7/6/2018

93. Industry Sponsored- A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of a Human Monoclonal Antibody, REGN2222, for the Prevention of Medically Attended RSV Infection in Preterm Infants.
Funding Source: Regeneron Pharmaceuticals, Inc.
Funding: $ 19,257.25

Period of funding: January 2016 – 12.21.17

92. Industry Sponsored- Clinical Evaluation of the Alere™ BinaxNOW Influenza A&B Card Assay and the Alere™ Reader. (Protocol 1518101)
Funding Source: Alere Scarborough, Inc.
Funding: $ 23,125.00
Period of funding: 11.2015 – 6.30.2016

91. NIH-NIAID- A Randomized Double-Blind, Phase 3 Study Comparing the Efficacy and Safety of High-Titer versus Low-Titer Anti-Influenza Immune Plasma for the Treatment of Severe Influenza A (IRC 005).
Funding Source: National Institute of Allergy and Infectious Diseases (NIAID)
Funding: $ 28,900.00
Period of funding: January 2016 – October 4, 2017

90. Industry Sponsored- A Randomized, Double-blind, Placebo-controlled, 2-Part Study of Orally Administered ALS-008176 to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single Ascending Dosing and Multiple Ascending Dosing in Infants Hospitalized with Respiratory Syncytial Virus (RSV) Infection.
Funding Source: Alios BioPharma
Funding: $ 64,095.00
Period of funding: January 2016 – April 25, 2018

89. NIH-NIAID Collaborative Antiviral Study Group- A Safety and Dose-Determining Study of CMX-001 in Infants with Neonatal Herpes Simplex Virus (HSV) Infection Involving the Central Nervous System (CNS Disease) (DMID 11-0068 CASG 402).
Funding Source: NIH-NIAID Collaborative Antiviral Study Group.
Funding: Pending- $5,000
Period of funding: Study failed to start due to unavailability of study drug. Closed 5/2016.

88. NIH-NICHD Pediatric Fungal Network- Fungal Biomarkers for Diagnosis and Response to Therapy for Pediatric Candidemia (BIOPIC)
Funding source: NIH-NICHD Pediatric Fungal Network
Funding: Pending- $32,000.00
Period of funding: 1.30.2015 – 2020

87. Industry Sponsored- Clinical Evaluation of an Improved BinaxNOW Influenza A&B Card.
Funding Source: Alere Scarborough, Inc.
Funding: $17,550
Period of funding: 12.2014 – 2.2015

86. Industry Sponsored- A Phase 1, Non-Comparative, Open-Label Study to Characterize the Pharmacokinetics of a Single Intravenous Dose of Ceftolozane/Tazobactam in Pediatric Patients Receiving Standard of Care Antibiotic Therapy for Proven or Suspected Gram-negative Infection or for Perioperative Prophylaxis.
Funding source: Cubist Pharmaceuticals, Inc
Funding: $ 37,050.00
Period of funding: 11.20.2014 – 9.27.17 (No longer Site PI as of 5/4/17)

85. Industry Sponsored- An Open Label, Dose-finding, Pharmacokinetics, Safety, and Tolerability Study of Oritavancin Single Dose Infusion in Pediatric Subjects Less Than 18 Years of Age with Suspected or Confirmed Bacterial Infections.

Funding Source: The Medicines Company
Funding: $ 40,844.00
Period of funding: 5.19.14 – 3.3.20

84. Investigator Initiated- Acyclovir Use in Young Infants
Funding source:
Funding: $15,000
Period of funding: 6.12.14 – 12.31.15

83. NIH-NIAID Collaborative Antiviral Study Group- Identification of Herpes Simplex Virus (HSV) Shedding in the Female Genital Tract of Pregnant and Nonpregnant Women by the Xpert HSV 1/2 Assay, Routine PCR, and Culture (DMID 11-0070 CASG 401).
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Funding: $ 143,495.00
Period of funding: 6.3.14 – 11.28.17

82. Investigator Initiated- Epidemiology of Hepatitis C Virus Infection Among Patients Cared for by the Pediatric Infectious Disease Clinic at the Arkansas Children's Hospital.
Funding source:
Funding: $30,000
Period of funding: 3.6.14 – 6.2.22

81. NIH-NIAID Collaborative Antiviral Study Group - Evaluation of the Pharmacokinetics and Pharmacodynamics of Ganciclovir in Premature Infants Receiving Treatment for Cytomegalovirus Infection (DMID 11-0067 CASG 41104).
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Funding: Pending- $ 93,544.00
Period of funding: 6.26.2013 – 9.1.2019

80. NIH-NIAID Pediatric Fungal Network- Multi-Center Studies to Improve Diagnosis and treatment of Pediatric Candidiasis (PEACE).
Funding source: NIH-NIAID Pediatric Fungal Network
Funding: Pending- $ 5,000.00
Period of funding: 6.21.2013 – 3.1.2019

79. Industry Sponsored- A Phase I Study to Assess the Pharmacokinetics, Safety and Tolerability of a Single Dose of Ceftazidime-Avibactam (CAZ-AVI) in Children From 3 Months of Age to <18 Years Who Are Receiving Systemic Antibiotic Therapy for Suspected or Confirmed Infection
Funding source: AstraZeneca
Funding: $5,185.70
Period of funding: 5.28.2013 - 12.2014

78. Industry Sponsored- An Open-Label, Multi-Center, Single Arm Study to Evaluate the Safety and Tolerability of Intravenous Zanamivir in the Treatment of Hospitalized Adult, Adolescent and Pediatric Subjects with confirmed Influenza Infection (NaI 113678)
Funding source: GlaxoSmithKline
Funding: Pending- $31,271.86 per patient, $104,304.95
Period of funding: 2010 – 1.2015

77. Investigator Initiated- Microbiology Specimen Repository
Funding source: Horace C. Cabe Foundation
Period of funding: 10.11.12 - Active

76. Cooperative Group Initiated- Multicenter Pneumococcal Surveillance Study
Funding source: Baylor College of Medicine
Funding: $113,089.00
Period of funding: 2010 – 6.2.22

75. Industry Sponsored- The Sentinel Laboratory Influenza and Respiratory Syncytial Virus Surveillance.
Funding source: imshealth
Funding: 9,320.00 received in 2016
Period of funding: 2010 – 2018

74. Industry Sponsored- SENTRY Antimicrobial Surveillance study with JMI Laboratories
Funding source: JMI Laboratories
Funding: $6,750.00
Period of funding: 2010 – July 29, 2016

73. Industry Sponsored- Postmarketing Observational Study of the Impact of Prevnar 13 (Pneumococcal 13 Valent Conjugate Vaccine) on Otitis Media in Children
Funding source: Pfizer
Funding: $1,267.50
Period of funding: 2012 – 2014

72. NIH-NIAID Collaborative Antiviral Study Group - A double blind, placebo-controlled, virologic efficacy trial of pleconaril (VP63843) in the treatment of neonates with enteroviral sepsis syndrome (CASG 106).
IRB number:
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Funding: $29,375
Period of funding: June 1999 - November 4, 2013

70. Industry Sponsored- BD Veritor System Clinical Evaluation for Rapid Detection of Respiratory Syncytial Virus- Reference Testing
Funding source: Beckton-Dickenson
Funding: $63,987.00
Period of funding: 10.1.2012 – 9.30.2013

70. Industry Sponsored- BD Veritor System Clinical Evaluation for Rapid Detection of Respiratory Syncytial Virus
Funding source: BD Diagnostics
Funding: 11,106.00
Period of funding: 2/2012 – 11/2012

69. Industry Sponsored- A Multi Center Outpatient Surveillance Study of Respiratory Syncytial Virus (RSV) Infection and RSV related Hospitalizations Among Subjects 24 Months of Age with a Medically Attended Respiratory Tract Infection
Funding source: Gilead
Funding: $20,895.00
Period of funding: 11/2012 – 10/2013

68. Industry Sponsored- A Prospective Randomized Double Blind Multicenter Study to Establish the Safety and Tolerability of Doripenem Compared With Cefepime in Hospitalized Children With Complicated Urinary Tract Infection
Funding source: Johnson & Johnson
Funding: $13,351.25
Period of funding: 7/2010 – 2/2013

67. Industry Sponsored- A Prospective Randomized Double Blind Multicenter Study to Establish the Safety and Tolerability of Doripenem Compared With Cefepime in Hospitalized Children With Bacterial Pneumonia
Funding source: Johnson & Johnson
Funding: $12,351.25
Period of funding: 7/2010 – 2/2013

66. Industry Sponsored- A Phase 3 Open Label Randomized Study of the Antiviral Activity Safety and Tolerability of Intravenous Peramivir in Hospitalized Subjects with Confirmed or Suspected Influenza Infection
Funding source: Quintiles
Funding: $57,282
Period of funding: 3/2010 – 3/2012

65. Industry Sponsored- Clinical Trial Protocol NS EZQ MRSA
Funding source: Novartis
Funding: $140,209.68
Period of funding: January 2010 - December 2010

64. Investigator Initiated- Retrospective Chart Review of Children < 6 months of age hospitalized with H1N1 Influenza infection at ACH.
Funding source: Horace C. Cabe Foundation
Funding: $10,000
Period of funding: October 2009 – October 2010

63. Industry Sponsored - A Phase 1/2a, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study to Evaluate the Safety, Tolerability, Immunogenicity and Vaccine-like Viral Shedding of MEDI-534, a Live, Attenuated Intranasal Vaccine Against Respiratory Syncytial Virus (RSV) and Parainfluenza Virus Type 3 (PIV3), in Healthy 6 to < 24 Month-Old Children and in 2 Month Old Infants (MI-CP178)
Funding source: MedImmune
Period of funding: July 2009 – June 2012

62. NIH-NIAID Collaborative Antiviral Study Group - A Phase III, Randomized, Placebo-Controlled, Blinded Investigation of Six weeks versus Six Months of Oral Valganciclovir Therapy in Infants with Symptomatic Congenital Cytomegalovirus Infection (CASG 112), DMID # 06-0046
Protocol number: CASG 112
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Period of funding: January 2009- June 2011

61. Industry Sponsored- A Phase 3b, Randomized, Open-Label, Multi-Center Study to Evaluate the Safety and Immunogenicity of 2 or 3 Doses of MenACWY Conjugate Vaccine in Healthy Infants and the Effects of a Booster Dose of MenACWY Administered in the Second Year of Life.
Funding source: Novartis Vaccines and Diagnositics
Period of funding: August 2010 – May 2011

60. NIH-NIAID Collaborative Antiviral Study Group - A Pharmacokinetic/Pharmacodynamic and Safety Evaluation of Oseltamivir (Tamiflu) for the treatment of Children less than 24 months of age with Confirmed Influenza Infection (CASG 114) (DMID Protocol # 06-0059) (Roche Protocol # WP-20749) Version # 2.0 November 22, 2006
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Period of funding: January 2009 – February 2011

59. Industry Sponsored- A Phase 3, Open-Label, Randomized Study of the Antiviral Activity, Safety, and Tolerability of Intravenous Peramivir in Adult and Adolescent Hospitalized Subjects with Confirmed or Suspected Influenza Infection
Funding source: Novartis
Period of funding: 2010 – May 2011

58. Industry Sponsored- Clinical Performance Evaluation of the 3M™ Rapid Detection RSV Test From Patients with Suspected RSV Infections.
Funding Source: 3M Diagnostics/Response Biomedical Corp
Period of Funding: December 2008 – March 2009

57. Industry Sponsored- A Phase 3b, Open-Label, Randomized, Parallel-Group, Multi-Center Study to Evaluate the Safety of Novartis MenACWY Conjugate Vaccine when Administered with Routine Infant Vaccinations to Healthy Infants
Funding source: Novartis
Period of funding: August 2009- October 2009

56. Industry Sponsored- Clinical Evaluation of NucliSens® EasyQ Influenza A/B Test
Protocol Number: B0243
Funding Source: bioMerieux
Funding: $112,155
Period of Funding: February 2008 – July 2008

55. Industry Sponsored– A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate a Single Intravenous Dose of Motavizumab (MEDI-524), a Humanized Enhanced Potency Monoclonal Antibody Against Respiratory Syncytical Virus (RSV), for the Treatment of Children Hospitalized with RSV Illness
Protocol Number: MI-CP-141
Funding Source: MedImmune, Inc.
Funding: $33,288
Period of Funding: October 2007 – July 2008

54. NIH-NIAID Collaborative Antiviral Study Group - A pharmacokinetic/pharmacodynamic and safety evaluation of Oseltamivir (Tamiflu®) for the treatment of children less than 24 months of age with confirmed influenza infection.
Protocol Number: CASG114
Funding Source: NIH-NIAID Collaborative Antiviral Study Group
Funding: $36,288
Period of Funding: October 2007 – July 2008

53. Industry Sponsored– An epidemiological study to evaluate the seasonality of respiratory syncytial virus-associated lower respiratory tract infections (LRI) or apnea in infants in the emergency department.
Protocol Number: MI-MA133

Funding Source: MedImmune, Inc.
Funding: $37,422
Period of Funding: October 2006 – May 2008

52. Industry Sponsored– A prospective, non-interventional study to evaluate the incidence of hospitalizations and medically-attended lower respiratory tract infection (MALRI) in premature infants 32 to 35 weeks gestational age who are not recommended to receive prophylaxis for RSV.
Protocol Number: MI-MA140
Funding Source: MedImmune, Inc.
Funding: $23,660
Period of Funding: December 2006 – December 2007

51. NIH-NIAID Collaborative Antiviral Study Group - A Phase II pharmacokinetic and pharmacodynamic evaluation of oral valganciclovir in neonates with symptomatic congenital cytomegalovirus (CMV) infection involving the central nervous system.
Protocol Number:
Funding Source: NIH-NIAID Collaborative Antiviral Study Group (CASG)
Funding:
Period of Funding: September 2004-2005

50. Industry Sponsored- A multicenter, randomized, open-label, comparative study to compare the efficacy and safety of Levofloxacin and standard of care therapy in the treatment of children with community-acquired pneumonia in the hospitalized or outpatient setting.
Protocol number: LOFBIV-PCAP-003 (PRI/LOF-INT-1)
Funding Source: Johnson & Johnson Pharmaceutical Research and Development.
Funding: $25,000
Period of funding: April 2002-April 2005

49. Industry Sponsored- A multicenter, randomized, comparative study to evaluate the efficacy and safety of Levofloxacin in treatment of children who have recurrent and/or persistent acute otitis media.
Protocol number: LOFBO-OTMD-002 (PRI/LOF-INT-2); Phase 3
Funding Source: Johnson & Johnson Pharmaceutical Research and Development.
Funding: $55,000.
Period of Funding: November 2002 – April 2005

48. Industry Sponsored– Evaluate the safety, tolerability, pharmacodinetics and immunogenicity of MEDI-524 in children with hemodynamically significant congenital heart disease.
Protocol number: MI-CP124
Funding Source: MedImmune, Inc.
Funding: $162,000
Period of Funding: September 2005-October 2006

47. Industry Sponsored– A pivotal Phase 3 study of MEDI-524 (Numax), an enhanced potency humanized respiratory syncytial virus (RS) monoclonal antibody, for the prophylaxis of serious RSV disease in high-risk children.
Protocol Number: MI-CP110
Funding Source: MedImmune, Inc.
Funding: $190,385
Period of Funding: September 2004 – August 2006

46. Industry Sponsored– GlaxoSmithKline (GSK) Biologicals inactivated hepatitis A vaccine (Havrix) containing 720 ELISA Units (EL.U.) of hepatitis A antigen per 0.5 mL dose absorbed onto 0.25 mg of aluminum hydroxide.
Protocol Number: 2-91-022-(HAV-220)
Funding Source: GlaxoSmithKline (GSK)
Funding: $54,750
Period of Funding: September 2003 – July 2004

45. Industry Sponsored– A randomized, double blind trial to assess the safety and relative efficacy of CAIV-T against inactivated influenzae vaccine in children 6-59 months of age.
Protocol Number: MI-CP111
Funding Source: MedImmune, Inc.
Funding: $561,320
Period of Funding: September 2004 – December 2005

44. Industry Sponsored– Clinical evaluation of the NucliSens® EasyQ Enterovirus Test
Funding Source: bioMérieux, Inc.
Funding: $65,023
Period of Funding: June 2005 – September 2005

43. Industry Sponsored– An open-label, single-arm trial to assess the shedding, immunogenicity and safety of Flu-Mist administered to healthy individuals 5-59 years of age.
Protocol Number: FM026
Funding Source: MedImmune, Inc.
Funding: $181,386.00
Period of Funding: June 2004-June 2005

42. Industry Sponsored- A Phase III, double-blind, randomized, comparative, multicenter study of the immunogenicity and safety of three doses of GlaxoSmithKline Biologicals' thiomersal-free hepatitis B vaccine (10 mcg/0.5 ml) compared to the US-liscenced GlaxoSmithKline Biologicals' preservative-free hepatitis B vaccine (Engerix-B, 10 mcg/0.5 ml) when administered intramuscularly on a 0, 1, 6-month schedule to healthy infants in their first two weeks of life.
Protocol Number:
Funding Source: GlaxoSmithKline Biologicals
Funding: $ 79,360
Period of funding: May 2003 – June 2005

41. Investigator Initiated- Latent tuberculosis infection (LTBI): Prevalence and epidemiology in Nebraska and evaluation of three methods of Pediatric LTBI prophylaxis.
Funding Source: Minority Health, Education and Research Office, UNMC
Funding: $55,055
Period of Funding: March 2005 – October 2006

40. Investigator Initiated- Measuring the impact of social marketing on testing for sexually transmitted diseases in a predominantly African American community.
Funding Source: Minority Health, Education and Research Office, University of NE Medical Center
Funding: $98,157
Period of Funding: March 2005 – July 2006

39. Industry Sponsored- Pre-booster Concentration of Anti-PRP Antibodies in Serum Samples Obtained from Toddlers (12-18 months of age) who have Completed the Primary Series of Vaccination with Licensed HIB-containing Vaccines.

Protocol number: EM501
Funding Source: Aventis Pasteur
Funding: $80,170
Period of funding: May 2003 - February 2004

38. Industry Sponsored- Respiratory Viral Testing Survey: A questionnaire-based study of 400 emergency room and clinical laboratory directors.
Protocol number: N/A
Funding Source: MedImmune, Inc.
Funding: $15,000
Period of Funding: January-May 2004

37. Industry Sponsored- Synagis® (palivizumab) outcomes registry.
Protocol number: None
Funding Source: MedImmune.
Funding: None
Period of funding: October 2003 – May 2004

36. Investigator Initiated- A compassionate use study of pleconaril in the treatment of severe picornaviral illness in adults, children and neonates.
Protocol number: VP843-038
Funding source: ViroPharma, Inc.
Funding: None
Period of funding: August 1997-February 2004

35. Industry Sponsored- A comparison of safety and efficacy of Cefdinir Oral Suspension versus Azithromycin in Pediatric Subjects with Acute Otitis Media
Protocol number: M03-630
Funding Source: Abbott Laboratories
Funding: $3,500
Period of funding: November 2003 – March 2004

34. Industry Sponsored- A multicenter, long-term, active-surveillance study of musculoskeletal disorders that occur after initiating a course of Levofloxacin or non-fluoroquinolone therapy for acute infectious diseases in children who were enrolled in Phase 3 clinical trials involving Levofloxacin therapy.
Protocol number: LOFBO-LTSS-001
Funding Source: Johnson & Johnson Pharmaceutical Research and Development
Funding: $50,400
Period of funding: April 2002-November 2003

33. Industry Sponsored-A Phase IV Comparative Study of the Safety and Efficacy of Cefdinir Oral Suspension, versus Amoxicillin/clavulanate in Pediatric Subjects with Otitis Media
Protocol number: M02-541
Funding Source: Abbott Laboratories
Funding: $1500
Period of funding: April - July 2003

32. Industry Sponsored- A phase III, observer-blinded, randomized, multicenter, clinical study of the safety, immunogenicity and consistency of three manufacturing lots of GlaxoSmithKline Biologicals' dTaP candidate vaccine as compared to a US-licensed Td vaccine (Massachusetts

Public Health Laboratories) when given as a booster dose to healthy adolescents (10-18 yrs of age).
Protocol number: 776423/001 (dTpa 0.3-001)
Funding Source: GlaxoSmithKline Biologicals'
Funding $114,000
Period of funding: October 2002-September 2003

31. Industry Sponsored- A randomized, placebo-controlled trial to assess safety, tolerability and immunogenicity of influenza virus vaccine, trivalent, types A and B, life cold-adapted (FluMist™) and measles, mumps, rubella (MMRIIO) and varicella (VARIVAXO) vaccines administered concurrently to healthy children.
Protocol number: AV018
Funding Source: MedImmune
Funding: $21,000
Period of funding: April-December 2002

30. Industry Sponsored- Synagis® (palivizumab) outcomes registry.
Protocol number: N/A
Funding Source: MedImmune
Funding: $1,050
Period of funding: October 2001-May 2002

29. Industry Sponsored- A double blind, placebo-controlled, randomized study to evaluate the efficacy and safety of prophylactic administration of pleconaril in the prevention of picornaviral respiratory illness in healthy adult subjects.
Protocol number: VP843-062
Funding Source: ViroPharma, Inc.
Funding: $180,324
Period of funding: September 2001-March 2002

28. Industry Sponsored- A randomized, double-blind, placebo-controlled study to evaluate the clinical efficacy, virologic activity, and safety of pleconaril (oral suspension) in the treatment of viral respiratory infection in children 7 to 12 years of age.
Protocol number: VP843-059
Funding Source: ViroPharma, Inc.
Funding: $3,500 per patient
Period of funding: September 2001-March 2002

27. Industry Sponsored- A randomized, double blind, placebo-controlled study to evaluate the clinical efficacy, virologic activity, and safety of pleconaril (oral suspension) in the treatment of viral respiratory infection in children 1-6 years of age.
Protocol number: VP843-061
Funding Source: ViroPharma, Inc.
Funding: $3,500 per patient.
Period of funding: September 2001-March 2002

26. John A. Wiebe, Jr. Children's Health Care Fund - Molecular characterization of the genomic determinant of cardiovirulence in coxsackievirus B3 clinical isolates.
Protocol number: 0002-106
Funding source: John A. Wiebe, Jr. Children's Health Care Fund
Funding: $100,600.
Period of funding: April 2001-October 2003

25. Industry Sponsored- A natural history study of neonates with enteroviral sepsis syndrome. Protocol number: VP843-041
IRB number:
Funding source: ViroPharma, Inc.
Funding: $90 per case.
Period of funding: September 2000-2003

24. Edna Ittner Pediatric Research Grant- Molecular epidemiology of coxsackievirus B3: 1954-1998. Protocol number: EI 0300
Funding source: Edna Ittner Pediatric Research Foundation
Funding: $14,987
Period of funding: July 1999-June 2001

23. NIH-NIAID Collaborative Antiviral Study Group - A double blind, placebo-controlled, virologic efficacy trial of pleconaril (VP63843) in the treatment of infants with enteroviral meningitis. Protocol number: NIH-CASG 107
Funding source: NIH-NIAID Collaborative Antiviral Study Group
Funding: $2,000 per subject.
Period of funding: June 1999-2002

22. John A. Wiebe, Jr. Children's Health Care Fund - Molecular epidemiology of Coxsackievirus B3 in the United States: Genomic and antigenic diversity of clinical isolates from 1956-1998.
Protocol number: 99-011-09
Funding source: John A. Wiebe, Jr. Children's Health Care Fund
Funding: $79,024.
Period of funding: July 1999-June 2001

21. National Science Foundation NE-EPSCoR Grant - Non-receptor determinants of species and tissue tropism of the picornaviridae.
Protocol number: EPS 972-0643
Funding source: National Science Foundation NE-EPSCoR Grant
Funding: $80,000
Period of funding: February 1999-January 2001

20. Industry Sponsored- Natural history study of viral meningitis in young children (4-7 years of age).
Protocol number: VP843-033
Funding source: ViroPharma, Inc.
Funding: $1,734 per patient.
Period of funding: October 1999-October 2000

19. Industry Sponsored- An open-label, single and multiple dose pharmacokinetics evaluation of the liquid formulation of pleconaril in pediatric patients with acute enteroviral meningitis. Protocol number: VP843-033
Funding source: ViroPharma, Inc.
Funding: $2,368 per patient.
Period of funding: October 1999-October 2000

18. Industry Sponsored- A double blind, randomized, placebo-controlled evaluation of Pleconaril in the prevention of otitis media in children with a history of otitis media following picornavirus respiratory infection.
Protocol number: VP843-023

Funding source: ViroPharma, Inc.
Funding: $2,370 per subject
Period of funding: August 1998 - May 2001

17. Edna Ittner Pediatric Research Grant- Virulence determination in clinical isolates of coxsackievirus B3.
Protocol number: EI 843-97-109-08
Funding source: Edna Ittner Pediatric Research Foundation
Funding: $14,988
Period of funding: July 1997-June 1999

16. Industry Sponsored- A double blind, placebo-controlled trial of VP63843 in the treatment of enteroviral meningitis in adolescents and children.
Protocol number: VP843-019
Funding source: ViroPharma, Inc.
Funding: $17,000
Period of funding: November 1998 - June 1999

15. Industry Sponsored- A double blind, placebo-controlled trial of VP63843 in the treatment of enteroviral meningitis in adolescents and adults.
Protocol number: VP843-018
Funding source: ViroPharma, Inc.
Funding: $8,500
Period of funding: November 1998 - June 1999

14. Industry Sponsored- A double blind, placebo-controlled trial of VP63843 in the treatment of enteroviral meningitis in adolescents and children.
Protocol number: VP843-012
Funding source: ViroPharma, Inc.
Funding: $3,000 per subject.
Period of funding: May 1997-November 1998

13. Industry Sponsored- A double blind, placebo-controlled trial of VP63843 in the treatment of enteroviral meningitis in adolescents and adults.
Protocol number: VP843-009
Funding source: ViroPharma, Inc
Funding: $3,000 per subject
Period of funding: May 1997-November 1998

12. John A. Wiebe, Jr. Children's Health Care Fund - Outcome based research to assess the impact of reverse transcription polymerase chain reaction diagnosis of enterovirus infections on patient management and health care costs.
Funding source: John A. Wiebe, Jr. Children's Health Care Fund
Funding: $30,726
Period of funding: May 1997-April 1998

11. Primary Care/Outcomes Seed Grant - Effect of rapid diagnosis of enteroviral infections using RT-PCR on patient care and health care costs.
Funding source: University of Nebraska Medical Center
Funding: $7,370.
Period of funding: July 1996-June 1998

10. Industry Sponsored- A double blind, placebo-controlled phase II study to determine the effect of two dose levels of VP63843 on the natural history of adult aseptic meningitis.
Funding source: ViroPharma, Inc.
Funding: $3,000 per subject.
Period of funding: June 1996-November 1996

9. Health Futures Foundation Grant - Translational initiation among echoviruses with different neurovirulent phenotypes.
IRB number: N/A
Funding source: Health Futures Foundation, Creighton University
Funding: $10,000
Period of funding: November 1995-October 1997

8. Ryan White Title IV HIV Program for Children Research Grant - Number 1MCH-PRW801-01-0. Period of funding: August 1995-July 1998. Collaboration with University of Colorado Health Sciences Center, Denver, CO.

7. Investigator Initiated- Evaluation of the potential health care cost savings of rapid enteroviral diagnosis in the management of the febrile infant.
Funding source: Roche Molecular Systems
Funding: $5,000.00 (supplies and reagents)
Period of funding: August 1995-January 1996

6. NIH Research Supplement for Underrepresented Minority Investigators - Supplement to grant 2R01 HL 4030-482-NHLBI/NIH
Funding source: NHLBI/NIH
Funding: $84,864 total direct cost.
Period of funding: March 1995-February 1996

5. Seed Research Grant - University of Nebraska Medical Center; Funding: $7,130.00. Period of funding: July 1994 - June 1995. Declined by recipient.

4. NIH Research Supplement for Underrepresented Minority Investigators - Supplement to grant number 2RO1 HL 40303-05-
Funding source: NHLBI/NIH
Funding: $59,382
Period of funding: March 1994-January 1995

3. Edna Ittner Pediatric Research Support Grant - Sequencing, cloning and functional analysis of the 5'NTR of phenotypically distinct echoviruses
Funding source: Edna Ittner Foundation
Funding: $14,570
Period of funding: July 1994 - September 1995

2. Minority Medical Faculty Development Grant - Sequencing of echovirus 9 (Hill strain) and Role of the 5'NTR in echovirus pathogenesis.
Funding source: Robert Wood Johnson Foundation
Funding: $162,920
Period of funding: July 1991-June 1993

1. Minority Medical Faculty Development Grant - Polyclonal antibodies to the poliovirus VP3 and 2C proteins for the detection of the human enteroviruses and Cloning of echovirus 9 (Hill strain).

Funding source: Robert Wood Johnson Foundation
Funding: $120,000
Period of funding: July 1987-June 1989

EXHIBIT B

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

CHARTER
of the
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Authority

The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

The Advisory Committee on Immunization Practices has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

Description of Duties

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations.

Upon the licensure of any vaccine or any new indication for a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the

committee does not make a recommendation at the committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review.

The committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents as well as special situations or populations that may warrant modification of the routine recommendations.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed, economic analyses and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations or other data become available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Official to Whom the Committee Reports

The committee reports to the Director, CDC. The CDC Director informs the Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations.

Support

Management and support services shall be provided by the Office of the Director, National Center for Immunization and Respiratory Diseases, Office of Infectious Diseases, CDC.

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding staff support, is $130,963. Estimate of annual person-years of staff support required is 2.5, at an estimated annual cost of $343,823.

Designated Federal Officer

CDC will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting policies and agendas, call all of the committee and subcommittee meetings, adjourn any meeting when the DFO deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held approximately three times per year at the call of the DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Director, CDC, or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. § 552b(c)) and Section 10(d) of the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Duration

Continuing.

Termination

Unless renewed by appropriate action, the Advisory Committee on Immunization Practices will terminate two years from the date this charter is filed.

Membership and Designation

The committee shall consist of 15 members, including the Chair. Members and the Chair shall be selected by the Secretary, HHS, from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The committee also shall consist of eight nonvoting ex-officio members: the Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration; the Deputy Director for Scientific Activities, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense; the Under Secretary for Health, Department of Veterans Affairs; the Director, Center for Biologics Evaluation and Research, Food and Drug Administration; the Director, Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services; the Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health; the Director, Indian Health Service; and the Director, National Vaccine Program Office, HHS; or their designees.

If fewer than eight ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representatives from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Assistants; American College Health Association; American College of Nurse Midwives , American College of Obstetricians and Gynecologists; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Industry Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; National Association of County and City Health Officials; National Association for Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Immunization Council and Child Health Program, Mexico; National Medical Association; National Vaccine Advisory Committee; Pediatric Infectious Diseases Society; Pharmaceutical Research Manufacturers of America; Society for Adolescent Health and Medicine; Society for Healthcare Epidemiology of America and such other nonvoting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the committee. Liaisons shall be deemed representatives.

The Chair shall be appointed for a 3-year term. The Chair is selected from among ACIP members who have had at least one year experience as a voting member and have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with Federal agencies and partner organizations.

Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon the renewal of the committee by appropriate action prior to its termination. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees

Subcommittees composed of members of the parent committee and other subject matter experts may be established with the approval of the Secretary, HHS, or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

Filing Date

April 1, 2018

Approved:

3/27/18
Date

Director
Management Analysis and Services Office

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

CHARTER
of the
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP).

Authority.

The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §2l7a), as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities.

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

The ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations. Upon the licensure of any vaccine or any new indication for a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the committee does not make a recommendation at the

committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review.

Description of Duties.

The committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, as well as special situations or populations that may warrant modification of the routine recommendations.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Official to Whom the Committee Reports.

The committee reports to the Director, CDC. The CDC Director informs the Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations.

Support.

Management and support services shall be provided by the Office of the Director, National Center for Immunization and Respiratory Diseases, Deputy Director of Infectious Diseases, CDC.

Estimated Annual Operating Costs and Staff Years.

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding staff support, is $245,873. Estimate of annual person-years of staff support required is 2.5, at an estimated annual cost of $372,378.

Designated Federal Officer.

CDC will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting policies and agendas, call all of the committee and subcommittee meetings, adjourn any meeting when the DFO deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings.

Meetings shall be held approximately three times per year at the call of the DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Director, CDC, or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. § 552b(c)) and Section 10(d) of the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, the ACIP will terminate two years from the date this charter is filed.

Membership and Designation.

The committee shall consist of 15 special government employee members, including the Chair. Members shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The committee also shall consist of six nonvoting ex-officio members: the Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration; the Director, Center for Biologics Evaluation and Research, Food and Drug Administration; the Director, Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services; the Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health; the Director, Indian Health Service; and the Director, Office of Infectious Disease and HIV/AIDS Policy, HHS; or their designees.

If fewer than eight ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representative members from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Assistants; American College Health Association; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Industry Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; International Society for Travel Medicine; National Association of County and City Health Officials; National Association for Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research Manufacturers of America; Society for Adolescent Health and Medicine; Society for Healthcare Epidemiology of America and such other nonvoting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the committee. Liaisons shall be deemed representatives.

Members, including the Chair, shall be selected by the Secretary and shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees.

Subcommittees composed, in part, of members of the parent committee and other subject matter experts may be established with the approval of the Secretary, HHS, or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping.

The records of the committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

Filing Date.

April 1, 2020

Approved:

March 22, 2020
Date

s/ Kalwant S. Smagh
Director
Strategic Business Initiatives Unit

EXHIBIT C

Federal Advisory Committee (FAC) Membership Balance Plan

Please read the Federal Advisory Committee Membership Balance Plan Guidance prior to completing this form

(1) FEDERAL ADVISORY COMMITTEE NAME
State the legal name of the FAC

Advisory Committee on Immunization Practices

(2) AUTHORITY
Identify the authority for establishing the FAC

The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. § 2l7a), as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

(3) MISSION/FUNCTION
Describe the mission/function of the FAC

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Director, CDC, regarding the use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population. Upon licensure of any vaccine or any new indication of a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the committee does not make a recommendation at the committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review. The committee shall provide advice for control of diseases for which a vaccine is licensed in the U.S. ACIP recommendations address use of FDA-licensed vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling the same disease. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparation as a class of biologic agents, as well as special situations or populations that may warrant modification of the routine recommendations. Committee deliberations on the use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed; and economic analyses and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic consideration or other data becomes available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish, review and revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children (VFC) Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP, for the purpose of purchase, delivery, and administration of pediatric vaccines in the VFC program.

(4) POINTS OF VIEW

Based on understanding the purpose of the FAC,
(a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;
(b) consider indentifying an anticipated relative distribution of candidates across the categories; and
(c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members

The Committee comprises 15 voting members, including one consumer representative. ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Therefore, members are selected based upon the following criteria:

- **expertise in the field of immunization practices;**
- **multi-disciplinary expertise in public health;**
- **expertise in the use of vaccines and immunologic agents;**
- **knowledge of vaccine development, evaluation, safety and delivery;**
- **or, in the case of the consumer representative, knowledge about consumer perspectives and/or social and community aspects of immunization programs.**

The committee also includes liaison organizations, currently numbering 31. Appointments of liaison representatives, primarily from professional organizations, are based upon written requests from organizations that document the commitment of the organization to providing expert input into the ACIP decision-making process; support for immunization implementation and delivery as outlined in the organization's charter; travel and per diem support for their representative; and encouragement of their membership to adopt ACIP recommendations. Liaison representatives must represent organizations that have broad immunization interests and that represent large constituencies. Liaison representatives are active participants in ACIP Work Groups.

Organizations representing more narrow interests (e.g., interest in a single disease or vaccine) or small constituencies (e.g., organ transplant patients) are invited to participate in ACIP activities on an ad hoc basis whenever issues of interest and concern are being discussed rather than requesting liaison representation. Requests from interested organizations are reviewed by the ACIP Steering Committee* and, if found appropriate, are forwarded for final approval to the Secretary, DHHS, through the Director, CDC. A listing of current liaison organizations is available at http://www.cdc.gov/vaccines/acip/members.htm#reps .

Ex officio members, currently numbering eight, represent (and are financially supported by) other Federal agencies/Departments and are appointed based on written criteria that outline how the other agency/Department can contribute to the quality of ACIP deliberations and decisions and/or enhance implementation of ACIP recommendations.

***The ACIP Steering Committee comprises fourteen senior representatives from CDC's Office of Infectious Diseases National Centers (NCIRD, NCEZID, NCHHSTP), FDA, and the current ACIP Chair. Steering Committee members are aware of the need for balanced membership on the ACIP. Responsibilities of the ACIP Steering Committee include preparation of ACIP meeting agendas,**

review of applicants applying for ACIP membership, review of requests for liaison organization membership, and consideration of ACIP-related initiatives, e.g. review of economic data, evidence based recommendations, and guidelines for use of vaccines in pregnancy.

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

Departmental policy provides that Committee membership be fairly balanced in terms of points of view represented, and the Committee's function. Consideration is given to representation from diverse geographic areas. ACIP members must be citizens of the United States.

Aspects that are considered by the ACIP Steering Committee* at the time of candidate screening and review for inclusion in nomination packages forwarded to the Secretary, DHHS, include:

- Geographical balance. Efforts are made to ensure that voting members come from states representing a diversity of geographic locations within the U.S.
- Balance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, academic perspective, public health perspective, etc.).

Appointments are made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:
(a) describe the process
(b) identify the agency key staff involved (by position, not name)
(c) briefly describe how FAC vacancies, if any, will be handled by the agency; and
(d) state the membership term limit of FAC members, if applicable

The ACIP Secretariat, including the DFO, solicits candidate names through the following channels:

- Procedures for application for ACIP membership are detailed on the ACIP web site at http://www.cdc.gov/vaccines/acip/req-nominate.htm. The ACIP Secretariat accepts applications in a continuous process throughout the year, and the ACIP Steering Committee finalizes a proposed nomination package annually during November-December.
- Solicitation of potential candidates is conducted via e-mail request that is distributed widely on an annual basis, sent to all 31 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations such as the National Medical Association and the National Hispanic Medical Association, academic centers, and other contacts in the field of vaccinology.
- Solicitation of potential candidates is posted annually in the Federal Register.
- Applications are solicited at every ACIP meeting. A web link URL is provided on a meeting slide, and procedures for application are announced at the opening of meetings, which are broadcast via the internet ("webcast") to an audience of over 10,000 viewers.
- Applications for membership are reviewed in depth by the ACIP Steering Committee, which requires that interested applicants submit a current, complete CV and at least one letter of recommendation from a non-HHS source. The ACIP Steering Committee selects two proposed candidates for each vacant position based on the quality of the candidate's technical expertise, balance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer representative, state health department expertise, public health, etc.) and geographic distribution of recommended candidates. Members are deemed Special Government Employees.

Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon the renewal of the committee by appropriate action prior to its termination. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.
(7) SUBCOMMITTEE BALANCE *Subcommittees subject to FACA* should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different* **This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*
The process used to determine the member balance for the parent FACA group is the same used for any subcommittees that may be established.
(8) OTHER *Provide any additional information that supports the balance of the FAC*
Not applicable
(9) DATE PREPARED/UPDATED *Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated*
March 27, 2018

Federal Advisory Committee (FAC) Membership Balance Plan

Please read the Federal Advisory Committee Membership Balance Plan Guidance prior to completing this form

(1) FEDERAL ADVISORY COMMITTEE NAME
State the legal name of the FAC

Advisory Committee on Immunization Practices

(2) AUTHORITY
Identify the authority for establishing the FAC

The Advisory Committee on Immunization Practices was established under Section 222 of the Public Health Service Act (42 U.S.C. § 2l7a), as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

(3) MISSION/FUNCTION
Describe the mission/function of the FAC

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Director, CDC, regarding the use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population. Upon licensure of any vaccine or any new indication of a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the committee does not make a recommendation at the committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review. The committee shall provide advice for control of diseases for which a vaccine is licensed in the U.S. ACIP recommendations address use of FDA-licensed vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling the same disease. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparation as a class of biologic agents, as well as special situations or populations that may warrant modification of the routine recommendations. Committee deliberations on the use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, and economic analyses and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic consideration or other data becomes available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish, review and revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children (VFC) Program, along with schedules regarding the

appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines.

The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP, for the purpose of purchase, delivery, and administration of pediatric vaccines in the VFC program.

(4) POINTS OF VIEW

Based on understanding the purpose of the FAC,
(a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;
(b) consider indentifying an anticipated relative distribution of candidates across the categories; and
(c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members

The Committee comprises 15 voting members, including one consumer representative. ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Therefore, members are selected based upon the following criteria:

- expertise in the field of immunization practices;
- multi-disciplinary expertise in public health;
- expertise in the use of vaccines and immunologic agents;
- knowledge of vaccine development, evaluation, safety and delivery;
- or, in the case of the consumer representative, knowledge about consumer perspectives and/or social and community aspects of immunization programs.

The committee also includes liaison organizations, currently numbering 30. Appointments of liaison representatives, primarily from professional organizations, are based upon written requests from organizations that document the commitment of the organization to providing expert input into the ACIP decision-making process; support for immunization implementation and delivery as outlined in the organization's charter; travel and per diem support for their representative; and encouragement of their membership to adopt ACIP recommendations. Liaison representatives must represent organizations that have broad immunization interests and that represent large constituencies. Liaison representatives are active participants in ACIP Work Groups.

Organizations representing more narrow interests (e.g., interest in a single disease or vaccine) or small constituencies (e.g., organ transplant patients) are invited to participate in ACIP activities on an ad hoc basis whenever issues of interest and concern are being discussed rather than requesting liaison representation. Requests from interested organizations are reviewed by the ACIP Steering Committee* and, if found appropriate, are forwarded for final approval to the Secretary, DHHS, through the Director, CDC. A listing of current liaison organizations is available at https://www.cdc.gov/vaccines/acip/members/index.html.

Ex officio members, currently numbering six, represent (and are financially supported by) other Federal agencies/Departments and are appointed based on written criteria that outline how the other agency/Department can contribute to the quality of ACIP deliberations and decisions and/or enhance implementation of ACIP recommendations.

*The ACIP Steering Committee comprises fourteen senior representatives from CDC's Office of Infectious Diseases National Centers (NCIRD, NCEZID, NCHHSTP), FDA, and the current ACIP Chair. Steering Committee members are aware of the need for balanced membership on the ACIP. Responsibilities of the ACIP Steering Committee include preparation of ACIP meeting agendas, review of applicants applying for ACIP membership, review of requests for liaison organization

membership, and consideration of ACIP-related initiatives, e.g. review of economic data, evidence-based recommendations, and guidelines for use of vaccines in pregnancy.

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

Departmental policy provides that Committee membership be fairly balanced in terms of points of view represented, and the Committee's function. Consideration is given to representation from diverse geographic areas. ACIP members must be citizens of the United States.

Aspects that are considered by the ACIP Steering Committee* at the time of candidate screening and review for inclusion in nomination packages forwarded to the Secretary, DHHS, include:

- Geographical balance. Efforts are made to ensure that voting members come from states representing a diversity of geographic locations within the U.S.
- Balance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, academic perspective, public health perspective, etc.).

Appointments are made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:
(a) describe the process
(b) identify the agency key staff involved (by position, not name)
(c) briefly describe how FAC vacancies, if any, will be handled by the agency; and
(d) state the membership term limit of FAC members, if applicable

The ACIP Secretariat, including the DFO, solicits candidate names through the following channels:

- Procedures for application for ACIP membership are detailed on the ACIP web site at http://www.cdc.gov/vaccines/acip/req-nominate.htm. The ACIP Secretariat accepts applications in a continuous process throughout the year, and the ACIP Steering Committee finalizes a proposed nomination package annually during November-December.
- Solicitation of potential candidates is conducted via e-mail request that is distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations such as the National Medical Association and the National Hispanic Medical Association, academic centers, and other contacts in the field of vaccinology.
- Solicitation of potential candidates is posted annually in the Federal Register.
- Applications are solicited at every ACIP meeting. A web link URL is provided on a meeting slide, and procedures for application are announced at the opening of meetings, which are broadcast via the internet ("webcast") to an audience of over 10,000 viewers.
- Applications for membership are reviewed in depth by the ACIP Steering Committee, which requires that interested applicants submit a current, complete CV and at least one letter of recommendation from a non-HHS source. The ACIP Steering Committee selects two proposed candidates for each vacant position based on the quality of the candidate's technical expertise, balance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer

representative, state health department expertise, public health, etc.) and geographic distribution of recommended candidates. Members are deemed Special Government Employees. **Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon the renewal of the committee by appropriate action prior to its termination. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.**
(7) SUBCOMMITTEE BALANCE *Subcommittees subject to FACA* should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different* **This is relevant to those agencies that require their subcommittees to follow all FACA requirements.*
The process used to determine the member balance for the parent FACA group is the same used for any subcommittees that may be established.
(8) OTHER *Provide any additional information that supports the balance of the FAC*
None.
(9) DATE PREPARED/UPDATED *Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated*
February 5, 2020

EXHIBIT D

ACIP Steering Committee Meetings
2018 - 2019

Meeting Date	Day	Time	Topic
2018			
August 23	Thursday	1:00-3:00	Select nominees for ACIP Membership 2019-2023
September 6	Thursday	1:00-2:30	October 2018 – prepare agenda
2019			
January 10	Thursday	2:00-3:30	Prepare February 2019 Agenda
May 2	Thursday	2:00-3:30	Prepare June 2019 Agenda
August 22	Thursday	2:00-3:30	Select nominees for ACIP Membership 2020-2024
September 5	Thursday	2:00-3:30	Prepare October 2019 Agenda
2020			
January 9	Thursday	2:00-3:30	Prepare February 2020 Agenda
May 7	Thursday	2:00-3:30	Prepare June 2020 Agenda
August 27	Thursday	2:00-3:30	Select nominees for ACIP Membership 2021-2025
September 10	Thursday	2:00-3:30	Prepare October 2020 Agenda

EXHIBIT E

ACIP Candidate Review Meeting
CDC Roybal Campus Building 24 – conference room 8106
Thursday, August 24, 2017 1:00-3:00 p.m. EDT

Dial in: 1-866-453-2647
Participant Passcode: 9745001

CHAIR: Amanda Cohn, Executive Secretary, ACIP

Overview
We will meet to review candidates for ACIP membership. Members rotating off the committee (June 30, 2018) are:

Edward Belongia	Internal Medicine; Epidemiology
Nancy Bennett	Internal Medicine; Preventive Medicine
Cynthia Pellegrini	Consumer Representative
Laura Riley	Obstetrics/Gynecology; Maternal Fetal Medicine

A summary table of ACIP members, their expertise and other characteristics is attached.

Submission Process
We need to nominate four candidates including one consumer representative. We will nominate one principal and one alternate nominee for each position, for a total of eight nominees. The nomination package will be sent to DHHS, through CDC/OD, for their decision regarding appointments.

Selection Process
We have a total of **31** applications, including new applicants as well as those who have applied previously. Following our usual practice, we will aim to select candidates whose area of expertise/specialty/board certification is similar to that of the outgoing members.

We will assign CV review to Steering Committee members who are available to do this. Even if you will not be reviewing CVs, feel free to send us any comments you may have.

We are particularly interested in hearing from you if you know an applicant – we would like to hear any and all comments on the applicant's suitability to serve as an ACIP member.

Each applicant is assigned a primary and secondary reviewer, to review the CV and the letter(s) of support; the letter of support may help you to formulate a summary of the candidate. The primary reviewer will present a summary of credentials and their overall assessment (the secondary reviewer will supplement, and others can comment).

EXHIBIT F

Applicant Name	Specialty Area	Primary Reviewer	Rating	Secondary Reviewer	Rating2	State	Female	Minority	Comments
[redacted]	Pediatrics	[redacted]	Recommend	[redacted]	Strongly Recommend	CA	No	Unk	Prior applications: 2012, 2013, 2015, 2017, 2018, 2019
[redacted]	Pediatric Infectious Diseases	[redacted]	Strongly Recommend	[redacted]	Strongly Recommend	OH	No	No	Prior applications: 2018, 2019
[redacted]	Internal Medicine, Infectious Disease	[redacted]	Recommend	[redacted]	Strongly Recommend	MD	No	Yes	
[redacted]	Internal Medicine, Pediatrics	[redacted]	Neutral/Recommend	[redacted]	Neutral	RI	Yes	Yes	
[redacted]	Family Medicine	[redacted]	Reservations	[redacted]	Neutral	AZ	Yes	No	
[redacted]	Pediatrics, Health Services Research	[redacted]	Strongly Recommend	[redacted]	Strongly Recommend	CO	No	No	Prior Application: 2019
[redacted]	Internal Medicine	[redacted]	Neutral/Recommend	[redacted]	Reservations	DC	No	Unk	
[redacted]	Nursing	[redacted]	Strong Reservations	[redacted]	Strong Reservations	NY	Yes	No	
[redacted]	Family Medicine	[redacted]	Strongly Recommend	[redacted]	Recommend	PA	Yes	No	Prior application: 2018

	Pediatrics, Maternal Fetal Medicine		Strongly Recommend		Strongly Recommend	TX	Yes	No	Prior applications: 2017, 2018, 2019
	Internal Medicine/Infectious Diseases		Reservations		Strong Reservations	NY	Yes	Yes	Prior applications: 2017, 2018, 2019
	Family Medicine		Neutral		Neutral	AL	Yes	Yes	
	Infectious Diseases		Recommend/ Neutral		Strongly Recommend	MA	Yes	No	Prior application: 2019
	Family Medicine		Strongly Recommend		Neutral	NY	No	No	Prior applications: 2014, 2015, 2016, 2017, 2018, 2019
	Pediatric Infectious Diseases		Strongly Recommend		Strongly Recommend	PA	Yes	No	
	Physician Assistant, Family Medicine		Reservations		Reservations	TN	Yes	No	
	Internal Medicine, Infectious Diseases, Vaccines		Strongly Recommend		Strongly Recommend	NY	No	No	Prior application: 2019
	Pediatrics		Recommend		Recommend	MN	No	No	Prior application: 2014, 2019

[redacted]	Nursing	[redacted]	Strong Reservations	[redacted]	Strong Reservations	GA	Yes	Yes	
[redacted]	Pediatric Infectious Diseases	[redacted]	Recommend	[redacted]	Neutral/Recommend	HI	Yes	Yes	Prior application: 2019
[redacted]	Pediatrics	[redacted]	Recommend	[redacted]	Recommend	IA	No	No	Prior applications: 2017, 2018
[redacted]	Physician Assistant, Pediatrics, Family Medicine	[redacted]	Neutral	[redacted]	Neutral	SC	Yes	No	
[redacted]	Pediatric Infectious Diseases	[redacted]	Recommend/ Strongly Recommend	[redacted]	Strongly Recommend	CA	No	No	Prior applications: 2016, 2017, 2018

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF JASON M. GOLDMAN, MD, MACP

I, Jason M. Goldman, MD, MACP, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am a board-certified primary care physician, and I have owned my own private practice in South Florida since 2002. I see close to 2,000 patients per year. I am also an internal medicine specialist and a Master of the American College of Physicians.

2. I graduated from medical school at the University of Miami in 1998. I completed my residency in internal medicine at Jackson Memorial Hospital in Miami, Florida.

3. I am the current President of the American College of Physicians ("ACP"). I previously served as Governor of ACP's Florida Chapter from 2016 through 2020 and a Regent of the College from 2020 through 2024. I served as Chair of ACP's Medical Practice Quality Committee, and I currently serve on ACP's Immunization Committee.

4. ACP was founded in 1915 to promote the science and practice of medicine, and since then, has supported internal medicine physicians by sharing the most updated medical knowledge, offering top-notch educational resources, and providing optimal practice guidelines.

5. ACP is a national organization of internal medicine physicians who specialize in the diagnosis, treatment, and care of adults, and it is the largest medical specialty organization in the United States. ACP has over 162,000 members in more than 172 countries across the globe, which include internal medicine physicians, related subspecialists, and medical students. While most of our physician members treat adults, many of our physician members also currently provide direct care to immunocompromised persons, pregnant women, newborns, and children in both hospital and outpatient settings.

6. In 2018, I became the ACP liaison to the Advisory Committee on Immunization Practices ("ACIP"). In 2020, I joined the ACIP Covid-19 Vaccines Work Group as a liaison member representing the ACP. In 2019, I also joined the Pneumonia Vaccine Work Group. I served as the ACP's liaison member to the Covid-19 Vaccines Work Group and Pneumonia Work Group until on or about July 31, 2025, when I received an email that liaison organizations were terminated from participating in ACIP Work Groups.

7. From my five years of service on the Covid-19 Vaccines Work Group, and six years of service on the Pneumonia Vaccine Work Group, I am well-versed in the process and procedure that the Covid-19 Vaccines Work Group, Pneumonia Work Group, and the ACIP followed before Robert F. Kennedy, Jr. became the Secretary of the Department of Health and Human Services (the "Secretary") to make recommendations on how vaccines should be recommended for use in this country and how they should be listed on CDC immunization schedules. I have attended all public meetings of the ACIP since 2018.

8. I attended the April 15-16, 2025 public meeting, which was the last meeting of the members of the ACIP who were fired on June 9, 2025. At the April 15-16, 2025 meeting, true subject-matter experts presented the results of Evidence to Recommendation ("EtR") framework analyses on a number of different vaccines, including the Covid-19 vaccine. The EtR framework has been a best practice of the ACIP since before I became a liaison to the ACIP Covid-19 Vaccines Work Group. The current ACIP has abandoned this best practice, without explanation.

9. For the last eight years, I attended every public meeting of the ACIP. In my role on the Covid-19 Vaccines Work Gorup, I have participated in every major meeting and decision of the Covid-19 Vaccines Work Group relating to the evaluation and recommendation of Covid-19 vaccines for individuals.

10. Based on my experience participating directly in ACIP Work Groups and attending ACIP meetings for nearly eight years, significant scientific analyses relevant to CDC immunization schedule recommendations were shared with the relevant ACIP Work Group participants and discussed with ACIP Work Group participants through established deliberative channels before recommendations were finalized.

11. I have read the two memoranda produced by Defendants for the first time as exhibits to their opposition brief in this litigation: (a) a memorandum dated May 12, 2025, from Matthew Memoli, Principal Director, NIH, and Sara Brenner, Principal Deputy Commissioner, FDA, to the Secretary titled "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age"; and (b) a memorandum dated May 12, 2025, from Tracy Beth Hoeg to Secretary Robert F. Kennedy, Jr., concerning "COVID-19 vaccine safety in pregnant women". The first time I saw

these memos was on March 1, 2026. During my service on the ACIP Covid-19 Work Group, I never saw, received, discussed, or was informed of these memoranda.

12. During my service on the ACIP Covid-19 Vaccines Work Group, scientific analyses or memoranda bearing on vaccine recommendations were routinely discussed with Work Group participants and circulated for review to Work Group participants as part of the ACIP deliberative process. Neither I nor, to my knowledge based on my regular participation in the ACIP Covid-19 Vaccines Work Group meetings and communications with other members, any other Covid-19 Vaccines Work Group participant was consulted, provided with, or asked to evaluate these two May 12, 2025 memoranda prior to their production in this litigation. Had the memoranda been incorporated into the ordinary ACIP Work Group and EtR process, I would have expected these memoranda to be shared with the ACIP Covid-19 Vaccines Work Group members for scientific discussion and evaluation and incorporated into ACIP's established EtR process.

13. The absence of these memoranda from ACIP Covid-19 Work Group deliberations and the established EtR process is inconsistent with the longstanding scientific review process that governed CDC immunization schedule recommendation development during my years of service for the ACIP and ACIP Work Groups. The ACIP process relied on transparent evaluation of evidence through multidisciplinary expert review rather than undisclosed internal communications. Based on my experience working on ACIP Work Groups, bypassing the ACIP Covid-19 Vaccine Work Group and EtR processes deprives clinicians, professional organizations, and the public of the scientific transparency and evidentiary vetting necessary to evaluate vaccine recommendations and to implement them confidently in clinical practice. These departures from established ACIP processes have created, and continue to create, ongoing substantial uncertainty among ACP and ACP physician members regarding the scientific basis for the May Directive and

its changes to the CDC immunization schedules, which as I have stated in my prior declarations submitted in this matter, continue to impair the ability of ACP and ACP member physicians to provide consistent, evidence-based guidance on the Covid-19 vaccine to patients in practice.

14. ACP relies on the transparency and evidentiary rigor of the ACIP and EtR processes to develop guidance for physician members. Because the May Directive and September 2025 Covid-19 Action bypassed those processes, ACP has been and continues to devote substantial organizational time and resources to independently reviewing available literature, and responding to member inquiries on these changes to CDC immunization schedule for the Covid-19 vaccine without access to the scientific record that ordinarily accompanies ACIP and CDC changes to the CDC immunization schedule. These efforts have diverted ACP staff and physician leadership away from ACP's core mission of supporting internal medicine physicians and advancing patient care nationwide. The resources expended by ACP responding to ongoing uncertainty on the Covid-19 vaccine cannot be recovered through monetary compensation.

15. ACP continues to divert ACP staff time away from necessary initiatives to develop communications to counter the ongoing widespread confusion caused by the May Directive and September 2025 ACIP vote (adopted by the CDC) downgrading the Covid-19 vaccine (for essentially all adults) to SCDM. ACP staff have, and will continue to have to, divert their time to respond to inquiries from ACP members seeking guidance on how to navigate the conflicting and unexplained May 2025 and September 2025 actions changing the CDC immunizations schedule recommendations for the Covid-19 vaccine. These efforts by ACP staff are essential to mitigate the ongoing harm caused by the May Directive and September 2025 Covid-19 Action changing the Covid-19 vaccine recommendations.

16. As I have stated in my prior declarations submitted in this matter, ACP physician members depend on CDC immunization schedules as authoritative clinical tools used daily in patient counseling, treatment planning, and risk assessment. The absence of a transparent evidentiary foundation for the May 2025 and September 2025 changes to the CDC immunization schedule for the Covid-19 vaccine has and continues to impair ACP physician members ability to provide consistent, evidence-based recommendations to patients on the Covid-19 vaccine. This continues to expose ACP member physicians to professional liability. ACP physician members also continue to report spending additional uncompensated clinical time explaining the May 2025 and September 2025 conflicting and unclear changes to the CDC immunization schedule for Covid-19 vaccine and engaging in the now required shared clinical decision making ("SCDM") discussions. ACP member physicians continue to report having to spend their own time trying to reconcile the CDC immunization schedule prior recommendations for Covid-19 vaccines with the May 2025 and September 2025 changes to the CDC immunization schedule that lack the documented scientific review and evidence that ACP physician members rely on in their practice to consult with patients on vaccine recommendations.

17. As the Secretary, CDC, and ACIP release new allegedly supporting materials for their CDC immunization schedule changes, such as the two memoranda discussed above that were never presented to the ACIP Covid-19 Work Group or the public until being filed by the Defendants in this litigation, ACP and ACP physician members will continue to have to expend their time and resources reviewing and interpreting these materials so that they can provide the required guidance and respond to questions from patients in real time, in exam rooms across the country. This time and resources cannot be recovered after the fact by ACP and ACP physician members.

18. The harms that I have set forth in my prior declarations submitted in this matter are ongoing and worsening as additional actions by the Secretary, CDC, and ACIP occur without adherence to the established EtR processes. ACP and its members must repeatedly reassess guidance, update educational materials, and respond to new waves of patient and physician inquiries. In my professional judgment, these harms cannot be remedied after the fact. Once patient trust is undermined and clinical decisions are made without reliable guidance, the consequences for patient care and public health cannot be fully reversed.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C.§ 1746, and the laws of Florida that the foregoing is true and correct.

Executed on March 2, 2026, in Coral Springs, Florida

Jason M. Goldman, MD, MACP
President, American College of Physicians

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

[PROPOSED] ORDER

This matter comes before the Court on Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction. Having reviewed the Motion, and for good cause shown, it is hereby ORDERED that the Motion is GRANTED.

It is hereby ORDERED that Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction is GRANTED Plaintiffs are granted leave to file the Supplemental Declarations which are attached as Exhibits A-E to the Motion for Leave to File Supplemental Declarations.

SO ORDERED.

Dated: _____

_____
HON. BRIAN E. MURPHY
U.S. DISTRICT JUDGE